VALIDATION OF A NOVEL ULTRA-THIN WEARABLE ELECTROMYOGRAPHY SENSOR PATCH FOR MONITORING SUBMENTAL MUSCLE ACTIVITY DURING SWALLOWING

by

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Around the world, 62 million girls are not in school. Millions are fighting to stay there. This dissertation is dedicated to all girls who do not give up on their dreams despite the injustices that they face.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

EAT-10	Eating Assessment Tool-10
EMG	Electromyography
IOPI	Iowa Oral Performance Instrument
MoCA	Montreal Cognitive Assessment
MUAP	Motor Unit Action Potentials
OPSES	Oropharyngeal Sensorimotor Examination of Swallowing
PD	Parkinson's disease
SENIAM	Surface Electromyography for the Non-Invasive Assessment of Muscles
sEMG	Surface Electromyography
UES	Upper Esophageal Sphincter
VFSS	Videofluoroscopic Swallow Study

ABSTRACT

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The aim of this study was to compare a newly developed ultrathin wearable surface electromyography (sEMG) sensors patch (patent pending, inventors: Lee & Malandraki) (i.e., experimental sensors) to commercially available and widely-used sEMG sensors (i.e., conventional sensors) in monitoring submental muscle activity during swallowing in healthy older adults. A randomized crossover design was employed to compare the performance of the experimental sensors with the performance of conventional snap-on sensors. Forty healthy older adults participated (24F; age range 53-85). Participants completed the same experimental protocol with both sensor types in a counterbalanced order. Swallow trials completed with both types of sensors included 5 trials of 5ml and 10ml water swallows. Comparisons were made on: a) signal related factors (i.e., signal-to-noise ratio, baseline amplitude, normalized amplitude of the swallow trials, and duration of sEMG burst during swallow trials); and b) safety and pre-clinical factors (safety/adverse effects, efficiency, and satisfaction/comfort).

In terms of signal related factors (Aim 1), we hypothesized that the signal-to-noise ratio and baseline amplitude values acquired using the experimental sensors will not be inferior to the ones acquired using the conventional sensors. These hypotheses were tested using non-inferiority tests. Moreover, we hypothesized that the normalized amplitude values and the sEMG burst duration during swallow trials will be comparable/equivalent between the two sensor types. These hypotheses were tested using equivalency tests. In terms of safety and pre-clinical factors (Aim 2), we predicted that no adverse effects will be reported after using either type of sensors. We also hypothesized that sensor placement will be more efficient, and satisfaction/comfort level will be higher with the experimental sensors. These hypotheses were tested using paired t-tests.

Overall, the findings supported our hypotheses for Aim 1. Results showed that the experimental sensors did not perform inferiorly to the conventional sensors based on signal-to-noise ratio (left sensors: $t(39) = 3.95$, $p < 0.0002$; right sensors: $t(39) = 2.66$, $p < 0.0056$) and baseline amplitude values (left sensors: $t(39) = -7.72$, $p < 0.0001$; right sensors: $t(39) = -7.43$, p

<0.0001). The normalized amplitude values were deemed equivalent for all swallow trials (5ml left: t_u = 4.25, t_l = -6.22; overall *p-value <0.0001*; 5ml right: t_u = 2.07, t_l = -4.06; overall *p-value <0.0224;* 10ml left: t_u = 5.49, t_l = -7.20; overall *p-value <0.0001*; 10ml right: t_u = 3.36 t_l = -5.28; overall *p-value <0.0012*).The duration of sEMG burst was also deemed equivalent for all variables (5ml left: t_u = 9.48, t_l = -7.25; overall *p-value <0.0001*; 5ml right: t_u = 9.03, t_l = -6.35; overall *p-value <0.0001*; 10ml left: t_u = 6.75, t_l = -6.11; *p-value <0.0001*; 10ml right: t_u = 6.58, t_l = -6.23; overall *p-value < 0.0001*).

In terms of safety and adverse effects (Aim 2, hypothesis #1), mild redness and itchiness occurred with the conventional sensors in six participants, whereas only one participant reported itchiness with the experimental sensors. No redness or skin irritation was observed or reported by any of the participants after the removal of the experimental sensors. In terms of time efficiency of electrode placement (Aim 2, hypothesis #2), our hypothesis was not proven, as there were no statistically significant differences in the time it took to place both sensor types; ($t(39) = 1.87$, $p = 0.9657$). However, as hypothesized (Aim 2, hypothesis #3) satisfaction/comfort level was significantly higher with the experimental sensors than the conventional ones, albeit with a relatively small effect size, $t(39) = 1.71$, $p = 0.0476$, $d = 0.226$.

Taken together, these findings indicate that the newly developed ultrathin wearable sEMG sensors obtain comparable signal quality and signal parameters to conventional and widely used sEMG snap-on electrodes; have fewer adverse effects associated with them compared to the conventional sensors, and healthy older adults are highly satisfied and comfortable using them. Future research is warranted to optimize the wearable sEMG sensors, before clinical trials examining the effectiveness of these sensors in the treatment of dysphagia can be initiated.

CHAPTER 1. INTRODUCTION

How can we make specialized swallowing services more accessible so that patients with swallowing disorders (a.k.a. dysphagia) can have better health outcomes? This dissertation will begin tackling this question by validating an innovative approach for the remote monitoring of swallowing muscle activity. Dysphagia can be defined as experiencing any difficulty with the acceptance, manipulation, or transition of foods or liquids from the mouth into the stomach (Logemann, 2007). Although the prevalence of dysphagia varies among different patient populations and age groups, a recent study reported that it affects 1 in 25 adults every year (Bhattacharyya, 2014). In particular, dysphagia is highly prevalent in neurogenic disorders, including stroke and Parkinson's disease, in head and neck cancer patients, and in the elderly population (age > 65) (Takizawa, Gemmell, Kenworthy, & Speyer, 2016).

Signs and symptoms that individuals with dysphagia experience include: losing weight unexpectedly, experiencing pain during swallowing, sensing that foods are sticking in the throat, frequent choking, coughing or throat clearing during meals, drooling, and avoiding certain foods due to swallowing difficulties (Belafsky et al., 2008; Logemann, 1998; Roy, Stemple, Merrill, & Thomas, 2007). When these problems are not treated effectively, or when they persist, they can lead to serious health and quality of life related consequences.

Dysphagia has been reported to be an important risk factor for developing aspiration pneumonia, which is one of the leading causes of death in the elderly (Ebihara, Sekiya, Miyagi, Ebihara, & Okazaki, 2016; Kikuchi et al., 1994; Langmore et al., 1998; Marik & Kaplan, 2003). Furthermore, dysphagia has been associated with increased frequency and duration of hospital and post-acute care facility stays, higher mortality rates, and higher medical costs (Bhattacharyya, 2014; Logemann, 1998; D. A. Patel et al., 2018; Suttrup & Warnecke, 2016). In

addition, patients with dysphagia are more likely to experience malnutrition, dehydration, decreased quality of life, and social isolation due to not being able to partake in mealtimes (Bhattacharyya, 2014; Logemann, 1998; D. A. Patel et al., 2018; Suttrup & Warnecke, 2016). Due to the high prevalence and potentially dire consequences of swallowing problems, timely management of dysphagia is critical.

Current treatment approaches for patients with swallowing disorders include a) medical approaches (e.g., surgery, medications) (e.g., Peracchia et al., 1998), b) compensatory strategies (e.g., posture changes, diet modifications) (e.g., Bülow, Olsson, & Ekberg, 1999; McCulloch, Hoffman, & Ciucci, 2010; McCullough, Pelletier, & Steele, 2003; Welch, Logemann, Rademaker, & Kahrilas, 1993), and c) rehabilitative exercises which include strengthening exercises (e.g., Clark & Shelton, 2014; Logemann et al., 2009; Malandraki et al., 2012; McCullough et al., 2012; Robbins et al., 2005; Troche et al., 2010), and skill-based swallowing training approaches (e.g., Athukorala, Jones, Sella, & Huckabee, 2014; Carnaby-Mann & Crary, 2010; Malandraki et al., 2016). Medications and compensatory strategies often provide temporary solutions; whereas, surgery and rehabilitative exercises aim to change the underlying physiology and can lead to long-term gains.

Exercises have been studied extensively by rehabilitation scientists and findings from both animal and human models indicate that when exercise programs follow principles of exercise physiology and neuroplasticity, exercises can lead to neural adaptations and lasting improvements in function (Bayona, Bitensky, Salter, & Teasell, 2005). Such principles have been used to develop swallowing strength-training programs (e.g., Clark & Shelton, 2014; Logemann et al., 2009; Malandraki et al., 2016; McCullough et al., 2012; Pitts et al., 2009; Robbins et al., 2005; Troche et al., 2010; Wheeler, Chiara, & Sapienza, 2007), as well as approaches that aim at improving the coordination, timing, or the planning of motor aspects of

the swallow, i.e., skill-based training approaches (Athukorala et al., 2014; Huckabee & Macrae, 2014; Miller, 1993). Both approaches (strengthening and skill-based training) frequently utilize a key motor learning component, the use of extrinsic feedback. Specifically, the use and effectiveness of extrinsic feedback has been examined in numerous strengthening and skill-based training studies in the limb literature (Schmidt & Lee, 2005; Sciote, Horton, Rowlerson, & Link, 2003), as well as in small-scale studies in the dysphagia literature (Athukorala et al., 2014; Carnaby-Mann & Crary, 2010; Malandraki et al., 2012, 2016; Pitts et al., 2009; Robbins et al., 2007). Results have consistently showed that guidance and feedback, especially extrinsic feedback, during training are tied to increased strength, functional improvements, and cortical reorganization (Athukorala et al., 2014; Bayona et al., 2005; Logemann et al., 2009; Malandraki et al., 2012; Pitts et al., 2009; Robbins et al., 2007; Schmidt & Lee, 2005).

Although the evidence in the field of dysphagia is still emerging, studies have demonstrated that surface electromyography (sEMG) biofeedback can be effective during swallowing rehabilitation (e.g., Athukorala et al., 2014; Azola, Sunday, & Humbert, 2017; Crary, Carnaby (Mann), & Groher, 2006; Ding, Larson, Logemann, & Rademaker, 2002; Gupta, Reddy, & Canilang, 1996; Wheeler, Chiara, & Sapienza, 2007). Surface EMG is a non-invasive, practical, and radiation-free tool (Vaiman & Eviatar, 2009a) and these characteristics make sEMG an ideal tool for evaluating groups of oropharyngeal muscles and their performance during swallowing and for providing biofeedback during exercises. Specifically, surface EMG of the submental muscles (i.e., anterior belly of the digastric, geniohyoid, mylohyoid) has been used as a noninvasive tool to identify the presence of a swallowing event, analyze the timing and amplitude of swallowing muscle activity, and as a biofeedback tool during exercises (e.g., Athukorala et al., 2014; Azola, Sunday, & Humbert, 2017; Crary, Carnaby (Mann), & Groher,

2006; Ding, Larson, Logemann, & Rademaker, 2002; Gupta, Reddy, & Canilang, 1996; Wheeler, Chiara, & Sapienza, 2007).

Taking into account principles of exercise physiology along with the effects of skilled-based training on neuroplasticity (i.e., brain's ability to form new connections), it is clear that most exercise programs should tax the system beyond typical activity and exercises should be completed with high intensity and for an adequate duration to elicit neuromuscular adaptations. In addition, to further induce motor learning, using specialized biofeedback devices such as sEMG can be rather beneficial. However, for most patients with dysphagia, it is not feasible to have more than two to three sessions per week with their speech-language pathologist. Moreover, patients who live in underserved areas and/or who have mobility limitations may experience difficulties in accessing speech-language pathologists who specialize in dysphagia. Hence, these patients typically complete their exercises independently at home without receiving direct feedback from their clinicians.

Using devices that will allow clinicians to monitor and adjust the load and intensity of their patients' exercises remotely and simultaneously provide biofeedback to patients could be a solution to address this problem. In other areas of rehabilitation, using wearable sensors has been shown to be a feasible and reliable way of monitoring patients remotely (e.g., Bhosale, Kudale, Kumthekar, Garude, & Dhumal, 2016; Bonato, 2005; Patel, Park, Bonato, Chan, & Rodgers, 2012). In addition, wearable sensors could potentially increase patients' motivation to complete their exercises, thus, resulting in higher compliance rates and possibly better health outcomes.

In specific, wearable surface electromyography (sEMG) could be a useful tool to address the current limitations in clinical practice. However, currently, most high quality sEMG devices are expensive, not user friendly, and mainly used in research laboratories or large clinical centers. At this time, to our knowledge, there is only one portable sEMG system that can be used

by patients from home (Constantinescu, Kuffel, Aalto, Hodgetts, & Rieger, 2018). However, this device is still under development, bulky and currently not available in the U.S. Development and validation of new wearable sEMG systems that are specifically designed for the submental (under the chin) area, are reliable and inexpensive, and can be easily used by patients at home with remote access by the clinicians will advance the treatment of dysphagia.

1.1.The Current Project

Our goal was to start addressing this need in clinical practice by validating a newly developed wearable electromyography (EMG) sensor patch that will eventually be part of a system that will provide biofeedback to patients. In the future, this system will also allow clinicians to remotely monitor their patients' progress and exercise adherence and adjust exercise goals based on theirs needs and progress. Our lab collaboratively developed this wearable sEMG patch specifically designed for recording sEMG activity in the head and neck area (patent pending, inventors: Lee & Malandraki). Before examining the effectiveness of this new technology in the management of dysphagia, the present study aimed to compare the newly developed wearable sEMG sensors against commercially available and widely-used conventional sEMG sensors. This step is critical as it provides the initial evidence on device safety and signal quality.

Specifically, we compared the newly developed wearable sEMG sensors with conventional sensors on a) signal related factors (i.e., signal-to-noise ratio, baseline amplitude, normalized amplitude of the swallow trials, and duration of sEMG burst during swallow trials); and b) safety and pre-clinical factors (safety/adverse effects, efficiency of electrode placement, satisfaction/comfort). Based on our preliminary data (APPENDIX A), we hypothesized that the outcome measures obtained using the experimental sensors would be comparable or superior to the ones obtained using the conventional sensors. To achieve these aims, a randomized,

controlled two-period crossover design was used. Participants completed the same evaluation protocol under two different conditions, once using the experimental sensors and once using the conventional ones.

This dissertation comprises 5 chapters including this Introduction (Chapter 1). Chapter 2 provides detailed background information by examining the relevant literature on typical and impaired muscle activity during swallowing and during dysphagia rehabilitation and on the use of EMG in dysphagia management. The chapter concludes with a section describing in detail the specific aims and hypotheses of the study. Chapter 3 discusses the study methodology, including eligibility criteria for the participants, instruments used, experimental design, and data collection and analysis protocols, as well as results of the power calculations based on the preliminary data. Chapter 4 presents a comprehensive presentation of the results. Chapter 5, which is the last section of this dissertation, discusses the findings in the context of previous and current literature, identifies the limitations of the study, and offers possible next steps in research.

CHAPTER 2. LITERATURE REVIEW

Swallowing is an extremely rapid and intricate event in which many muscles are active at the same time. It is important to understand the swallowing mechanism and both healthy and impaired muscle activity during swallowing before discussing the use of electromyography in swallowing management. Therefore, this literature review begins with a brief overview of healthy swallowing and muscle involvement during the swallowing phases. Subsequently, abnormal muscle activity and resulting swallowing disorders (i.e., dysphagia) are described. Then, the current evidence in the use of electromyography in dysphagia management and gaps in current research and clinical practice are presented. The chapter concludes with the specific aims and hypotheses of the present study.

2.1. Healthy Swallowing and Muscle Involvement in Swallowing Phases

Swallowing (also known as deglutition) is one of the main components of eating. It involves a series of sensorimotor events that begin with recognizing the presence of saliva, foods, liquids, or medicine in the oral cavity (i.e., inside the mouth), followed by forming a cohesive mass that is ready to be swallowed (i.e., bolus), and finalized by the passage of the bolus from the oral cavity to the pharynx (i.e., throat), esophagus, and finally into the stomach (Logemann, 1998, 2007; Malandraki & Robbins, 2013). The sensory and motor aspects involved in swallowing are controlled by multiple components of the central and peripheral nervous system. Specifically, six nerves and approximately 40 pairs of muscles are involved in swallowing (Ertekin & Aydogdu, 2003; Lang, 2009; Malandraki, Sutton, Perlman, Karampinos, & Conway, 2009; Miller, 1993; Perlman, 1996). Oropharyngeal swallowing has been divided into two main phases – oral and pharyngeal (Dodds, 1989; Dodds, Stewart, & Logemann, 1990;

Lang, 2009; Logemann, 1998). It is important to note that swallowing is an extremely fast and dynamic event and these two phases often overlap in healthy individuals.

The oral and pharyngeal phases of swallowing and muscle involvement during each phase are discussed below. A more comprehensive understanding of these mechanisms should provide a rationale for the proposed methods of the current study. While the sensory aspects of swallowing are equally important, due to the focus of this dissertation, the following section will primarily focus on motor involvement and muscles involved in swallowing.

2.1.a. Phases of Swallowing and Muscle Involvement

2.1.a.i. Oral Phase of Swallowing and Muscle Involvement

The oral phase of swallowing is often subdivided into two sub sections—oral preparatory phase and oral transport phase (Logemann, 1998), due to the distinct physiological differences in these two sub phases. The oral preparatory phase begins with the sensory awareness of foods/liquids in the oral cavity and continues with assessing several sensory aspects of foods/liquids such as taste, temperature, volume, and viscosity. Then, foods/liquids are manipulated intra-orally to form a bolus (Logemann, 1998).

Movement patterns are different for different boluses. Specifically, for liquids, the tongue cups the liquid and the lateral parts of the tongue form a seal against the roof of the mouth (i.e., the hard palate) (Dodds et al., 1989, 1990; Matsuo & Palmer, 2008). For solids, the amount of manipulation required to break down the food into smaller pieces depends on the type of the solid food consumed (Dodds et al., 1989, 1990; Matsuo & Palmer, 2008). For soft solids, minimal level of tongue manipulation is needed; thus, the oral preparatory phase is somewhat similar to liquids. Most of the time, mastication is not necessary. However, regular solids (e.g., carrots) require chewing. The main muscles of mastication (i.e., masseter, temporalis, and the medial and lateral pterygoid muscles) and the submental muscles (i.e., anterior belly of the

digastric, mylohyoid, and geniohyoid) control the elevation and depression of the mandible during chewing (Dodds et al., 1990; Logemann, 1998; Miller, 1986; Perlman, 1996). In addition, the buccinator muscle aids in mastication by compressing the cheeks and preventing the bolus from falling into the lateral sulci (Dutra, Caria, Rafferty, & Herring, 2010).

The oral transport phase begins once the bolus is formed and the tongue tip is elevated towards the alveolar ridge (Dodds et al., 1989). During this phase, the levator veli palatini muscle contracts and elevates the soft palate to seal the entrance to the nasal cavity. Both the intrinsic lingual muscles (i.e., superior and inferior longitudinal muscles, vertical muscles, and transverse muscles) and the extrinsic lingual muscles (genioglossus, styloglossus, palataglossus, and hyoglossus) play an important role by changing the shape and the location of the tongue in the oral cavity. The posterior tongue depresses, and the tongue forms a groove to push the bolus posteriorly towards the oropharynx (Dodds et al., 1990). The lips remain closed throughout the oral phase. The orbicularis oris muscle helps the lips to remain closed and prevent the foods/liquids escaping from the mouth anteriorly (Murray, Larson, & Logemann, 1998).

There is great variability in the duration of the oral preparatory phase as the duration is based on viscosity (e.g., thin liquid vs. solid) and the amount of chewing required to form a bolus (Bhatka, Throckmorton, Wintergerst, Hutchins, & Buschang, 2004). The duration of the oral transport phase is generally around 1 to 1.5 seconds; however, it can be slightly longer with increased viscosity (Logemann, 1998).

2.1.a.ii. Pharyngeal Phase of Swallowing and Muscle Involvement

During the pharyngeal phase of swallowing, the main goal is to safely transit the bolus from the oropharynx into the esophagus. Several important events take place in the pharynx to protect the airway and propel the bolus into the esophagus, and there are many muscles that are active during this period. The bolus reaches the posterior portion of the tongue at the end of the

oral transport phase. Sensory fibers from Cranial Nerves V and IX innervate the sensation of the tongue and oropharynx (Doty & Bosma, 1956; Kitagawa, Shingai, Takahashi, & Yamada, 2002). The sensory input from the bolus modulates the triggering of the swallow. In healthy adults, the pharyngeal swallow is typically initiated or triggered when the bolus reaches the structures between the anterior faucial pillars (i.e., the palatoglossus muscle) and the valleculae, however some boluses may trigger the pharyngeal swallow even deeper in the pharynx (e.g., solid swallows) (Dodds et al., 1990; Konrad, 2005; Logemann, 1998; Martin-Harris, Brodsky, Michel, Lee, & Walters, 2007; Robbins, Hamilton, Lof, & Kempster, 1992; Tracy et al., 1989). The levator and tensor veli palatini muscles remain in the contracted state and keep the velum elevated. In addition, the base of tongue retracts towards the pharyngeal wall as the posterior pharyngeal wall moves anteriorly as a result of the contraction of the glossopharyngeus and the superior pharyngeal constrictor muscles (Dodds et al., 1990; Fujiu & Logemann, 1996). This allows for the nasal cavity to remain sealed and start building pressures inside the pharynx.

Concurrently, several mechanisms of airway protection are present at this phase and include the anterior and superior displacement of the hyolaryngeal complex, epiglottic inversion, tilting of the arytenoid cartilages, and adduction of the vocal folds. Regarding the first mechanism, the main muscles that help with the anterior and superior displacement of the hyolaryngeal complex are the submental muscles (i.e., anterior belly of the digastric, geniohyoid, and mylohyoid). This group of muscles (Figure 1) is in the submental area (under the chin). When they contract, they help move the hyoid bone anteriorly and superiorly during this stage (Dodds et al., 1988; J. B. Palmer, Rudin, Lara, & Crompton, 1992; Pearson, Hindson, Langmore, & Zumwalt, 2013; Spiro, Rendell, & Gay, 1994) and play an important role in airway protection (for specific roles of each muscle, refer to Table 1). These muscles and their activity are the focus of the present study.

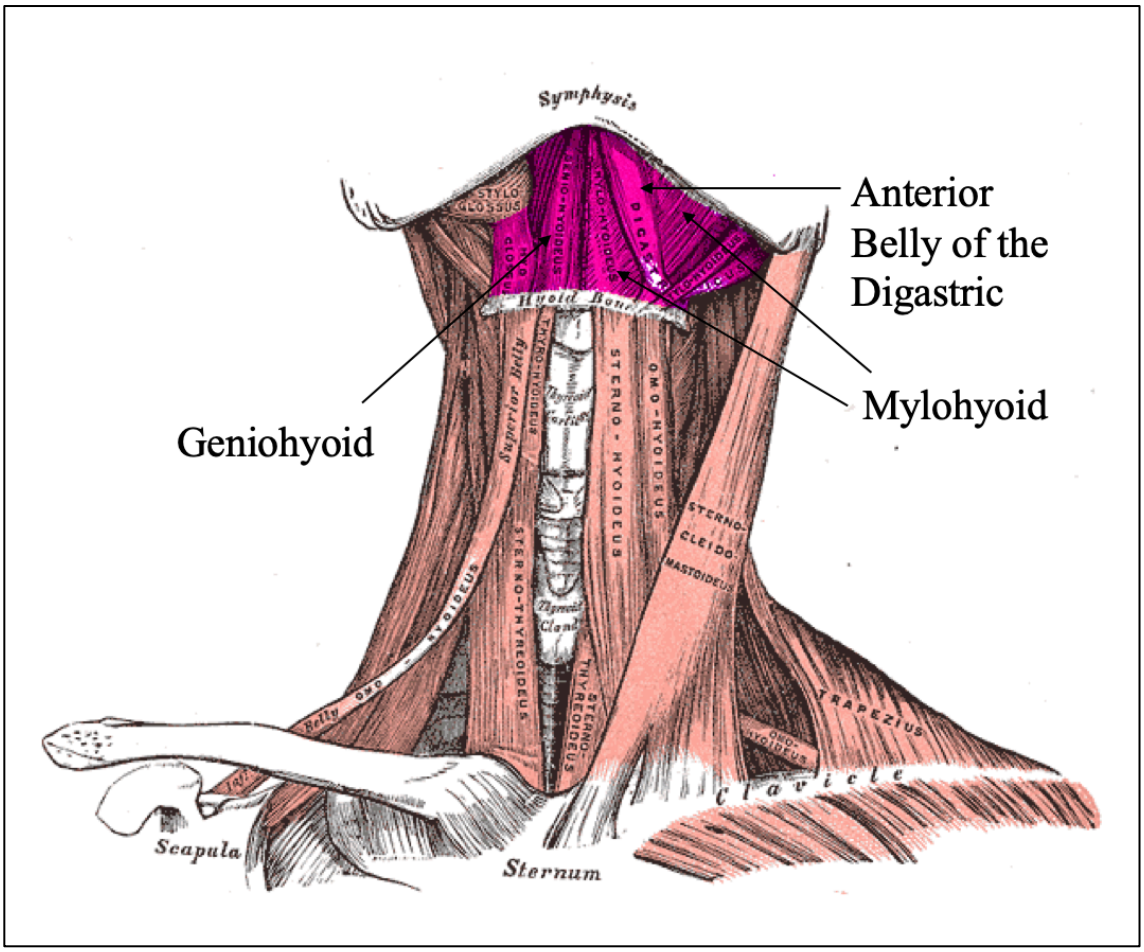


Figure 1. Submental Muscles
(Adapted from Gray's Anatomy of the Human Body, 1981)

Table 1. Submental Muscle Activity in Healthy Swallowing

Muscle	Innervation	Origin and Insertion	Role
Geniohyoid	C 1	From the mandible to the corpus of the hyoid bone	Elevation and anterior movement of the hyoid bone
Mylohyoid	CN V	Under the tongue to the corpus of the hyoid bone	Elevation of the hyoid bone
Anterior belly of the digastric	CN V	From the mandible to the hyoid bone	Elevation of the hyoid bone if jaw is fixed during the swallow

Source: Speech and Hearing Science, Anatomy and Physiology, 4th edition (Zemlin, 1998)

In addition to the aforementioned events, because the larynx is connected to the hyoid bone via the thyrohyoid membrane and the thyrohyoid muscle, when the submental muscles contract, the entire hyolaryngeal complex moves superiorly and anteriorly. Timely and adequate contraction of the submental muscles and this anterior and superior movement of the hyolaryngeal complex is also important for further facilitating the opening of the upper esophageal sphincter (UES), which is achieved primarily through the relaxation of the cricopharyngeus muscle (Cook et al., 1989; Perlman, Palmer, McCulloch, & Vandaele, 1999). The UES remains open until the bolus passes through due to intrabolus pressure (Cook et al., 1989; Jacob, Kahrilas, Logemann, Shah, & Ha, 1989). Adequate opening of the UES is critical for pharyngeal bolus clearance and prevention of post-swallow residue (Shaker et al., 1997).

Furthermore, during the pharyngeal stage, the arytenoid cartilages tilt forward and the laryngeal adductor muscles (i.e., lateral cricoarytenoid, transverse and oblique interarytenoid) contract. These movements result in vocal fold adduction and closure of the airway entrance (Dodds et al., 1990; Logemann et al., 1992). Thus, during the pharyngeal phase of swallowing, there is a brief period when respiration is inhibited (i.e., swallow apnea period) (Perlman, 1996).

The timing of the swallow apnea period depends on the coordination of swallowing and respiration (B. J. Martin, Logemann, Shaker, & Dodds, 1994). Healthy individuals typically follow the expiration-swallow-expiration pattern and failure to do so increases the chances of aspiration (B. J. Martin et al., 1994).

Lastly, with the contraction of the pharyngeal constrictor muscles (i.e., superior, middle, inferior constrictors), the bolus passes through the pharynx. The upper esophageal sphincter dilates further as a result of gravity and the pressure that is built in the pharynx (Cook et al., 1989). As such, the bolus passes through the UES. The duration of the pharyngeal phase is approximately 0.4 to 1.1 seconds, but can be longer during sequential swallowing (Hamlet, Muz, Patterson, & Jones, 1989; Jean, 2001; Kim, McCullough, & Asp, 2005; Rademaker, Pauloski, Colangelo, & Logemann, 1998).

This brief review of deglutition and muscle involvement in healthy individuals demonstrates the abundance of muscles involved in swallowing. Before discussing effects of exercise on swallowing muscles and the use of EMG in swallowing management, it is essential to provide an overview of the typical muscle structure of striated muscles (i.e., the primary type of muscles found in the head and neck and throughout the body) and neuromuscular physiology.

2.2. Typical Striated Muscle Anatomy and Physiology

A motor unit consists of a lower motor neuron cell body, dendrites, axon, and the muscle fiber(s) that it innervates (Bigland & Lippold, 1954). Each muscle fiber contains hundreds of myofibrils, which are the largest functional units of a muscle (Dias & Armstrong, 2004). These myofibrils consist of repetitive units of sarcomeres that connect via z-disks. Each sarcomere includes two different types of contractile proteins called actin and myosin. Myosin is comprised of two heavy (MyHC) and two light chains (MyLC) that work together with adenosine triphosphate (ATPase) to control the features of different muscle fibers (Kent, 2004). The sliding

filament theory states that a motor neuron's axon releases acetylcholine at the neuromuscular junction and as a result, the muscle fiber depolarizes and triggers an action potential (Hill, 1974). As the action potential propagates through the muscle fiber via the sarcoplasmic reticulum, calcium ions are released (Hill, 1974). Calcium binds to troponin, which allows the myosin head to bind with actin and the myosin head pulls the actin and they slide past each other (Hill, 1974). As a result, the sarcomere shortens; thus, the muscle fiber also shrinks. The actin filament moves slightly every time that the myosin filament pulls the actin, hence, many quick and repetitive flexions should occur throughout the entire muscle for any quantifiable movements to occur (Haff & Triplett, 2016).

Force production and duration of muscle contraction partly depend on the type of muscle fibers (Burkhead, Sapienza, & Rosenbek, 2007; Hill, 1974). Skeletal muscles contain distinctive types of muscle fibers that differ in their physiological characteristics from other types of muscles. The most commonly used classification system divides the skeletal muscle fibers into two groups: Slow twitch (Type I) or fast twitch (Type II) (Phillips, 1997). A slow twitch muscle fiber develops force slowly; therefore, it is less prone to fatigue than a fast twitch muscle fiber and has higher capacity for aerobic power (e.g., endurance training) (Haff & Triplett, 2016). On the other hand, a fast twitch muscle fiber develops force and relaxes quickly, but it is more prone to fatigue (Hill, 1974; Phillips, 1997). Therefore, it has higher anaerobic power (e.g., high intensity exercise over a short period of time) (Haff & Triplett, 2016). Type II fibers are further divided into Type IIa and Type IIb muscle fibers. Type Iia muscle fibers are also known as intermediate muscle fibers as they possess capabilities that are similar to both Type I and Type IIb muscle fibers. They can generate force relatively quickly, but they are more fatigue-resistant compared to Type IIb muscle fibers. While Type IIb muscle fibers can produce the most force, they also fatigue easily making them very inefficient. Typically, skeletal muscles are composed

of both Type I and Type II fibers but based on the function of the muscle, one type can be more prominent than the other. For example, postural muscles are predominantly comprised of Type I muscle since they are less prone to fatigue.

Numerous studies show that oral, pharyngeal, and laryngeal muscles are unique in their anatomical and physiological characteristics compared to other skeletal muscles (Kent, 2004; Mootoosamy & Dietrich, 2002). In addition to Type I and Type II muscle fibers, swallowing muscles are also comprised of hybrid fibers in which MyHC and MyLC appear simultaneously in different forms (Kent, 2004). This is not surprising given the different roles that they play in respiration, speech, chewing, and swallowing. Specifically, the suprahyoid muscles have a large range of contraction speeds (from slower to faster) and are also fatigue resistant due to their high oxidative properties (Kent, 2004; Sciote et al., 2003). Research has shown that swallowing muscles, including the main muscles of mastication, go through structural adaptations (i.e., changes in fiber types) in response to loading conditions (Burkhead et al., 2007; Robbins et al., 2008; Thompson, Throckmorton, & Buschang, 2001; Vincent et al., 2002). The type and degree of adaptation rely on the exercise type and duration and intensity of activity (Burkhead et al., 2007). It is important to keep these differences in mind when examining or planning any motor training including swallowing muscles since they may respond differently than other skeletal muscles. The next section will provide an overview of how aging affects the swallowing musculature.

2.2.a. Anatomical and Physiological Changes in the Swallowing Musculature due to Aging

There are several changes to the swallowing musculature and mechanism that come with aging. It is important to review these normal variations in swallowing due to aging before discussing swallowing disorders in order to differentiate the changes that are part of the normal aging process from disordered swallowing. In this section, we will now briefly discuss

presbyphagia and how aging affects the swallowing mechanism to further elucidate our decision to focus on healthy older adults in this dissertation.

Presbyphagia can be defined as the age-related changes in the swallowing mechanism in otherwise healthy older adults (Wakabayashi, 2014). Although presbyphagia does not cause swallowing disorders, it can put individuals at risk for developing signs and symptoms of dysphagia as a result of the changes that occur in the swallowing musculature and mechanism.

Changes in the physiology of the swallow have been extensively investigated. Specifically, studies show that aging increases the duration of oral and pharyngeal phases of swallowing, as well as the instances of residue in the oral and pharyngeal cavities (Logemann et al., 2000; Molfenter & Steele, 2012, 2013; Robbins et al., 1992). In older healthy adults the likelihood of delayed initiation of the pharyngeal swallow and of the bolus entering the laryngeal vestibule (i.e., penetration of the bolus) also increases (Martin-Harris et al., 2007; Robbins et al., 1992; Tracy et al., 1989). In addition, the swallow apnea period (i.e., respiratory cessation period during the pharyngeal phase of swallowing in which the entrance of the airway is protected) increases in duration to accommodate the delay in triggering (Hiss, Treole, & Stuart, 2001), and to possibly aid in the safe transportation of the bolus through the pharynx.

These physiological changes are thought to be associated with changes to the swallowing musculature. Sarcopenia refers to the loss of muscle mass of the striated muscle groups due to aging and is associated with reduced muscle strength (Shiozu, Higashijima, & Koga, 2015). Specifically, in swallowing musculature, sarcopenia has been reported in tongue muscles, resulting in decreased maximum lingual isometric pressures (Robbins et al., 2005). Tongue is a muscular hydrostat and plays an important role in the oral phase of swallowing, as well as in propelling the bolus from the oral cavity into the pharynx. Studies have shown that decreased tongue strength impacts bolus propulsion and puts individuals at risk for aspiration (Fujiu &

Logemann, 1996; Robbins et al., 2007). In addition, although mastication performance does not decrease significantly with age, increased number of chewing strokes have been observed in older adults likely due to decreased muscle mass of the main muscles of mastication (i.e., masseter, pterygoid, temporalis) (Feldman, Kapur, Alman, & Chauncey, 1980). Sarcopenia also affects the submental muscles, which were discussed in detail in Section 2.1.a. Specifically, lower amplitude values were reported in EMG recordings of the submental muscles in healthy older adults compared to younger adults during swallows (Sella, Jones, & Huckabee, 2014), and atrophy of the geniohyoid muscle has been linked to aging and aspiration (Feng et al., 2013). In addition, the flexibility of the cricopharyngeal opening (i.e., upper esophageal sphincter) decreases with age resulting in potentially increased pharyngeal residue.

It is important to note that all these changes are part of healthy aging and they typically do not cause dysphagia. However, they increase the risk of developing symptoms of dysphagia, especially in the presence of acute or chronic diseases. In the next section, a discussion on impaired muscle activity and related functional deficits in dysphagia will be provided before we delve deeper into the rehabilitation of dysphagia and the use of EMG in aiding dysphagia management.

2.3. Dysphagia and Impaired Muscle Activity

2.3.a. Dysphagia

As defined previously, disordered swallowing, or dysphagia, involves any difficulty with recognition, acceptance, manipulation, and safe transportation of foods, liquids, saliva, and/or medicine from the oral cavity into the esophagus (Logemann, 2007). Although the prevalence of dysphagia varies among different patient populations and age groups, a recent study reported that it affects 1 in 25 adults every year (Bhattacharyya, 2014). The prevalence of dysphagia ranges from 8% to 80% in patients with a history of stroke, 11% to 81% in patients with Parkinson's

disease, and 27% to 30% in patients who have experienced a traumatic brain injury (Takizawa et al., 2016). Moreover, dysphagia is highly prevalent in head and neck cancer patients (50-70%), in patients with community-acquired pneumonia (around 90%), and ranges from 5% to 72% even in the community dwelling elderly population (García-Peris et al., 2007; Madhavan, Lagorio, Crary, Dahl, & Carnaby, 2016; Nguyen et al., 2004; Takizawa et al., 2016).

2.3.b. Neuromuscular Impairments

Neuromuscular impairment is one of the leading causes of dysphagia. As mentioned earlier, swallowing requires the coordination of six cranial nerves and more than 40 pairs of muscles, thus, disturbances in these pathways may alter the physiologic components of swallowing. Force production deficits (i.e., muscle weakness), disrupted muscle tone, and movement pattern coordination deficits are some of the main neuromuscular impairments that impact swallowing (Clark, 2003; Haff & Triplett, 2016; Phillips, 1997). Weakness can be defined as decreased ability to exert force (Haff & Triplett, 2016). Neurological impairments such as damage to the lower/upper motor neurons or the neuromuscular junction may lead to weakness (Clark, 2003; Haff & Triplett, 2016). Tone refers to the myogenic resistance to passive stretching (Clark, 2003; Moritani, 1993). While hypertonicity is characterized by increased resistance to passive stretching, hypotonicity is characterized by decreased resistance to passive stretching. In clinical evaluations, hypotonicity can manifest as “floppiness” and hypertonia can manifest as rigidity and spasticity. Lastly, movement pattern coordination deficits (e.g., ataxia or dystaxia) can manifest as decreased or absent voluntary coordination of muscle movements. All these neuromuscular deficits frequently affect swallowing musculature and can result in different swallowing symptoms. Types of neurological impairments and their impact on muscle performance are presented on Table 3.

Table 2. Neuromuscular Impairments and Related Muscle Performance

Neuromuscular Impairment	Deficits in Muscle Performance	Definition of Deficits in Muscle Performance
Muscle Weakness (reduced power)	Reduced strength	Inability to exert large forces in short bursts
Muscle Weakness (reduced sustainability)	Decreased endurance	Inability to sustain small and repeated forces
Hypertonicity	Decreased range of motion	Reduced movement around a joint or specific body part
Ataxia or Dystaxia	Decreased coordination	Inability to use different parts of body together

2.3.c. Impaired Muscle Activity in Dysphagia

Patients with dysphagia can exhibit problems in sensory or motor aspects of swallowing as a result of a neurological or anatomical problem (Roden & Altman, 2013). Given the focus of this dissertation, in the following section we outline issues seen in the motor aspects of swallowing control. Specifically, the focus is on issues related to impaired muscle activity during the oral and pharyngeal swallow phases with an emphasis on the submental muscle group.

2.3.c.i. Impaired Muscle Activity and Resulting Deficits in the Oral Phase of Swallowing

During the oral phase of swallowing, any motor impairments affecting the muscles controlling the mandible, lips, tongue, velum, and/or, cheeks can result in difficulties accepting, containing, and manipulating foods intra-orally. For example, weakness or reduced tone of the orbicularis oris muscle can result in anterior loss of foods/liquids and even saliva (Murray et al., 1998). Furthermore, weakness and/or reduced tone of the buccal and peri-labial muscles can cause oral residue because of foods/liquids falling into the anterior or lateral sulci (Matsuo & Palmer, 2008). Decreased strength or coordination of the muscles of mastication typically results in poor bolus formation (Yven, Bonnet, Cormier, Monier, & Mioche, 2006). Finally, reduced lingual range of motion, strength or coordination can result in poor bolus formation, transport,

and spillage of the bolus into the pharynx (Clark, Henson, Barber, Stierwalt, & Sherrill, 2003; Matsuo & Palmer, 2008; Robbins et al., 2005).

2.3.c.ii. Impaired Muscle Activity and Resulting Deficits in the Pharyngeal Phase of Swallowing

During the pharyngeal phase, motor impairments affecting the muscles of the velum, hyolaryngeal complex, airway protection, and/or pharynx and UES can also result in swallowing problems. Motor impairments could be present as a result of weakness or paralysis, decreased range of motion due to rigidity of the muscles, sarcopenia (i.e., muscle loss due to aging), and/or discoordination. For instance, inadequate velopharyngeal closure may cause nasal regurgitation, as well as reduced pharyngeal pressure generation (Matsuo & Palmer, 2008). Moreover, weak/absent base of tongue retraction can yield to vallecular/pharyngeal residue and reduced pressure build up in the pharynx (Veis, Logemann, & Colangelo, 2000). Paresis/paralyses of the laryngeal adductor muscles can create problems with vocal fold adduction and airway closure (Bhattacharyya, Kotz, & Shapiro, 2002). Weakness or unilateral/bilateral paralysis of the pharyngeal constrictor muscles can cause poor pharyngeal bolus transit resulting in penetration/aspiration due to residue in the pyriform sinuses (Matsuo & Palmer, 2008). Also, decreased UES opening can result in post swallow residue in the pharynx (Logemann et al., 2009; Shaker et al., 1997).

As mentioned earlier, the submental muscle group plays an important role in the pharyngeal phase of swallowing (Logemann et al., 2009). Reduced submental muscle activation may result in penetration/aspiration due to incomplete airway closure, decreased upper esophageal sphincter opening, and residue in the pharynx (Logemann et al., 2009). Studies have demonstrated that these symptoms typically occur as a result of muscle weakness or discoordination (i.e., timing problems) of these muscles (Kendall & Leonard, 2001; Paik et al.,

2008). Thus, examining the resulting function of the submental muscles (i.e., hyolaryngeal complex displacement) is part of every swallow evaluation and this group of muscles are frequently targeted in therapy (Logemann et al., 2009; Robbins et al., 2005, 2007). The next section will provide a summary of the principles that govern muscle strength and rehabilitation for dysphagia with an emphasis on the submental muscles, i.e., the focus of this dissertation.

2.4. Muscle Strength and Training in Dysphagia Rehabilitation

Investigating changes in muscles and the central and peripheral nervous systems as a result of rehabilitation exercise has been a focus of deglutition scientists with the goal of developing exercises that are designed to target the needs of different populations and pathologies. Exercise involves all activities that are completed with the intention of maintaining or improving a specific function of the body; thus exercise should be purposeful, structured, and repetitive (Caspersen, Powell, & Christenson, 1984). Exercises that do not challenge the neuromuscular system will not result in desired neural plastic adaptations (Burkhead et al., 2007; Robbins et al., 2008).

2.4.a. Principles of Exercise Physiology

Specifically, physical rehabilitation programs have been found most effective when they adhere to principles of exercise physiology, especially the principles of specificity and overload. Specificity refers to training in a specific manner that will allow the desired training outcome and adaptation (Burkhead et al., 2007; Haff & Triplett, 2016). This involves using the muscles that are the focus of attention and training them for the desired muscle action. For example, while the best way to train for becoming a better runner is running, a marathon runner trains to build endurance, whereas a sprinter trains to increase speed during running. Since the demand placed on the body directs the type of adaptation that will take place, the best way to train for

swallowing would be swallowing (Burkhead et al., 2007; Haff & Triplett, 2016). However, for patients who are at risk for developing aspiration pneumonia due to frequent aspiration of the bolus, oral trials might not be an option at the beginning. In these instances, strength training exercises can be employed until the patient is safe to swallow (Burkhead et al., 2007). These exercises may increase force generation over time and prime the neuromuscular system for the movement of the swallowing muscles (Burkhead et al., 2007). Exercise programs that include task specific activities with sufficient load, repetition, and duration result in functional improvements by developing new neural connections in the brain (Burkhead et al., 2007).

The overload principle refers to completing exercises with higher intensity than the patient is used to (Haff & Triplett, 2016). When exercises are completed before muscles fatigue, results show little increases in endurance and strength. Optimal increase in muscle strength and endurance is achieved when exercises are performed with reaching muscular failure (i.e., fatigue) leading to neuromuscular adaptations (Clark, 2003).

Early adaptations to exercise (both strength and skill training) start with the changes in the nervous system, not the specific muscle of interest (Moritani, 1993). These early changes in the nervous system (i.e., plasticity), which result in increased and improved motor unit recruitment patterns, can improve the strength, coordination, and movement of the muscles (Burkhead et al., 2007; Kleim & Jones, 2008; Moritani, 1993). Thus, these functional changes may result in improvements in swallowing performance.

With increased duration of exercise (on average at least 6 weeks of training), muscles also experience structural changes (Moritani, 1993). Different types of exercises may lead to different myogenic changes. For example, it has been shown that strength training exercises can lead to hypertrophic changes (i.e., expansion in muscle size due to increased number of sarcomeres) (Moritani, 1993). Exercise can also lead to recruitment of additional motor units and

increased number of Type I fibers, which is the more fatigue-resistant type. Lastly, exercise can result in cortical reorganization of the motor cortex in the later phases of training (e.g., Hamdy & Rothwell, 1998; Hamdy, Rothwell, Aziz, & Thompson, 2000; Kleim et al., 2004; Malandraki, Johnson, & Robbins, 2011).

2.4.b. Principles of Motor Learning and Neuroplasticity for Dysphagia Rehabilitation

Although strength is one component needed for a functional swallow to occur, it is important to remember that swallowing is also a motor skill. During the last few decades, many neuroscientists have investigated the role neuroplasticity plays in learning and/or relearning a skill. Neuroplasticity can be defined as the structural and functional changes in the nervous system that occur as a result of changes in external or internal stimuli (R. E. Martin, 2009). Kleim and Jones reviewed 10 well-known principles of neuroplasticity in their famous 2008 article. A summary of these principles and their relevance to swallowing management can be found on Table 3 (Kleim & Jones, 2008; Robbins et al., 2008).

Table 3. Principles of Experience-Dependent Plasticity and Their Role in Swallowing

Principle	Description of Principle as it relates to Swallowing
Use It or Lose It	Not using the swallowing muscles regularly may result in decreased cortical representation; thus, lead to further functional decline
Use It and Improve It	Using the swallowing muscles with increased competence (i.e., target practice) can lead to improvement in swallowing function
Specificity	For maximum benefit, swallowing exercises should target swallowing skills
Repetition Matters	Neural plasticity requires sufficient amount of practice consistently (i.e., repetition of the swallowing exercises)
Intensity Matters	Neural plasticity requires sufficient amount of training intensity (what does that mean? Same as repetition?)
Time Matters	Different changes occur in different times of swallowing training
Salience Matters	Neural plasticity can occur when the swallowing exercises are purposeful and related to the patient's life
Age Matters	Younger patients are more responsive to training; thus, more likely to experience neural plasticity
Transference	A specific training can result in acquisition of similar behaviors due to neural plasticity
Interference	A specific training can interfere with the acquisition of other behaviors due to neural plasticity

Note. This table is adapted from Kleim & Jones (2008) and Robbins et al, 2008

Motor learning principles are a group of strategies that can be incorporated into exercise programs to optimize the learning or relearning of a motor skill. While there is only emerging evidence in applying these principles in the treatment of swallowing disorders, the evidence from basic science and motor learning literature demonstrates that incorporating these strategies into rehabilitative programs after a neurological event and during the window of increased plasticity can result in large gains in motor function (Kitago & Krakauer, 2013).

Extrinsic feedback, which is a key component of motor learning, has been shown to be effective in limb rehabilitation. Visual feedback (i.e., looking at their limbs) allows patients to see the discrepancy between motor planning and execution and adjust their movement based on the feedback that they receive. However, since swallowing is an internal (inside the body) and

very abstract task, the same type of visual feedback is not available for this task. Thus, using a non-invasive tool, such as electromyography sensors, that can provide visual feedback of muscle activity, could be an effective way to address this challenge.

Indeed, the use of surface electromyography has been shown to be effective when used as biofeedback during swallowing rehabilitation. Historically, sEMG biofeedback has been used mostly to facilitate swallowing exercises such as effortful swallows, however, recent studies show that the use of sEMG can also facilitate precision of movement using skill-based rehabilitation protocols (For detailed review, see 2.5.d.ii) (Athukorala et al., 2014). The following section briefly outlines the main components of electromyography especially as they relate to the head and neck musculature, before a discussion of the specific uses of EMG in dysphagia management is introduced.

2.5. Use of Electromyography in Dysphagia Rehabilitation

2.5.a. Electromyography– A Brief Overview of the Method

Swallowing is a neuromuscular activity, i.e., during swallowing, the brain sends electrical signals to the swallowing muscles to activate muscle contraction. The steps of muscle contraction are described in detail in Section 2.2. This contraction produces small electrical signals (action potentials) that can be captured by the electromyography sensors (Perlman, 1993). Specifically, EMG sensors allow us to measure the electrical excitation of the muscle cells/fibers by detecting the activity of all the innervated fibers within a motor unit or across many motor units of an activated muscle (Konrad, 2005; Stepp, 2012). The contracted muscle fibers trigger action potentials and these action potentials sum up to “Motor Unit Action Potentials” (MUAP), i.e., a superposed signal of the entire activated motor unit (Konrad, 2005; Perlman, 1993; Stepp, 2012). This raw signal is later processed and analyzed in order to obtain values such as the amplitude (i.e., area under the curve), timing/duration, and highest peak. As discussed in the next

section, several of these measures correlate with the strength and duration of muscle activity during swallowing and swallowing tasks (Crary et al., 2006; Dantas & Dodds, 1990; Perlman et al., 1999).

Electromyography signals can be detected using two different types of sensors (i.e., electrodes) – intramuscular (i.e., wire or needle) and surface. Intramuscular electrodes can be inserted into the skin to detect the electrical activity of single muscles, but this is difficult in the muscles of the head and neck area due to interdigitization among these muscles (Perlman, 1993; Stepp, 2012). In addition, these types of electrodes are invasive. They need to be inserted into the muscle, require special training to reliably locate the muscle, and cannot be used by patients at home independently (Stepp, 2012). In addition, detecting the electrical activity from a group of muscles is more challenging with these electrodes as different electrodes need to be inserted in different muscles (Stepp, 2012). On the other hand, surface electrodes are noninvasive, can be easily attached to the skin, and record electrical activity from a group of superficial muscles. Thus, they are a good alternative to intramuscular electrodes and as described in the next section, have been frequently used by clinicians and researchers managing dysphagia (Azola et al., 2017; Crary et al., 2006; Crary, Carnaby Mann, Groher, & Helseth, 2004; Ding et al., 2002; Gupta et al., 1996; McCullough et al., 2012; Perlman et al., 1999; Weiss, 2004; Wheeler-Hegland, Rosenbek, & Sapienza, 2008).

2.5.b. Electromyography in Swallowing Research – Delineating the Role of the Submental Muscles in Swallowing

Early studies of electromyography for swallowing used intramuscular electrodes to study the muscles involved (Doty & Bosma, 1956; Perlman, Luschei, & Du Mond, 1989). These studies provided our first insights on timing of muscle activation and involvement during swallowing. Doty and Bosma's (1956) early work in dogs, cats, and monkeys examined twenty

muscles during swallowing using intramuscular electrodes. The results of their work showed that posterior intrinsic lingual muscles, palatal muscles (specifically, the palatopharyngeus and palatoglossus), the superior pharyngeal constrictor muscles, and the submental muscles (mylohyoid, geniohyoid) were all activated simultaneously with the initiation of the pharyngeal swallow. Mylohyoid muscle activation preceded the activation of the geniohyoid and stylohyoid muscle by 30-40 msec (Doty & Bosma, 1956). The anterior belly of the digastric was not active in cats and dogs and only occasionally active in monkeys. Kawasaki and colleagues showed that in dogs, the swallow was initiated when mylohyoid was contracted (Kawasaki, Ogura, & Takenouchi, 1964).

The majority of the studies conducted in human subjects using intramuscular electromyography have also examined the different muscle groups during the pharyngeal phase of swallowing. Moller studied the activation of the submental muscles during chewing and swallowing in 36 young adult males and showed that the mylohyoid and the digastric muscles were active concurrently during swallowing (Moller, 1966). Hrycyshyn and Basmajian (1972) examined the submental muscle group and the genioglossus in 20 healthy adults using electromyography to determine the temporal relationship between these muscles. Participants were asked to swallow their saliva and small amounts of water, and results showed that all studied muscles were activated simultaneously during the swallow (Hrycyshyn & Basmajian, 1972).

The results of these early seminal studies using intramuscular EMG demonstrated that electrical activity from the submental muscle group occurs at the beginning of the swallow. Palmer and colleagues (1999) used a hybrid approach and simultaneously recorded the activity of the submental muscles using surface electromyography and intramuscular electrodes. The electrodes were inserted into the mylohyoid, geniohyoid, anterior belly of the digastric and

genioglossus muscles and the platysma (Palmer, Luschei, Jaffe, & McCulloch, 1999). The surface electrodes were placed on the submental region. Participants completed five swallows of varying volumes and viscosities. The results showed that most of the muscle activity recorded via surface electromyography during swallows stemmed from the mylohyoid, anterior belly of the digastric, and the geniohyoid muscles (i.e., the submental muscles). The contributions of the genioglossus muscle and the platysma were minimal. This study provided initial support for the use of surface electromyography as a non-invasive marker of the contraction of the submental muscles during the onset of the pharyngeal swallow.

2.5.c. Surface Electromyography (sEMG) and the Submental Muscle Group

Based on the results of the aforementioned studies, in more recent years, investigators also examined the use of surface EMG of the submental muscles and its correlations with kinematic swallow events as seen in videofluoroscopy. These studies have provided further support for the clinical utility of surface EMG in dysphagia rehabilitation. Specifically, Crary and colleagues (2006) examined the biomechanical correlates of sEMG signal in seventeen healthy adults using both sEMG and videofluoroscopy (VFSS) simultaneously. From the sEMG data, they identified the onset, peak, and offset of muscle activity during each swallow (i.e., beginning, peak point and end of swallow event) (Crary et al., 2006). From the VFSS images, they determined timing events, and specifically the duration of hyoid elevation, pharyngeal constriction, and UES opening/closing (Crary et al., 2006). As expected, their analysis showed that sEMG activity of the submental muscles started before the biomechanical events. In addition, they found a close temporal relationship between the onset of submental sEMG activity and the onset of hyoid movement during the pharyngeal swallow. Offset of the sEMG signal was similar to the offset of hyoid movement. Duration of sEMG activity, hyoid movement, and pharyngeal constriction were comparable. These findings indicate that submental muscle activity

begins slightly before the superior and anterior movement of the hyoid bone. They also provide further support for the use of submental sEMG as an indicator of the swallow onset as signified by the movement of the hyoid bone.

In addition, Wheeler-Hegland and colleagues (2008) examined the biomechanical and electromyographic properties of regular swallow trials, effortful swallows, and the Mendelsohn maneuver using videofluoroscopy and surface electromyography recordings simultaneously. They also found associations between the onset of submental muscle activity and the onset of hyoid movement and maximum hyoid displacement. Aligned with the findings of other studies, increased submental activity at the beginning of tasks were coupled with the elevation of hyoid bone (Wheeler-Hegland et al., 2008).

These findings collectively and the easy application of sEMG for muscle training led several research teams and clinicians to start examining the use of submental sEMG in the rehabilitation of dysphagia. The following section will summarize the current evidence on the use of submental sEMG in dysphagia rehabilitation.

2.5.d. Use of Surface EMG in Dysphagia Rehabilitation

The pathophysiology of dysphagia including abnormal submental muscle activity can be managed by speech-language pathologists using exercise protocols that aim to increase the strength and coordination of the swallowing muscles (e.g., tongue strength training, head-lift exercise, expiratory muscle strength training) (Malandraki et al., 2016; Robbins et al., 2005; Troche et al., 2010), and b) skill-based training during functional swallowing tasks (Athukorala et al., 2014; Carnaby-Mann & Crary, 2010; Malandraki et al., 2016). Surface electromyography has been used commonly as a biofeedback tool in both strengthening exercises and skill-based swallowing training approaches (Athukorala et al., 2014; Azola et al., 2017; Crary et al., 2004; McCullough et al., 2012; Wheeler et al., 2007).

2.5.d.i. Use of Surface EMG for Strengthening Swallowing Exercises

Strengthening exercises are the most commonly used exercises in dysphagia. These exercises aim to strengthen the muscles involved in swallowing. Commonly prescribed strengthening exercises include: tongue strength training, expiratory muscle strength training, effortful swallows, Mendelsohn maneuver, and the Shaker exercise (Logemann et al., 2009; McCullough et al., 2012; Robbins et al., 2005; Troche et al., 2010). Numerous studies have demonstrated that strengthening exercises can be effective, elicit changes in the swallowing mechanism, and lead to long-term gains in swallowing (Carnaby-Mann & Crary, 2010; Clark & Shelton, 2014; Logemann et al., 2009; Robbins et al., 2005). In many of these studies sEMG was the modality used to deliver the therapeutic protocol.

Specifically, two of the most frequently investigated strengthening exercises for which use of sEMG for biofeedback has been utilized are the effortful swallow and the Mendelsohn maneuver (Azola et al., 2017; Bryant, 1991; Crary et al., 2004; Ding et al., 2002; McCullough & Kim, 2013). One of the early such studies involved a head and neck cancer patient with profound dysphagia and aspiration (Bryant, 1991). Pre-treatment, the patient was using a feeding tube for his nutrition and was not eating orally. The author reported that the effortful swallow and Mendelsohn maneuvers were taught and practiced using sEMG biofeedback and the patient completed these exercises three times per week for ten weeks (Bryant, 1991). The difficulty of the exercises was increased gradually. Post-treatment sEMG amplitudes of the patient's submental muscles increased and the results of the videoflouroscopic swallow study indicated that the patient's swallowing physiology improved (Bryant, 1991). Post-treatment the patient was discharged and allowed to be on full oral intake diet (Bryant, 1991). This single-case study was the first preliminary piece of evidence for using sEMG as a biofeedback for swallow strengthening.

Following this study, a case series also using sEMG as biofeedback was published by Crary and colleagues (1995). Six brainstem stroke patients with chronic dysphagia participated in this study. Patients were not consuming any foods orally and all used a gastrostomy tube as their primary means of nutrition. Patients received intensive swallowing treatment, which required daily visits to the clinic for three weeks. Participants swallowed a small amount of liquid bolus and surface EMG was used as biofeedback during the treatment sessions. A target threshold of sEMG activity was calculated before each session. Patients were asked to swallow the small bolus at the target threshold level and hold the swallow for 2 seconds. Once patients reached 80% accuracy, the threshold was increased. In addition, patients also completed some exercises at home using a portable sEMG device. Outcome measures included coordination of the swallowing muscles, duration of the contraction, and peak/average EMG activity (Crary, 1995). The authors reported that the majority of the participants improved their swallowing function (i.e., improved coordination, peak and average muscle activity during swallow trials) and resumed oral intake of foods/liquids. Patients maintained these gains up to two years post treatment.

Crary and colleagues (2004) also investigated the effects of using sEMG on functional swallowing outcomes in a retrospective study. Forty-five patients' charts were examined for change in functional oral intake rated via the Functional Oral Intake Scale (Crary et al., 2004; Crary, Mann, & Groher, 2005). All patients presented with pharyngeal dysphagia due to stroke or head and neck cancer. All therapy sessions completed daily for 50 minutes included effortful swallow trials and used sEMG as biofeedback. Results showed that 87% of the patients increased their Functional Oral Intake Scale scores as a result of the therapy provided.

In a more recent study, McCullough and colleagues (2013) examined the effects of Mendelsohn maneuver coupled with sEMG for biofeedback. Eighteen stroke patients with

dysphagia participated in this study (McCullough & Kim, 2013). Patients completed the Mendelsohn maneuver using sEMG twice a day in the clinic. Videofluoroscopic swallow studies were performed pre and post treatment. Results showed significant changes in the duration of the superior and anterior movement of the hyoid bone. In addition, patients displayed improved penetration/aspiration and residue scores.

In summary, these studies demonstrated that using sEMG, as a biofeedback tool during strengthening exercises, was effective in the patients tested. It is noteworthy, however, that these were mostly small-scale studies and larger-scale randomized-controlled trials are needed.

2.5.d.ii. Use of Surface EMG for Skill-Based Swallowing Training

In recent years, an emerging body of work has started investigating the effectiveness of skill-based swallowing training in dysphagia rehabilitation. Such work is particularly relevant for some patient groups in which weakness of the swallowing muscles is not the primary underlying pathophysiology that causes dysphagia. In addition, for some patients, using strengthening exercises exclusively may not be enough for full recovery. Furthermore, despite all the benefits, some strengthening exercises have been criticized for not adhering to the neuroplasticity principle of specificity (i.e., practicing the specific skill of swallowing). In addition, both skill training and strength training have been found to correlate with increased cortical plasticity changes in limb rehabilitation (Adkins, Boychuk, Remple, & Kleim, 2006; Hamzei, Glauche, Schwarzwald, & May, 2012; Jensen, Marstrand, Nielsen, Lundbye, & Jens, 2005).

Skill-based swallowing training is a relatively new treatment approach and aims to improve specific skills or subskills that are involved in swallowing through the repetition and refinement of functional swallowing tasks (Athukorala et al., 2014; Huckabee & Macrae, 2014; Malandraki et al., 2016; Martin-Harris et al., 2015; Steele, Bailey, Molfenter, & Yeates, 2015). Typically, patients relearn to use their swallowing muscles in a skillful and effective way to

achieve a functional task. In swallowing treatment, these functional tasks could include activities such as practicing swallowing different consistencies, chewing, or removing the bolus from the spoon.

Currently, there is one study that has focused on functional swallowing skill training using surface electromyography. Athukorala and colleagues (2014) examined the effects of skill training in patients with Parkinson's disease (PD) using the Biofeedback in Swallowing Skill Training (BiSSkiT) software, which has been developed by their group. Ten patients with PD participated in this study. Patients participated in skill training activities that focused on increasing the coordination of muscle contraction during swallowing by developing control over the timing and strength of each swallow (Athukorala et al., 2014). The difficulty of the tasks increased as the patients mastered the skills at a particular level. Patients attended a total of 10 sessions within a two-week period at their swallowing clinic. Findings showed significant improvements in this group of patients in the following parameters: swallow duration (i.e., time it takes to swallow a bolus decreased between pre and post treatment) as measured by the Test of Mastication and Swallowing Solids (Huckabee et al., 2018), premotor time and pre-swallow time measured using sEMG, as well as quality of life measured using the SWAL-QOL (Athukorala et al., 2014; McHorney et al., 2002).

2.6. Gaps-Limitations in the Use of Surface EMG in Dysphagia Rehabilitation

As can be seen from the aforementioned evidence, there is slowly accumulating evidence that strength training and skill-based swallowing exercises can lead to improvements in several motor aspects of swallowing. Further small-scale studies support that the use of sEMG as a biofeedback tool may facilitate these effects through enhancement of motor learning principles. However, for optimum muscle and skill gains, these exercises need to be completed with adequate intensity and frequency as dictated by principles of exercise physiology and

neuroplasticity (Burkhead et al., 2007; Kleim & Jones, 2008). In addition, to further induce motor learning, using specialized biofeedback equipment (such as sEMG) can be very beneficial. However, this equipment is not always available. For most patients, including patients who live in underserved areas, it is not feasible to have sessions with a speech-language pathologist several times per day or week once they return home from the hospital or clinic. Moreover, patients with mobility restrictions as a result of stroke, Parkinson's disease, or other disorders may have difficulty leaving their house to attend sessions with the speech-language therapist. Therefore, in real life, the majority of patients complete their exercises independently at home without receiving direct feedback from a device or their speech-language pathologists.

Currently, speech-language pathologists do not have reliable, cost effective, and user-friendly surface electromyography tools that will enable them to remotely monitor their patients' progress, to adjust their exercise intensity, and to track their exercise adherence. To start addressing these limitations, we developed a set of user-friendly ultrathin wearable electromyography (EMG) sensors (patent pending, inventors: Lee & Malandraki) and we compared them to traditional commercially available surface electromyography sensors.

2.7. Aims and Hypotheses

As a first step in validating the use of these newly developed sensors, the present study aims to examine the safety and effectiveness of these sensors and participant satisfaction/comfort compared to conventional EMG electrodes (a crossover study design was used). We chose to begin this validation with a group of healthy older adults because the prevalence of dysphagia increases in adults over 50 (Bhattacharyya, 2014). Thus, if validated, individuals above 50 would be the potential candidates for using the wearable EMG sensors in therapy. In addition, as people age, skin loses its elasticity, resulting in the loosening of the skin, therefore, examining the adherence of the wearable sensors in older adults (rather than young adults) becomes more

critical. Testing the sensors in healthy older adults is an important first step before testing this patch with patients with dysphagia in the future.

2.6.a. Specific Aim 1

Signal Related Factors: To compare signal related factors obtained using the new wearable sEMG sensors (i.e., experimental sensors) with signal related factors obtained using the commercially available sEMG sensors (i.e., conventional sensors) in healthy older adults. To accomplish this aim, participants were tested wearing both sensors (sequentially in a randomized order) and comparisons were made between the two types of sensors on **signal related factors** (i.e., signal quality measurements: signal-to-noise ratio, and baseline amplitude, as well as on normalized amplitude during swallow trials, and duration of sEMG burst during swallow trials). Left and right channels were analyzed separately.

Hypotheses:

1. **Signal-to-Noise Ratio**: We hypothesize that the average signal-to-noise ratio acquired using the experimental sensors will not be inferior to the average signal-to-noise ratio acquired using the conventional sensors. This was established using a non-inferiority test.

$$Ho = \mu_{experimental} - \mu_{conventional} < lower\ margin$$

$$Ha = \mu_{experimental} - \mu_{conventional} \geq lower\ margin;$$

where $\mu_{experimental}$ represents the mean signal-to-noise ratio obtained with the experimental sensors and $\mu_{conventional}$ represents the mean signal-to-noise ratio obtained with the conventional sensors.

2. **Baseline Amplitude:** Lower baseline values indicate better signal quality. Thus, we hypothesize that the average baseline amplitude obtained using the experimental sensors

will not be inferior to the average baseline amplitude obtained using the conventional sensors. This was also established using a non-inferiority test.

$$Ho = \mu_{experimental} - \mu_{conventional} > upper\ margin$$

$$Ha = \mu_{experimental} - \mu_{conventional} \leq upper\ margin;$$

where $\mu_{experimental}$ represents the mean baseline amplitude obtained via the experimental sensors and $\mu_{conventional}$ represents the mean baseline amplitude obtained via the conventional sensors.

3. **Normalized Amplitude of the Swallow Trials**: We hypothesize that the normalized amplitude values obtained using the two types of sensors will be equivalent. This was established based on an equivalency test.

$$Ho = \mu_{experimental} - \mu_{conventional} < lower\ margin$$

$$OR\ \mu_{experimental} - \mu_{conventional} > upper\ margin$$

$$Ha = lower\ margin \leq \mu_{experimental} - \mu_{conventional} \leq upper\ margin;$$

where $\mu_{experimental}$ represents the mean amplitude of the swallows obtained using the experimental sensors and $\mu_{conventional}$ represents the mean amplitude of the swallows obtained using the conventional sensors.

4. **Duration of sEMG Burst During Swallow Trials:** We hypothesize that the difference between the mean duration of sEMG burst obtained using the conventional sensors and the experimental sensors will be equivalent. This was established based on an equivalency test.

$$Ho = \mu_{experimental} - \mu_{conventional} < lower\ margin$$

$$OR\ \mu_{experimental} - \mu_{conventional} > upper\ margin$$

$$Ha = lower\ margin \leq \mu_{experimental} - -\mu_{conventional} \leq upper\ margin;$$

where $\mu_{experimental}$ represents the mean duration of the sEMG burst obtained using the experimental sensors and $\mu_{conventional}$ represents the mean duration of the sEMG burst swallows obtained using the conventional sensors.

2.6.b. Specific Aim 2

Safety and Pre-Clinical Factors: To examine the safety/adverse effects, efficiency, and satisfaction/comfort with the experimental sEMG sensors as compared to conventional sEMG sensors in healthy older adults. To accomplish this aim, comparisons were made between the two types of sensors on safety/adverse effects, efficiency of electrode placement, and satisfaction/comfort.

Hypotheses:

1. **Safety and Adverse Effects:** We do not expect to observe any adverse effects during or after using either type of sEMG sensors.
2. **Efficiency:** We hypothesize that the amount of time it takes to place the experimental sensors will be shorter than the amount of time it takes to place the conventional sensors. This was established using a regular paired t-test.

$$Ho = \mu_{experimental} - \mu_{conventional} = 0$$

$$Ha = \mu_{experimental} - \mu_{conventional} < 0;$$

where $\mu_{experimental}$ represents the mean duration of electrode placement with the experimental sensors and $\mu_{conventional}$ represents the mean duration of electrode placement with the conventional sensors.

3. **Satisfaction/Comfort:** We hypothesize that satisfaction expressed after using the experimental sensors will be higher than the satisfaction reported using the conventional sensors. This was established using a regular paired t-test.

$$Ho = \mu_{experimental} - \mu_{conventional} = 0$$

$$Ha = \mu_{experimental} - \mu_{conventional} > 0;$$

where $\mu_{experimental}$ represents the mean satisfaction with the experimental sensors and $\mu_{conventional}$ represents the mean satisfaction with the conventional sensors.

The following chapter offers details on the methods that were used to accomplish these specific aims.

CHAPTER 3. METHODOLOGY

3.1. Participants

Forty healthy older adult participants were recruited for this study. This sample size was determined via a power analysis based on pilot study results (see Section 3.8., page 76 for details). Inclusion criteria were 1) age range: 50-90 years of age; 2) no history of dysphagia; 3) no history of neurological disease; 4) a score in the normal range (a score of 26 or higher out of 30) on the Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 2005); and 5) a score of <3 on the Eating Assessment Tool (EAT-10) (Belafsky et al., 2008). Exclusion criteria were: 1) history of head/neck cancer, surgery, or radiation exposure to the head and neck area; 2) gastrointestinal disease; and 3) chronic respiratory disease. All participants met the criteria for the study.

3.1.a. Recruitment

Participants were recruited from the Greater Lafayette-West Lafayette and Indianapolis areas through flyers, word of mouth, newspaper ads, and written announcements describing the study. Some participants were recruited from the Purdue Department of Speech, Language, and Hearing Sciences' Human Participants Registry. Purdue's Institutional Review Board approved this study. Informed consent was obtained from all participants.

3.2. Experimental Design

A randomized crossover design was used. Allocations were made using computer-generated random numbers such that an equal number of participants were randomly assigned to Groups A and B. The order of the experimental conditions differed across groups. Group A participants completed the experimental protocol with the conventional sensors first, and Group

B participants completed the protocol with the experimental sensors first (Table 4). There was a 10-minute break between Part 1 and Part 2. A quick screening was completed after randomization.

Table 4. Study Design

	Part 1		Part 2
Group A	1. **Screening tests** 2. **Experiment:** Conventional sensors and other peripheral devices 3. **Post-experiment tests**	→	1. **Experiment:** Experimental sensors and other peripheral devices 2. **Post-experiment tests**
Group B	1. **Screening tests** 2. **Experiment:** Experimental sensors and other peripheral devices 3. **Post-experiment tests**	→	1. **Experiment:** Conventional sensors and other peripheral devices 2. **Post-experiment tests**

3.3. Materials

3.3.a. Screening Materials

3.3.a.i. Phone Screening

The Pre-visit Screening Questionnaire (PSQ, APPENDIX B) is a brief screening that was completed over the phone. This questionnaire includes questions on demographics (e.g., age, medical history) and swallowing/eating skills. All potential participants who contacted the investigators in the Purdue Imaging, Evaluation and Treatment of Swallowing Research (I-EaT) Laboratory about this study provided verbal consent before completing the PSQ to determine initial eligibility. If they did not qualify for the study based on this screening, the Pre-visit Screening Questionnaire was shredded (See Figure 8. Consort Diagram for details).

3.3.a.ii. In-house Screening

The Eating Assessment Tool-10 (EAT-10, APPENDIX C) is a self-administered tool that has been validated with 235 patients who were diagnosed with voice and swallowing disorders (Belafsky et al., 2008). It includes ten questions related to symptoms dysphagia. Each question is rated from zero to four and the total score ranges between zero and 40. A score of 3 or above indicates increased likelihood of experiencing difficulty with swallowing (Belafsky et al., 2008). The EAT-10 was administered to screen for self-reported swallowing problems. Participants who scored 3 or above were excluded from the study (See Section 3.1 for inclusion and exclusion criteria.)

In addition to the EAT-10, an Oropharyngeal Sensorimotor Examination of Swallowing (OPSES) and trial swallows were also completed. The OPSES, developed by Malandraki (unpublished), is a short clinical neurological exam to check the function of the cranial nerves related to swallowing (Logemann, 1998). The function of cranial nerves V, VII, IX, X, XII was assessed by asking the participants to complete simple tasks such as raising their eyebrows, pursing their lips, and raising their shoulders against resistance. Participants who exhibited impaired cranial nerve function or signs of oropharyngeal swallowing difficulty during the trial swallows as determined by a dysphagia clinician were excluded from this study.

The Montreal Cognitive Assessment (MoCA) is a brief cognitive screening tool that assesses nine different cognitive domains: visuospatial skills, executive function, naming, memory, attention, language, abstraction, calculations, delayed recall and orientation (Nasreddine et al., 2005). The final score ranges from zero to 30. A score of 26 and higher indicates normal cognitive function. The MoCA was administered to screen for cognitive skills and ability to follow directions.

3.3.b. Data Collection Materials

This section provides a detailed description of the materials that were used for data collection. The experimental protocol included examining the swallowing muscles using surface electromyography. Each participant completed the research protocol twice, once with the experimental sensors and once with the conventional sensors. Peripheral devices, i.e., a wireless physiological monitoring device, a Respiratory Inductance Plethysmography belt, a nasal cannula, and the Iowa Oral Performance Instrument (IOPI), as well as several forms to document patient-related factors were also used in the experiments. Table 5 presents a brief list of materials that are discussed in detail in this section.

Table 5. Data Collection Materials

Session	Tasks	Timing	Materials
Part 1	In-house Screening	25-30 minutes	• EAT-10 • MoCA • OPSES
	Pre-Experiment	5 minutes	• Case History Form
	Experiment	25-30 minutes	• BioRadio, RIP belt, nasal cannula, IOPI • EMG sensors
	Post-Experiment	10 minutes	• Visual Inspection Form • Pain Screening Form • Satisfaction/Comfort Questionnaire
BREAK (10 minutes)			
Part 2	Experiment	25-30 minutes	• BioRadio, RIP belt, nasal cannula, IOPI • EMG sensors
	Post-Experiment	10 minutes	• Visual Inspection Form • Pain Screening Form • Satisfaction/Comfort Questionnaire

Note: EAT-10: Eating Assessment Tool-10, MoCA: Montreal Cognitive Assessment, OPSES: Oropharyngeal Sensorimotor Examination of Swallowing, RIP belt: Respiratory Inductance Plethysmography belt, IOPI: Iowa Oral Performance Instrument, EMG: Electromyography

3.3.b.i. Case History Data Sheet

A brief case history form was used to collect information on demographics, communication skills, medical history, and swallowing and feeding skills.

3.3.b.ii. Wireless Physiology Monitoring Device and Software

The BioRadio (Great Lakes NeuroTechnologies, Cleveland, OH) (Figure 2) is a biomedical device with four programmable channels and has the ability to record and transmit human physiological signals wirelessly via Bluetooth. The BioRadio was used to wirelessly collect surface EMG (sEMG), respiration, and airflow signals in this study. These three signals were all used to confirm the swallow events (Lee, Steele, & Chau, 2011; Martin et al., 1994; Moreau-Gaudry, Sabil, Benchetrit, & Franco, 2005; Palmer & Hiiemae, 2003). BioRadio's data acquisition software "BioCapture" was used to display the signals. Output was displayed on a Dell laptop (Processor: Intel Core i7 vPro, CPU: 2.80 GHz, RAM: 8 GB, screen size: 15.6", screen resolution: 3200 X 1800).

Figure 2. BioRadio Device (handheld)

3.3.b.iii. Respiratory Inductance Plethysmography (RIP) Band

Movement of the chest and changes in thoracic circumference during respiration and swallowing were recorded using a respiratory inductance plethysmography (RIP) band with a piezoelectric sensor (Great Lakes NeuroTechnologies, Cleveland, OH). The elastic RIP band was placed around the rib cage under the axilla to track the movement of the rib cage (Moreau-Gaudry et al., 2005; Wheeler Hegland, Huber, Pitts, Davenport, & Sapienza, 2011). The RIP band is stretchable and can be adjusted for individuals with different weights.

As mentioned in Chapter 2, the coordination of swallowing and respiration is vital for airway protection during swallowing (Martin-Harris et al., 2005; B. J. Martin et al., 1994). The RIP band was used to capture inhalation and exhalation patterns at rest and the apnea period during the pharyngeal phase of the swallowing event. This signal was used as one of two guides in the identification of the swallows (outlined below) to help us confirm the swallow signal.

3.3.b.iv. Nasal Airflow Cannula

A nasal airflow cannula (Great Lakes NeuroTechnologies, Cleveland, OH) was also used to record inhalation and exhalation at rest and during swallowing (Figure 3). The nasal airflow cannula consists of a 2 feet hollow tube and has two small, curved prongs that can be inserted into participants' nostrils to monitor nasal airflow during swallowing tasks (Hiss et al., 2001; Lee et al., 2011). The respiratory signals obtained from the RIP band and nasal airflow cannula were used as complementary tools to verify the inhalation/exhalation patterns and the swallow apnea period. Results from our preliminary study showed that the RIP band is particularly useful in capturing the inhalation and exhalation patterns at rest and the swallow apnea period in larger boluses. On the other hand, the nasal airflow signal captures the swallow apnea period in smaller boluses more accurately, and clearly shows the end of the swallow apnea period. Therefore, both

devices were used for this experiment. These signals were used to confirm the swallowing signal during the analysis phase.

Figure 3. RIP Belt (Left) and Nasal Airflow Cannula (Right)

3.3.b.v. Iowa Oral Performance Instrument

The Iowa Oral Performance Instrument (IOPI, IOPI Medical, Redmond, WA) was used to obtain the maximum voluntary contraction of the submental muscles during electromyography. The IOPI is a handheld device that is connected to an air-filled bulb via a connector tube. The air-filled bulb was placed on the anterior portion of the tongue. Participants were asked to push the air-filled bulb against the roof of their mouth with maximum effort. Maximum lingual pressures were displayed on an LCD screen. Three maximum anterior lingual pressure values (in kilopascals) that differ by less than 5% were obtained and recorded. Previous studies have shown the relationship between maximum lingual pressures and submental muscle group activity (Robbins et al., 2005; Steele & Huckabee, 2007; Yeates, Steele, & Pelletier, 2010).

The maximum voluntary contraction of the submental muscles was used to normalize EMG amplitude in the analysis phase. Because of the inherent variability of the EMG signal, it should be normalized against a criterion reference task in order for us to make valid comparisons across conditions and/or participants (Stepp, 2012). For the anterior neck musculature, the maximal lingual voluntary contraction has been found to be a reliable way to normalize the submental sEMG data (Netto & Burnett, 2006). Thus, the IOPI was used to obtain the maximum voluntary contraction of the submental muscles.

3.3.b.vi. Surface Electromyography Sensors

Two different types of surface EMG sensors were used in this study: conventional and experimental. Description of each sensor type is provided below:

Conventional Sensors

Commercially available, reusable, Ag/AgCI snap-on bipolar electrodes (Great Lakes NeuroTechnologies, Cleveland, OH) were used as the control condition in this study (i.e., conventional sensors). These electrodes were connected to the BioRadio via 40-inch lead wires for the measurement of the activation of the submental muscles. The thickness and the diameter of the electrodes was 1.5 millimeters.

Figure 4 shows an image of a conventional sEMG electrode used in the study.

Figure 4. Conventional Sensors

Experimental Sensors

The version of the experimental sensors that were used in this study is shown in Figure 5 (patent pending; inventors: Lee & Malandraki). The sensor patch is designed using polyimide with 13 µm thickness and is cut in honeycomb shape to increase flexibility. The mesh structure allows breathability of the skin for prolonged use. Slibione (i.e., a biocompatible skin adhesive) was incorporated onto the sensor patch as an adhesive. A water-soluble body adhesive was also applied (i.e., JOBST It Stays! Roll-On Body Fixative) on the sensor patch 30 minutes prior to data collection to increase adhesion. The four electrodes are created from copper and

electroplated with gold for biocompatibility. The inter-electrode distance is 1.5 centimeters from edge to edge and the electrodes are aligned with the muscle fibers.

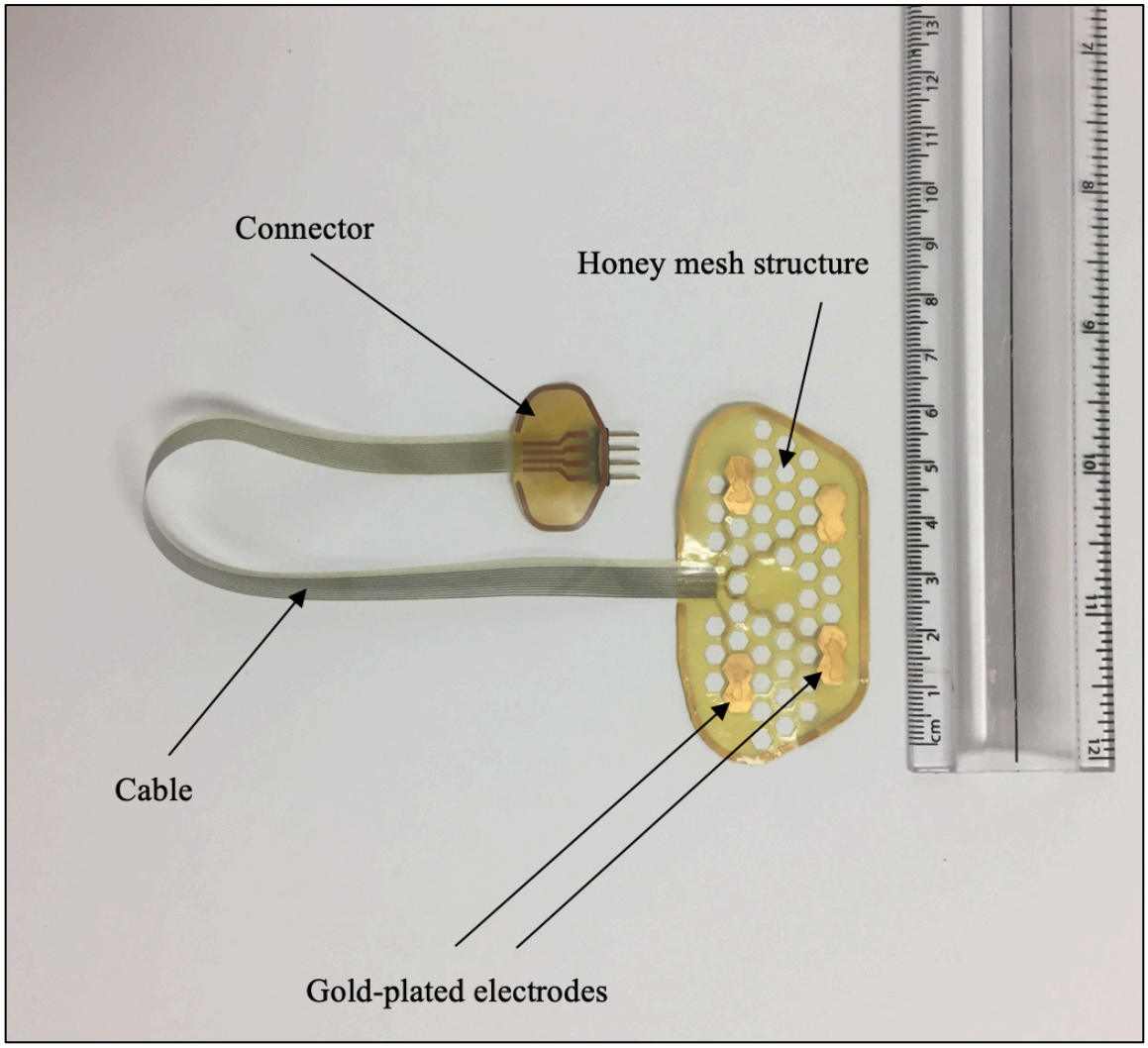


Figure 5. Experimental Sensors (patent pending)

3.3.b.vii. The Visual Inspection Form

The Visual Inspection Form (APPENDIX D) was completed after the removal of the sensors to check for adverse effects (e.g., redness or skin irritation). This questionnaire was completed by an experimenter who was not part of the data collection process and who was blind to sensors tested to avoid any bias. The experimenter conducted a thorough examination of the

submental area first, right after the removal of the sensors and then five minutes after the removal of the sensors and rated the appearance of the skin on a binary scale (presence of symptoms or absence of symptoms). This delayed input allowed us to investigate whether any allergic reactions or discomfort was occurring or still present 5 minutes after the experiment. The same procedure was followed post removal of both the conventional and the experimental sensors.

3.3.b.viii. The Pain Screening Form

The Pain Screening Form (APPENDIX E) is a quick pain screening that includes one Yes/No question and the Wong-Baker FACES Pain Rating Scale (Kim & Buschmann, 2006). This form was completed by the participants twice: once after the completion of the experimental protocol, and then 5 minutes post-experiment (after the Visual Inspection Form has been completed). This delayed input allowed us to investigate whether any pain was occurring or still present 5 minutes after the experiment. This form was also completed in the presence of the experimenter who is not part of the data collection process to avoid bias. The same procedure was followed post removal of both the conventional and the experimental sensors.

3.3.b.ix. Satisfaction/Comfort Questionnaire

A satisfaction/comfort questionnaire was also completed at the end of each condition (i.e., once after the completion of the protocol with the experimental sensors and once after the completion of the protocol with the conventional sensors). The satisfaction/comfort questionnaire included five questions related the participants' experiences during the experimental protocol. The answers were rated on a 10-point scale (i.e., 1 = extremely uncomfortable, 10 = extremely comfortable).

3.4. Data Collection Protocol

3.4.a. Screening

3.4.a.i. Pre-visit Phone Screening

Researchers completed a brief phone screening (approximately 2 minutes) using the PSQ with potential participants interested in this study. If potential participants passed the phone screening, they were invited to participate. During this communication, male participants were asked to shave prior to the EMG session to ensure good skin-to-electrode contact during the experiment, which is important for signal quality.

3.4.a.ii. In-person Screening

During Part 1 of the study, researchers obtained informed consent from each participant. The study was explained in detail and enough time was given to each participant to read the consent form and ask any questions. Upon consenting, participants completed the Eating Assessment Tool-10 (EAT-10) (Belafsky et al., 2008) and received a clinical swallowing assessment (OPSES and trial swallows) to ensure healthy oropharyngeal swallowing function. After the swallowing screening, participants also completed the Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 2005). Participants who fit all the study inclusion and none of the exclusion criteria proceeded to the experiment.

3.4.b. Experimental Protocol

The doctoral student was in charge of collecting data during the pre-experimental and experimental phases of the study. The data from the post-experiment part was collected by a trained research assistant (RA) to prevent bias.

3.4.b.i. Pre-Experiment

First, participants completed a case history form that included questions on demographics, general health, and swallowing and eating skills. The following experimental protocol was completed on the same day.

3.4.b.ii. Experiment

First, the respiratory belt was placed around the participant's upper thorax, and a nasal airflow cannula was placed on the participants' nostrils to capture pressure-based airflow during swallowing (Figure 6) (Hirst, Ford, Gibson, & Wilson, 2002; Lee et al., 2011). These two signals were used to increase accuracy in determining the exact timing of the swallow trials (Daimon & Yamaguchi, 2014; Martin-Harris et al., 2005).

Then, the examiner visually inspected the area under the chin and cleaned the skin with alcohol wipes to prepare it for optimum sensor-to-skin contact. The submental muscles were palpated to identify their location while asking the participant to push the tongue against the roof of the mouth. The experimenter marked (with a highlighter) the area where the location of the submental muscles was identified to ensure that both types of sensors were placed on the same location. Both the experimental and the conventional sensors were placed on the surface of the left and right submental muscles over the platysma (Figure 6). The inter-electrode distance was approximately 1.5 centimeters from edge to edge (Konrad, 2005; Stepp, 2012). Last, the ground electrode was placed on the mastoid process of the temporal bone since this bone is close to the EMG sensors (Stepp, 2012). To verify the location of the electrodes, the participants were asked to swallow their saliva, open/close their jaw, and push against the roof of their mouth with the tongue to visualize the signal showing activation of the submental muscles. The amount of time

it takes to place the sensors on the submental muscles was measured in order to examine the efficiency of sensor placement (pre-clinical outcome variable #2, see Section 3.6).

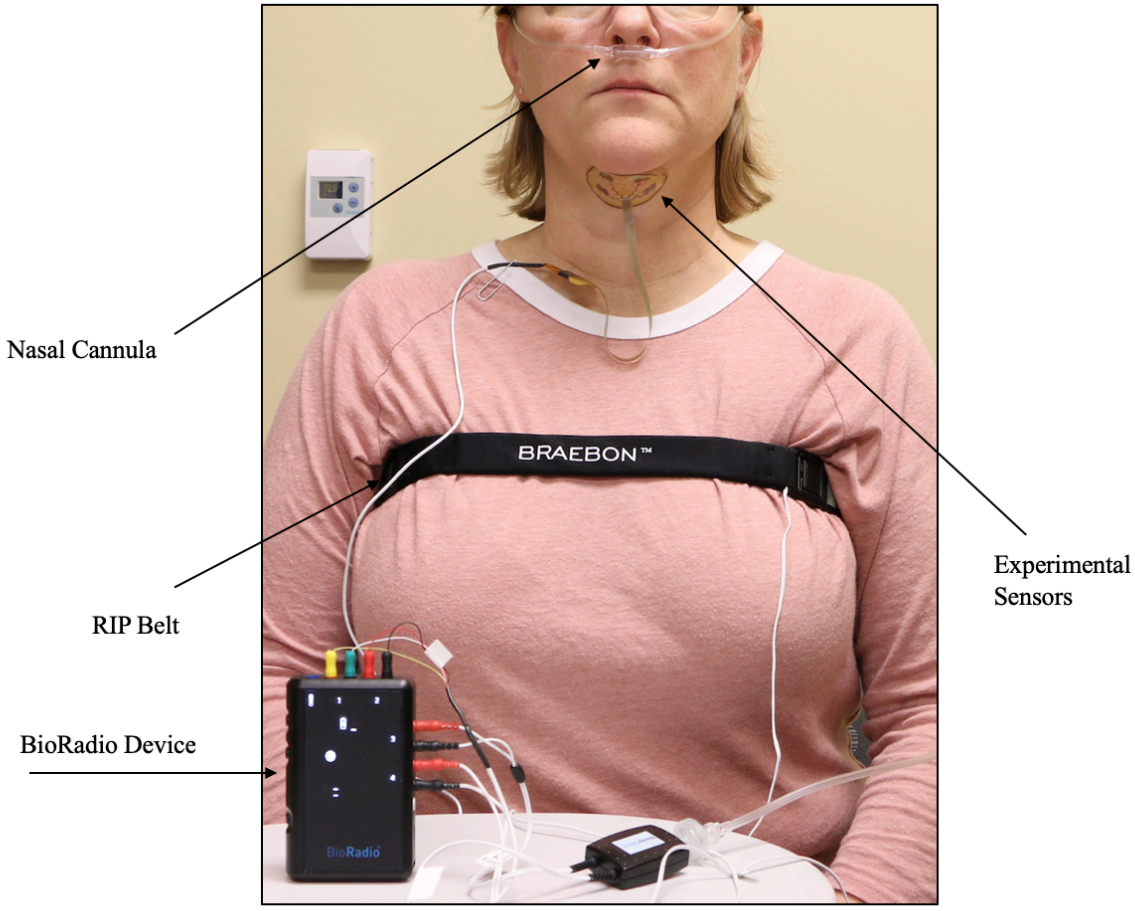


Figure 6. Data Collection Materials and Setup with Experimental Sensors

After placing all equipment, the participants were asked to sit still and breathe normally for thirty-seconds to obtain a baseline for the sEMG signal and investigate the quality of all signals. Subsequently, a criterion-reference task was completed comprising of the maximum voluntary contraction of the submental muscles using the IOPI (Konrad, 2005; Stepp, 2012). Participants were asked to push the air-filled balloon against the roof of their mouth with

maximum effort. Three maximum lingual press values that differed by less than 5% for the anterior tongue were obtained simultaneously with the sEMG data acquisition to capture the maximum contraction of the submental muscles with both sensors. These trials were used to normalize the EMG amplitude data. Normalization of the EMG data is important in order to enable comparisons across trials, participants, and sessions (Stepp, 2012; Van Houtte, Claeys, D'Haeseleer, Wuyts, & Van Lierde, 2013).

The swallow trials were completed next. The following trials were completed five times each: 5 ml thin liquid and 10 ml thin liquid boluses using a medicine cup. A researcher in our laboratory created computer-generated random numbers to randomize the order of the swallow trials in order to control for fatigue. There were 2 different randomization sequences used in this study (Table 6). The order of trials was counter-balanced, half of the participants were assigned to randomization order 1 and the other half was assigned to randomization order 2.

Table 6. Randomization Order of the Swallowing Tasks

	Randomization 1	**Randomization 2**
Task 1	10 ml thin liquid	5ml thin liquid
Task 2	5ml thin liquid	10 ml thin liquid

Participants were asked to sit as still as possible to prevent any additional motion artifact. The following directions were provided before each swallow: "Here is some water. Put it all in your mouth, hold it for a few seconds, and swallow when you are ready." All bolus trials were self-administered. The experimenter marked the approximate timing of the swallow by visually inspecting the thyroid notch and closely monitoring the raw signal. In addition, the timing of the swallow was further verified by the signals obtained from the respiratory belt and nasal cannula.

3.4.b.iii. Post-Experiment

After the completion of the experimental protocol, first the examiners removed the sensors from the submental area. Then, a trained research assistant (RA) who was typically blinded to type of sensor and was not directly involved in this dissertation work completed or assisted the participant to complete the following questionnaires. The RA was trained by the doctoral student and read the instructions written on each questionnaire verbatim. The doctoral student was not in the room during this process.

The Visual Inspection Form

First, the RA visually inspected the skin for any signs of adverse effects (i.e., redness, itchiness, and irritation) and completed the Visual Inspection Form (APPENDIX D) once right after the experiment and once 5 minutes after the experiment to investigate whether any adverse effects were occurring or still present 5 minutes later.

The following script was read: "Now, I am going to check your neck for any redness or skin irritation." (The RA checked the skin and marked "Yes" or "No"). Then the RA asked the following question to the participant "Does your skin feel itchy?" The RA marked the answer on the Visual Inspection Form. If the participant reported any problems, then the RA wrote down the additional information provided in the comments section of the form.

The Pain Screening Form

Then, the RA helped the participants complete the Pain Screening Form by asking, "Do you have any pain in the neck area? If the participants said "No", the RA marked 0. If the participants say "Yes", the RA said, "Please rate your pain on a scale of 0 to 10, where zero is having no pain and 10 is having the worst pain possible." Once the participants rated the pain level on the Pain Rating Scale, the RA then asked, "Please describe the pain." If the participants

provided any additional information, the RA added it to the comments section. This form was also completed once after the completion of the experimental protocol and then 5 minutes after the experiment.

Satisfaction/Comfort Questionnaire

Lastly, the RA helped the participants complete the Satisfaction/Comfort Questionnaire by reading the following statement: "Please read each statement carefully and rate it based on your experience with using the sensors." After the completion of the experimental protocol with the first set of sensors, the same procedure was completed with the alternate sensors.

3.5. Data Analysis Protocol

3.5.a. Surface Electromyography

All EMG data was de-identified before the analysis. The doctoral student (i.e., the dissertator) who completed the analysis was blinded to type of sensors and subject ID. The sEMG data were analyzed using a custom-built MATLAB code (MATLAB Inc., Natick, MA). The following procedure was used for both sensors. First, the raw EMG data were visually inspected for contamination and other artifacts. Any artifact that occurred during the rest periods was removed. Then, signal was divided by the amplifier gain and raw data were demeaned, rectified, filtered, and smoothed using the MATLAB code. Demeaning is the process of calculating the mean amplitude of all data and subtracting the mean from each data point to remove low amplitude voltage offset typically present in hardware (Stepp, 2012). Rectification is another important step since the raw EMG data has a zero mean with positive and negative spikes being almost equal above and below zero (Stepp, 2012). Because of this reason, before smoothing the raw data, it is important to rectify the signal and convert all the negative amplitudes in the raw data to positive amplitudes. Then, the signal was smoothed using a

hamming window (200 msecs) and the energy below 20 Hz and above 500 Hz was filtered (Stepp, 2012). After processing the data, the beginning and end times of all tasks were selected to calculate amplitude and duration. Selection was either automatic or manual. Automatic selection identifies the onset and offset of the peaks by looking back and forth in 0.5 second windows and detects a change in baseline that is higher than 2 SDs. In some cases when there was movement before or after the swallow, automatic selection did not identify the onset and offset of the swallow signal accurately. In these instances, the onset and offset of the swallow signal were identified manually. Normalization was completed using the maximum effort value of the criterion reference task to enable us to make direct comparisons between different trials/tasks (Stepp, 2012).

3.5.b. Post-Experiment Forms

The data from the Visual Inspection Form, Pain Screening Form, and the Satisfaction/Comfort Questionnaire was entered into a database by an undergraduate research assistant. The data was de-identified and the doctoral student who completed the analysis was blinded to type of sensor and subject ID. An RA double-checked all data entry for accuracy.

3.6. Outcome Variables

3.6.a. Signal Related Factors

Signal related factors were examined by investigating the signal characteristics at rest and during swallow trials.

3.6.a.i. Signal Quality

Signal quality was examined by computing two outcome variables, i.e., the signal-to-noise ratio and the baseline amplitude of the signal. Baseline amplitude at rest was examined

using the 30-second baseline measurement obtained at the beginning of the examination. The average noise level was measured by calculating the mean amplitude of the signal for 5 seconds (Konrad, 2005). Signal to noise ratio was calculated using the following formula:

$$SNR = 20 \log_{10} \frac{Signal}{Noise}$$

3.6.a.ii. Signal Amplitude and Duration During Tasks

Signal amplitude and duration during tasks (two additional signal related variables) were examined by calculating the normalized amplitude (i.e., area under the curve) and the duration of sEMG burst values for all swallow trials (Stepp, 2012) (Figure 7). The onset and offset of muscle activity during a swallow were selected using the custom-built MATLAB code (Section 3.5.a.). Two amplitude values were obtained for each swallow – one from the left submental muscles and one from the right submental muscles.

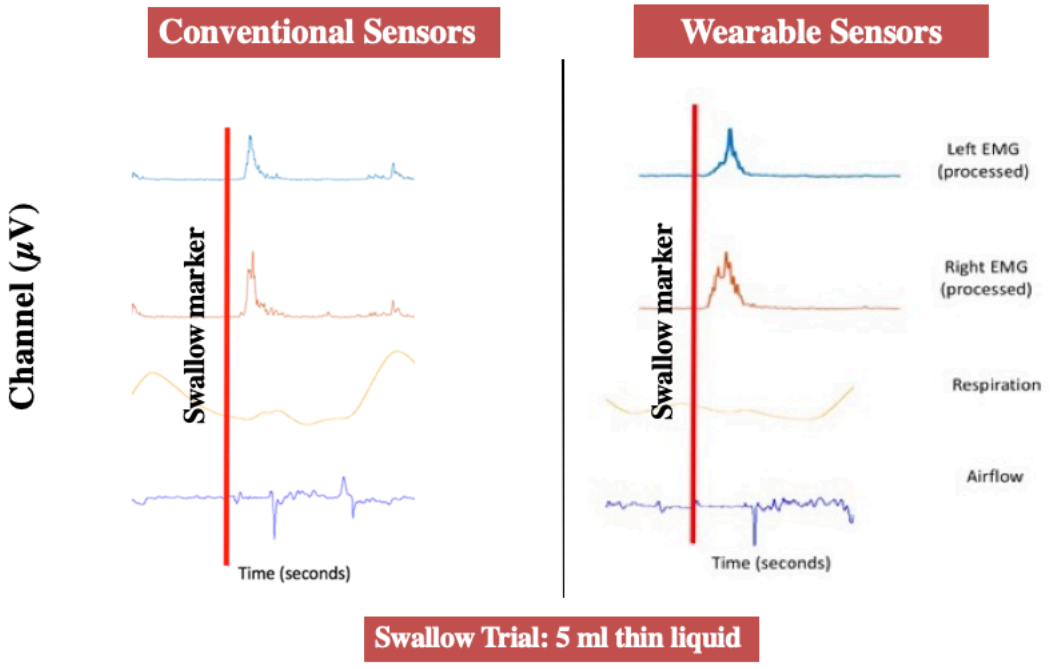


Figure 7. Processed EMG Signal and Swallow Verification Markers

3.6.b. Safety and Pre-Clinical Factors

3.6.b.i. Safety/Adverse Effects

Safety was examined by visually inspecting the skin for irritation, redness, and any other problems and by completing the Visual Inspection Form (Appendix D). Pain level (if present) was examined using the Pain Screening Form (Appendix E). As mentioned before, a trained research assistant facilitated the completion of these forms. The Visual Inspection Form was rated on a binary scale (Presence of Symptoms/Absence of Symptoms). The Pain Screening Form was rated on a binary scale (Yes/No) and the subject rated the pain level from 0-10 with 0 being no pain at all, and 10 being worst pain possible.

3.6.b.ii. Efficiency

Efficiency of electrode placement was measured by the length of time it took for the experimenter to place the electrodes on the submental muscles. It was measured in minutes; seconds using a digital timer/stopwatch. The experimenter started the timer when she first touched the sensors to pick them up for placement on the submental area and stopped it when she connected all the electrodes to the BioRadio device.

3.6.b.iii. Satisfaction/Comfort

Satisfaction/comfort was examined using the Satisfaction/Comfort Questionnaire detailed above. Responses were scored on a 10-point scale (1 = extremely uncomfortable, 10 = extremely comfortable). The same research assistant facilitated the completion of the Satisfaction/Comfort Questionnaire as well.

3.7. Statistical Analyses

The statistical analyses were carried out using SAS version 9.4 (SAS Institute, Cary, N.C.) (SAS Institute Inc, 2014). This study was designed to have at least 80% power to detect a

difference between the experimental and conventional sensors in the primary variables of interest –signal-to-noise ratio, baseline amplitude, and normalized amplitude of swallow trials (see Section 3.8 for details). Data were visualized using line graphs. Quantile-quantile (Q-Q) plots were also used to assess normality. Data collected from ten percent of the sample was analyzed by the doctoral student and by the director of the Purdue I-EaT laboratory to calculate inter- and intra-rater reliability. Intra- and interrater reliability measures were assessed through intraclass correlation coefficients (ICCs). To compare the signal-to-noise ratio and baseline amplitude values obtained using the two sensors types, non-inferiority tests were used. To compare the normalized amplitude values and the duration of sEMG burst during swallow trials, equivalency tests were used. Lastly, to compare efficiency of electrode placement and satisfaction/comfort, paired-samples t-tests were used. Effect sizes were computed using Cohen's *d*.

3.8. Basis for Power Analysis and Determining Margins - Preliminary Study

Five healthy adults were recruited to participate in the preliminary study, which formed the basis for the power analysis for the larger study. Three older females and two older males completed the preliminary study. The mean age was 69. Sample size calculations were based on the results of this preliminary study (See Appendix A for detailed information and results of the preliminary study) on the primary variables of signal-to-noise ratio, baseline amplitude at rest, and normalized amplitude of swallow trials. The sample sizes were calculated to achieve at least 80% power for each primary variable of interest. Alpha level was set to 0.025 to correct for multiple comparisons for each variable.

Sample size calculations were completed based on a non-inferiority test for baseline amplitude at rest and signal-to-noise ratio (see Specific Aim 1, Hypothesis 1 and 2, page 51), and an equivalence test for EMG amplitude during swallows (see Specific Aim 1, Hypothesis 3, page

52). Both of these tests require the identification of margins. Typically, these margins are identified from previous studies that have been published in the area of interest (Walker & Nowacki, 2011). We started our power calculations by searching the literature to find similar studies; however, these are typically not reported in swallowing research (a detailed explanation on our search can be found in APPENDIX A). Instead, we used our pilot data to determine our sample sizes.

Two methods were used to calculate the sample size. Since the 5ml and 10ml swallow trials were repeated five times, we were able to obtain five normalized amplitude values for 5ml and five normalized amplitude values for 10ml water swallows from each subject. This allowed us to assess the within subject variability in different trials of 5ml and 10ml of water swallows using the conventional sensors, which was considered the current gold standard. However, only one signal-to-noise ratio and one baseline amplitude value at rest were obtained from each participant (one from the left side and one from the right side). Therefore, we could not assess the within subject variability on these two parameters. Instead, we examined the variability of the difference between the two types of sensors to set the non-inferiority margins for these two variables (explained below).

Subject 2 had abnormal tongue strength values in addition to highly variable normalized EMG amplitude results (please refer to APPENDIX A for details). Therefore, power calculations for amplitude values were completed without this participant.

3.8.a. The Margins for the Non-Inferiority Tests

In order to determine the margins needed for power calculations related to signal-to-noise ratio and baseline amplitude, we first pooled the data from left and right side of the body together and computed the observed difference between the experimental and conventional sensors for

each participant using the data from the preliminary study (Refer to Appendix A, Table 18 and Table 19). We then calculated the mean and standard deviation of the difference. Standard deviation of the difference was multiplied by 0.5 and this number was used as the non-inferiority margin (i.e., null difference). Then, to determine the sample sizes, we calculated the standard deviation of the values obtained with each sensor and the correlation between the two sensors. Based on these values, the sample sizes presented on Table 7 were obtained.

Table 7. Results of the Power Calculations for Non-Inferiority Tests Based on Data from Preliminary Study

	Mean Difference	Null Difference (Margin)	SD of Conventional Sensors	SD of Experimental Sensors	Correlation	Sample Size
S/N Ratio	0.82	-0.99	6.43	6.44	0.95	12
Baseline	-0.39	0.2	5.25	5.26	0.99	15

Note. Mean difference: Observed mean difference of two sensor types. Null difference: Standard deviation of the difference of two sensor types. A minus sign was added before the null difference values for SNR because of the direction of the test. SD = Standard Deviation

3.8.b. The Margins for the Equivalency Tests

To set the lower and upper margins for the equivalency tests (used for the comparisons of the task related normalized amplitude), we used the pilot data obtained using the conventional sensors, which was considered the current gold standard. The goal here was to examine the within subject variability obtained when using the conventional sensors in the pilot study. We would therefore be able to assess within what margin the values obtained using the experimental sensors need to be, to be considered equivalent to the conventional sensors.

Given that there were five normalized amplitude values from the left and right side of the submental muscles for 5 and 10ml water swallows, there were 25 possible differences for each

subject and condition. Left and right-side values were pooled together. First, we calculated all possible differences from four participants (as a reminder one subject's amplitude values were deemed too variable to include in these calculations) and then, took the standard deviation of these values. Our equivalency margin was set as ± of the standard deviation. Mean difference for the power analysis was set to zero (marker of equivalency). Table 8 shows the normalized amplitude values for each participant of the preliminary study across different swallow trials and the mean and within subject standard deviation.

Table 9 shows the results of the sample size calculations for the equivalency tests.

Table 8. Normalized Amplitude Values (%) for Each Swallow Trial and each Participant of the Preliminary Study using the Conventional Sensors

ID	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Mean	SD
				5ml Left			
1	18.30	24.42	30.60	23.73	26.02	24.61	4.43
2	40.00	29.48	30.06	30.75	36.00	33.26	4.57
3	16.05	10.30	11.47	11.92	8.40	11.63	2.82
4	19.50	17.92	16.04	15.84	20.17	17.89	1.96
5	5.96	5.87	5.19	5.48	5.84	5.67	0.32
				10ml Left			
1	39.32	26.12	26.56	26.59	22.61	28.24	6.41
2	27.48	30.61	35.22	39.35	33.42	33.22	4.51
3	12.91	15.79	10.48	14.51	12.80	13.30	1.99
4	22.70	20.00	20.33	19.63	18.18	20.17	1.63
5	6.26	5.99	8.88	7.57	9.42	7.62	1.52
				5ml Right			
1	21.28	21.46	26.93	22.12	21.74	22.71	2.38
2	26.12	19.22	20.37	19.96	20.86	21.31	2.75
3	15.35	13.93	14.00	12.42	9.18	12.98	2.36
4	19.95	18.28	17.22	14.41	19.75	17.92	2.25
5	5.76	5.93	5.72	5.61	5.58	5.72	0.13

				10ml Right			
1	37.44	22.78	25.27	21.80	22.57	25.97	6.54
2	18.69	21.03	23.39	24.62	22.25	22.00	2.28
3	13.63	14.10	10.55	11.99	12.70	12.59	1.40
4	25.36	19.91	20.48	17.41	23.97	21.43	3.21
5	6.76	5.92	9.94	7.49	9.80	7.98	1.81

Note. These values are reported in percentages, as they were normalized.

Table 9. Results of the Sample Size Calculations for the Equivalency Tests Based on the data from the Preliminary Study

	Equivalence Margins	**Standard Deviation**	**Correlation between Two Sensors**	**Sample Size**
Amplitude 5ml	±3.1	3.6	0.87	6
Amplitude 10 ml	±4.68	5.73	0.71	12

Note: Standard deviation is the SD of the mean difference (from pilot data)

Based on the results of our power calculations, it was deemed appropriate to aim for a sample size of 40 subjects that would definitely provide >80% power for the analysis of our primary variables.

CHAPTER 4. RESULTS

Forty healthy adults were recruited for this study. Section 4.1 reports the results of the study, with Section 4.1.a focusing on the participants, Section 4.1.b. providing a detailed description of the results of the signal related factors, and Section 4.1.c focusing on the results of the safety and pre-clinical factors.

4.1. Results of the Study

4.1.a. Participants Enrollment and Demographics

Fifty-one adults were screened for this study (See Consort Diagram in Figure 8). Out of the 51 screened individuals, seven people did not meet the inclusion criteria. Specifically, four people did not qualify due to a history of gastrointestinal disease, two people did not qualify due to a diagnosis of Chronic Obstructive Pulmonary Disease (COPD), and one person reported experiencing swallowing difficulties. Three more people did not show up or canceled their appointment due to illness or scheduling conflicts. Finally, one person declined to participate, because he did not want to shave his beard for the experiment. As a result, forty subjects participated in this study.

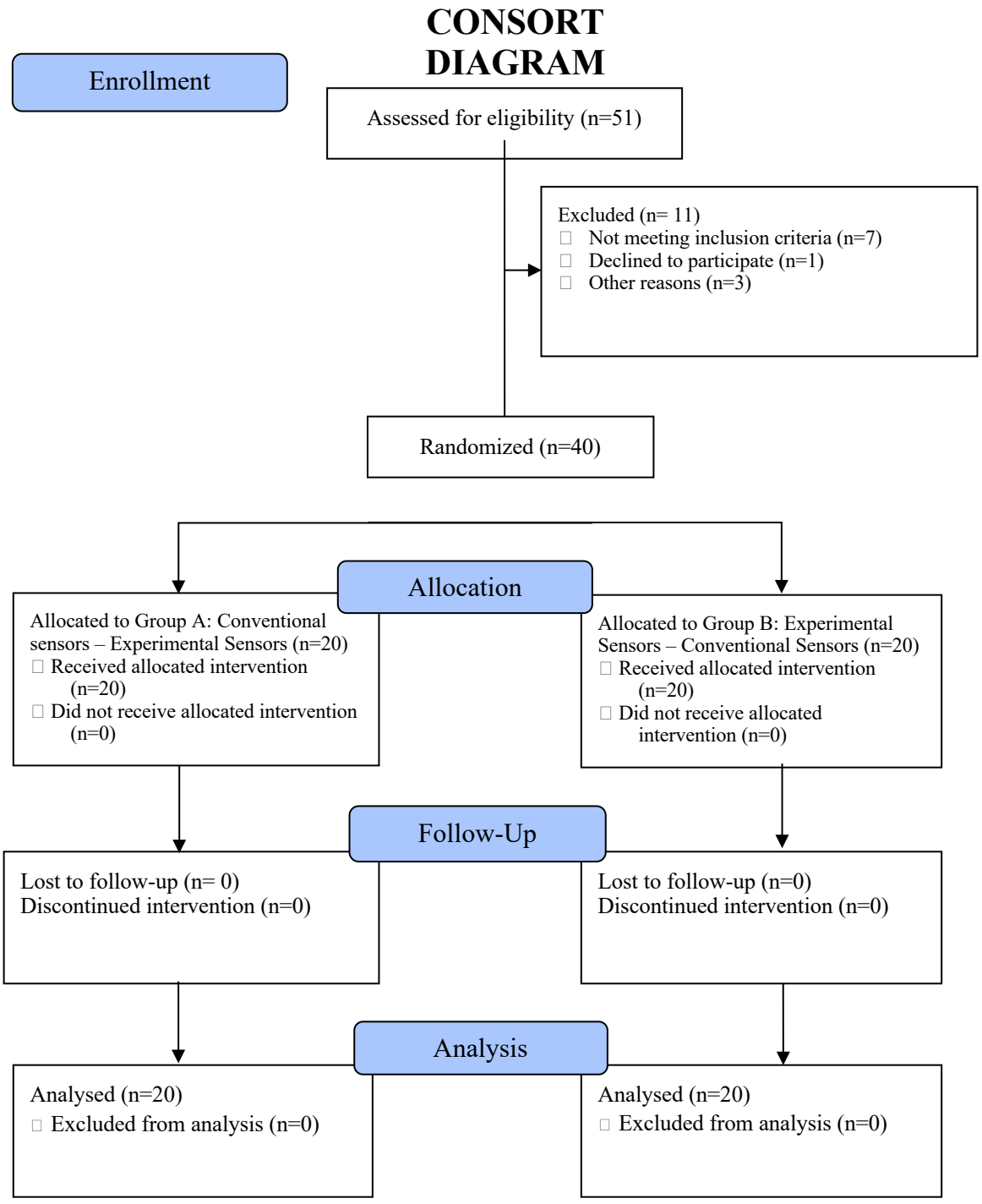


Figure 8. Consort Diagram

Table 10 contains details on the participants' demographics and screenings results. Twenty-four females and 16 males completed the study (n=40). The mean age was 67.5 with a range of 53 to 85 years of age. The EAT-10 scores ranged between 0 and 2 (cut-off score is 3), with a mean EAT-10 score of 0.375. The MoCA scores ranged between 26 and 30 (cut-off score is 26). The mean MoCA score was 28.1.

Table 10. Participant Demographics and Characteristics

Variable		Participants	
		N	%
Sex	Female	24	60
	Male	16	40
Age	Mean ± SD: 67.5 ±7.85		
	Range: 53-85		
Eating Assessment-10	Mean ± SD: 0.35±0.62		
	Range: 0-2		
MoCA	Mean ± SD: 28.1±1.21		
	Range: 26-30		
BMI	Underweight	0	0
	Healthy	13	32.5
	Overweight	14	35
	Obese	13	32.5
IOPI	Mean ± SD: 51.23± 11.3		
	Range: 20-84		

Note. EAT-10: Eating Assessment Tool-10, MoCA: Montreal Cognitive Assessment, IOPI: Iowa Oral Performance Instrument

4.1.b. Reliability

Reliability analysis was completed for 10% of the sample data for the primary variables of interest (i.e., signal-to-noise ratio, baseline amplitude, and normalized amplitude of the

swallow trials). Intraclass correlation coefficients for inter-rater reliability exceeded 0.80 for all variables: SNR left and right (0.884 and 0.928), baseline amplitude left and right (0.998 and 0.986), amplitude 5ml left and right (0.996 and 0.988), amplitude 10ml left and right (0.997 and 0.988). Intraclass correlation coefficients for intra-rater reliability also exceeded 0.80 for all variables: SNR left and right (0.98 and 0.98), baseline amplitude left and right (0.99 and 0.99), amplitude 5ml left and right (0.98 and 0.98), amplitude 10ml left and right (0.98 and 0.98).

4.1.c. Signal Related Factors Results

Our first aim was to compare signal related factors obtained using the experimental sensors with signal related factors obtained using the conventional sensors. In regard to signal quality, we hypothesized that the average signal-to-noise ratio obtained using the experimental sensors would not be inferior to the average signal-to-noise ratio obtained using the conventional sensors. We also hypothesized that the average baseline amplitude obtained using the experimental sensors would not be inferior to the average baseline amplitude obtained using the conventional sensors. These hypotheses were tested using a one-sided non-inferiority test. The results are presented below,

4.1.c.i. Signal Quality Results

Signal-to-Noise Ratio

Mean signal-to-noise ratio (SNR) values for both sensors' types for each participant are reported in Figure 9 for both left and right sEMG channels. Results are reported as mean (± standard deviation), unless otherwise stated.

For the **left** channel of submental muscle activity, the mean signal-to-noise ratio obtained using the conventional sensors was *19.44 (SD = 4.86),* and the mean signal-to-noise ratio obtained using the experimental sensors was *20.64 (SD = 4.67).* For the channel recording activity from the **right** submental muscles, the mean signal-to-noise ratio obtained using the

conventional sensors was *19.65 (SD =5.43),* and the mean signal-to-noise ratio obtained using the experimental sensors was *20.31 (SD = 5.19).* To compare the signal-to-noise ratio obtained with these two sensor types for both left and right channels, first, we calculated the mean difference of the values obtained using the experimental and conventional sensors and assessed the distribution of the difference (Table 11). The mean difference was 1.19 *(SD = 3.49)* for the left channel, and 0.65 *(SD = 3.91)* for the right channel. The non-inferiority margin was set to -0.99 for the left and right channels, based on our pilot data. Results indicated that the mean signal-to-noise ratio obtained using the experimental sensors was not inferior to the mean signal-to-noise ratio obtained using the conventional sensors for either the left [$t(39) = 3.95$, $p < 0.0002$], nor the right channel [$t(39) = 2.66$, $p < 0.0056$]. These results collectively support the first hypothesis of Aim 1 and show that the experimental sensors did not perform inferiorly to the conventional sensors in regard to signal-to-noise ratio values.

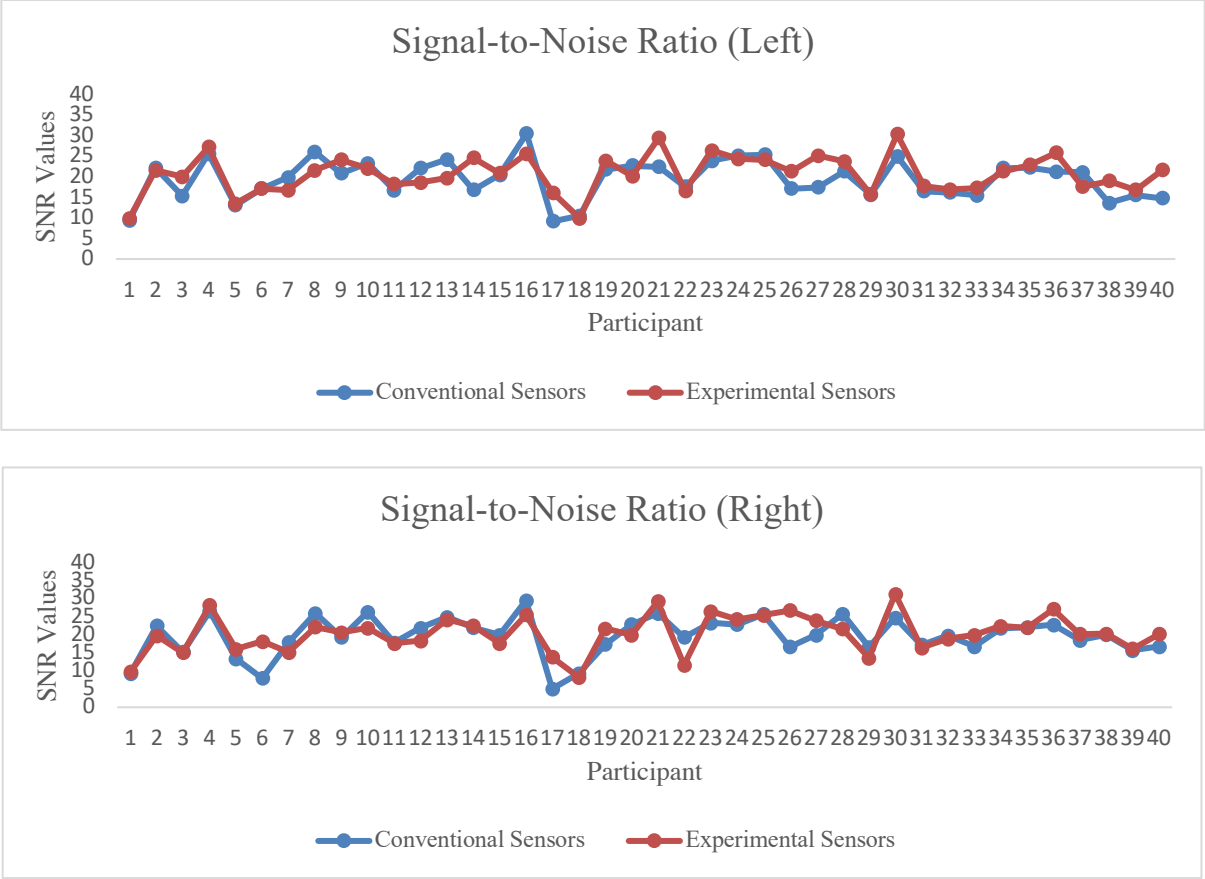


Figure 9. Signal-to-Noise Ratio Values for Each Participant (Left and Right)[1]

Baseline Amplitude

The mean baseline amplitude values for both sensors' types for each participant are reported in Figure 10 for both left and right EMG channels. For the channel recording activity from the **left** submental muscles, the mean baseline amplitude obtained using the conventional sensors was *1.66* µV *(SD = 2.07),* and the mean baseline amplitude obtained using the experimental sensors was *1.33* µV *(SD = 2.00).* For the channel recording activity from the **right** submental muscles, the mean baseline amplitude using the conventional sensors was *1.7* µV *(SD = 2.14),* and the mean baseline amplitude obtained using the experimental sensors

[1] Higher values indicate better signal-to-noise ratio

was *1.36* μV *(SD = 2.06*). To compare the baseline amplitude obtained with these two sensor types for both left and right channels, first, we calculated the mean difference of the values obtained using the experimental and conventional sensors and assessed the distribution of the difference. The mean difference was -0.33 μV *(SD = 0.51)* for the left channel, and -0.34 μV *(SD = 0.64)* for the right channel (Table 11). The difference was not normally distributed. Thus, we transformed the data using the BoxCox transformation. The non-inferiority margin was set to 0.2 for the left and right channels, based on our pilot data, but the margin was also shifted using the same transformation to match the scale of the transformed data. Results indicated that the mean baseline amplitude obtained using the experimental sensors was not inferior to the mean baseline amplitude obtained using the conventional sensors for either the left [$t(39) = -7.72$, $p < 0.0001$] nor the right channel [$t(39) = -7.43$, $p < 0.0001$]. Similarly, these results support the second hypothesis of Aim 1 and show that the experimental sensors did not perform inferiorly to the conventional sensors in regard to baseline amplitude.

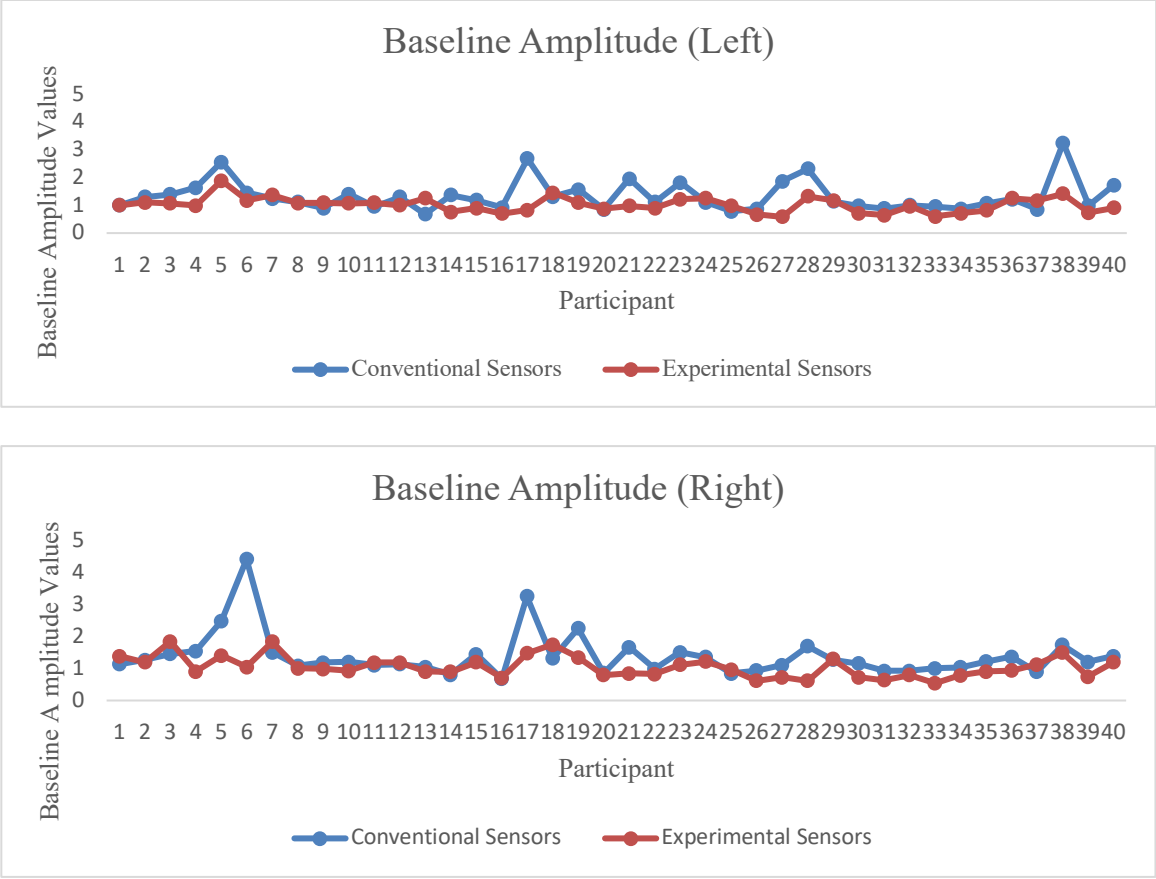


Figure 10. Baseline Amplitude Values for Each Participant (Left and Right)[2]

Table 11. Mean and Standard Deviation of Signal-to-Noise Ratio and Baseline Amplitude Results for Submental Muscles for Both Sensor Types

		Experimental Sensors		**Conventional Sensors**		**Difference**	
		Left	**Right**	**Left**	**Right**	**Left**	**Right**
SNR	Mean	20.64	20.31	19.44	19.65	1.19**	0.65**
	SD	4.67	5.19	4.86	5.43	3.49	3.91
Baseline	Mean	1.33	1.36	1.66	1.7	-0.33**	-0.34**
	SD	2.0	2.06	2.07	2.14	0.51	0.64

Note. **p < 0.05

[2] Lower values indicate better baseline noise.

4.1.c.ii. Results on Normalized Amplitude and Duration of sEMG Burst During Tasks

In addition to the aforementioned signal quality variables, we also examined whether the two sensors types were equivalent in terms of signal parameters typically evaluated in the clinical domain, i.e., normalized amplitude and duration of sEMG burst during swallowing tasks. In regards to these two outcome variables, we hypothesized that the difference between the mean normalized amplitude values and duration of sEMG burst obtained during swallows using the conventional sensors and the experimental sensors will be equivalent. These hypotheses were tested using an equivalency test.

Four hundred three swallow trials were completed using the conventional sensors (201 with 5ml and 202 with 10ml). During the analysis of amplitude of activity of the left submental muscles, nine swallows were not analyzed because of the quality of the sEMG signal. Specifically, a swallow was not analyzed when there was too much EMG activity or artifact (most likely from movement) either immediately before and/or immediately after the swallow, which deemed the exact onset and offset of the swallow-related muscle activity unclear. Therefore, a total of 394 swallows collected via the conventional sensors were analyzed for this variable. Out of the 394 swallows, 342 were analyzed using the automatic selection (86.8%), and 52 were analyzed using the manual selection option (13.2%). During the analysis of the right submental muscles, 10 swallows were not analyzed for similar reasons. Thus, 393 swallows were analyzed from the right channel. Out of the 393 swallows, 341 were analyzed using the automatic selection option (86.76%), and 52 using the manual selection option (13.23%).

Four hundred six swallow trials were completed using the experimental sensors (202 with 5ml and 204 with 10ml). During the analysis of the left side, 22 swallows were not analyzed similarly due to excessive movement/artifact, hence, 384 swallows were analyzed. Out of the 384 swallow trials, 328 were analyzed using the automatic option (85.5%), and 56 were analyzed

using the manual option (14.5%). During the analysis of the right side, 21 swallows were not analyzed for the same reasons, thus 385 were analyzed. Out of the 385 swallows, 322 were analyzed using the automatic option (83.7%) and 63 using the manual option (16.3%). Subjects who participated in the pilot were included in the final analysis. One subjects (Subject 2 from the pilot) was removed from the analysis of the task related amplitude, because equivalency margins were calculated without this subject.

Normalized Amplitude of the Swallow Trials Results

Amplitude 5ml water trials

For the 5ml water trials, means of individual normalized amplitude values for each participant are shown in Figure 11 for both channels. For the **left** submental muscles, the mean normalized amplitude across subjects obtained using the conventional sensors was 12.15% *(SD = 7.01),* and the mean amplitude obtained using the experimental sensors was 11.57% (*SD = 6.73*). For the **right** submental muscles, the mean amplitude obtained using the conventional sensors was 13.04% (*SD = 7.79*), and the mean amplitude obtained using the experimental sensors was 12.03% (*SD = 7.13*) (Table 12). To compare the normalized mean amplitude values obtained with these two types of sensors, first, we calculated the mean difference of the values obtained using the experimental and conventional sensors and assessed the distribution of the difference. The mean difference was -0.58 (*SD=3.69*) for the left channel, and 1.0027 (*SD = 6.31*) for the right channel. The margins for equivalency testing were set to ±3.1 for the left and right channels, using the pilot data information (see Table 8). For the left EMG channel, the t-values for the upper bound and lower bound one-sided t-tests were t_u = 4.25 and t_l = -6.22 respectively, with an overall *p-value <0.0001*, indicating equivalent mean amplitude values for the experimental and conventional sensors for this channel. For the right channel, the t-values for the upper bound and lower bound one-sided t-tests were t_u = 2.07 and t_l = -4.06 respectively,

with an overall *p-value = 0.0224*. Thus the normalized amplitude values for the right channel on the 5ml water trials were deemed statistically equivalent as well.

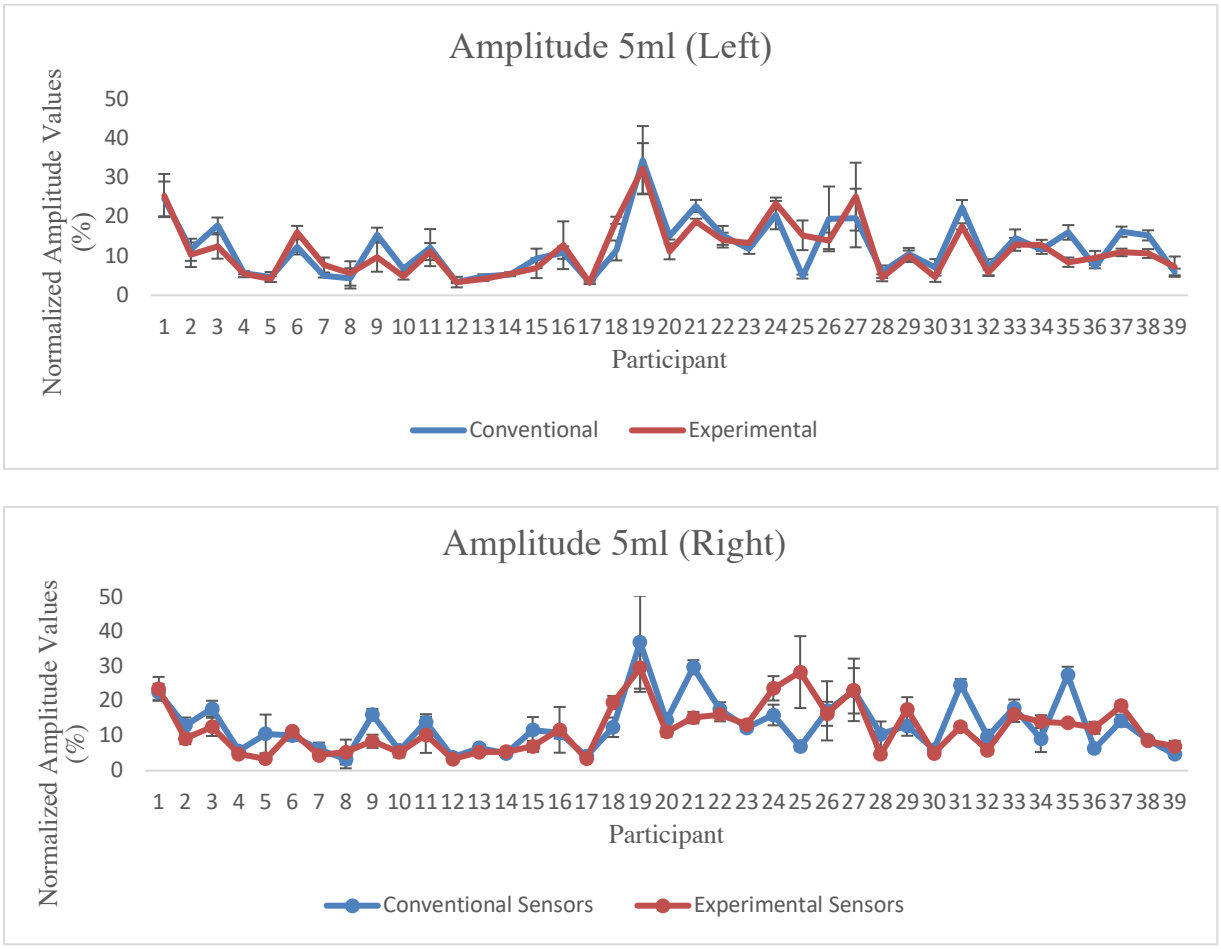


Figure 11. Normalized Mean Amplitude Values During 5ml Swallow Trials for Each Participant (Left and Right)

Table 12. Normalized Mean Amplitude Values for 5 and 10ml Swallow Trials

		Experimental Sensors		Conventional Sensors		Difference	
		Left	**Right**	**Left**	**Right**	**Left**	**Right**
5ml	Mean	11.57	12.03	12.15	13.04	-0.58**	-1.0027
	SD	6.73	7.13	7.01	7.79	3.69	6.31
10 ml	Mean	11.9	12.83	12.54	13.94	-0.63**	-1.1**
	SD	7.29	7.66	7.13	8.16	4.54	6.84

Note. These values are reported in percentages, as they are normalized. **$p < 0.05$

Amplitude 10ml water trials

For the 10ml water trials, the mean normalized amplitude values for each participant are shown in Figure 12 for both channels. For the **left** submental muscles, the mean amplitude obtained using the conventional sensors was 12.54% (*SD = 7.13*), and the mean amplitude obtained using the experimental sensors was 11.9% (*SD = 7.29*). For the **right** submental muscles, the mean amplitude obtained using the conventional sensors was 13.94% *(SD = 8.16),* and the mean amplitude obtained using the experimental sensors was 12.83% *(SD = 7.66).* To compare the normalized amplitude values obtained using the two types of sensors, first, we calculated the mean difference of the values and assessed the distribution. The mean difference for the left channel was -0.63% *(SD = 4.54),* and the mean difference for the right channel was -1.1% *(SD = 6.84).* The margins to test equivalence were set to ±4.68 for the left and right side based on the pilot data (see Table 8 for details). Results indicated that the normalized mean amplitude values obtained using both types of sensors were equivalent/comparable for both the left [t_u = 5.49 and t_l = -7.20; overall *p-value <0.0001*] and right channels [t_u = 3.36 and t_l = -5.28; overall *p-value <0.0012*].

Collectively these results support our third hypothesis of Aim 1, as normalized amplitude values obtained with the two sensor types were deemed equivalent for all swallow trials.

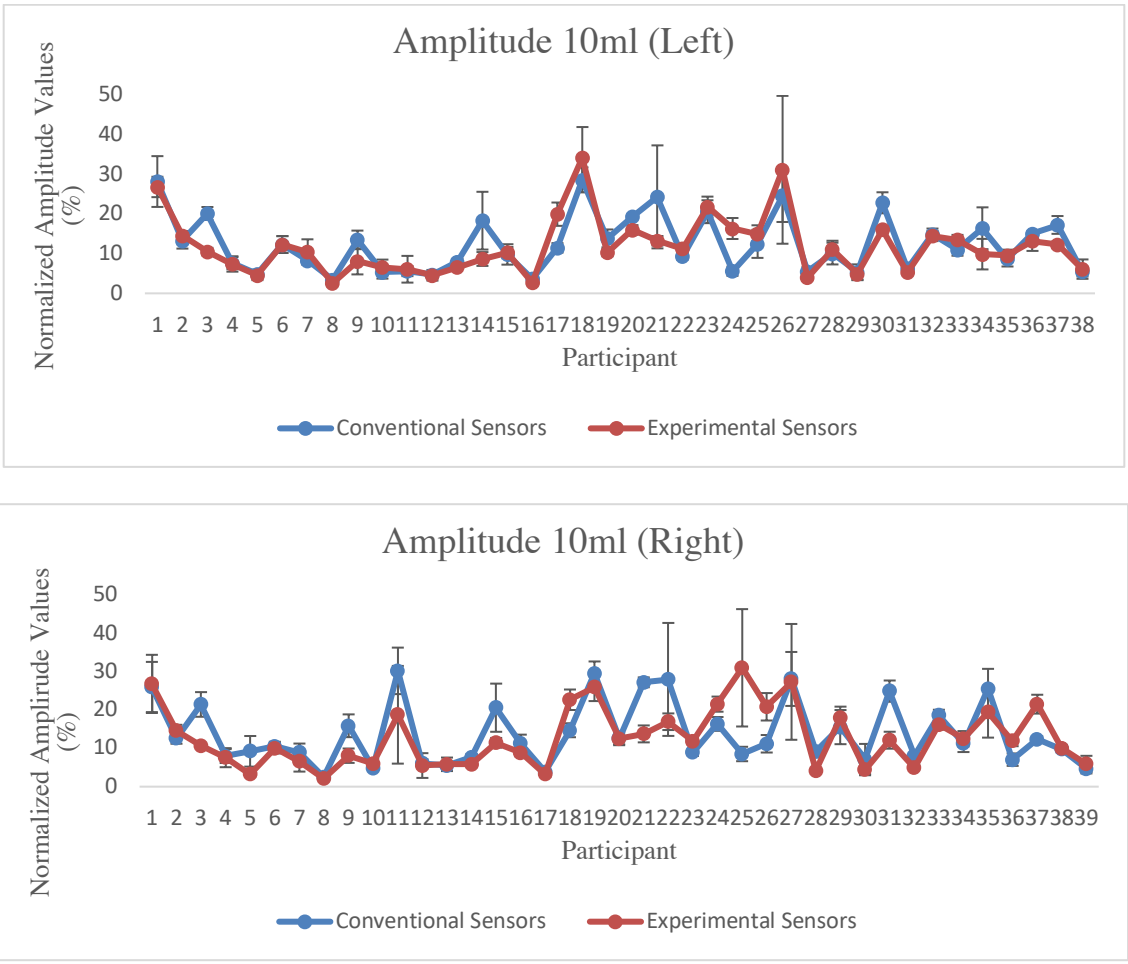


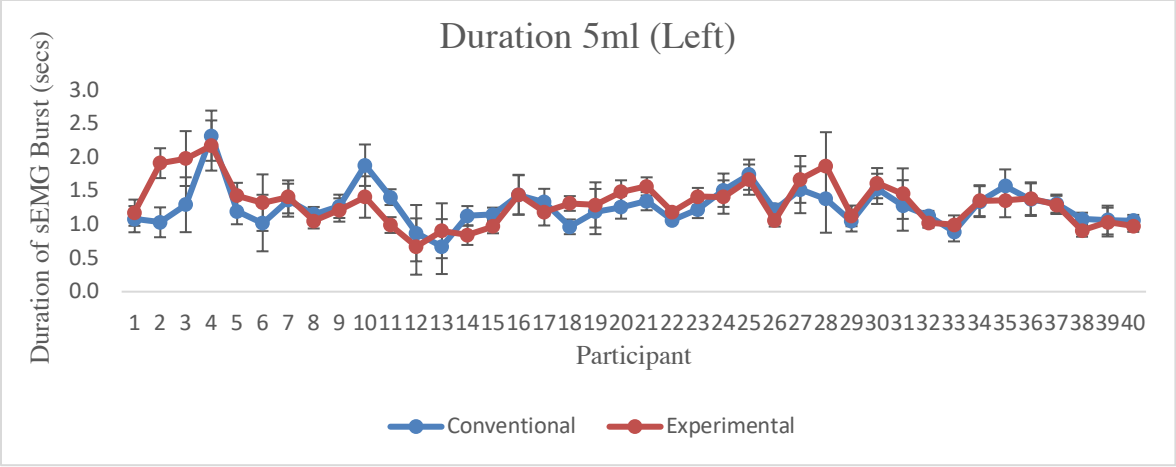
Figure 12. Normalized Mean Amplitude Values During 10ml Swallow Trials for Each Participant (Left and Right)

Duration of sEMG Burst during Swallows

Duration 5ml water trials

For the 5ml water trials, the mean duration of sEMG burst values for each participant are shown in Figure 13 for both channels. For the channel recording activity from the **left** submental muscles, the mean duration of sEMG burst obtained using the conventional and experimental sensors was 1.27 seconds (*SD = 0.2*) and 1.31seconds *(SD = 0.3),* respectively. For the **right**

side, the mean duration of sEMG burst obtained using the conventional sensors was 1.25 seconds *(SD = 0.3),* and the mean burst duration obtained using the experimental sensors was 1.31 *(SD = 0.3)* seconds. To compare these duration values, first, we calculated the mean difference of the values obtained with the experimental and conventional sensors and examined the distribution, which was normally distributed. The mean difference was 0.04 seconds *(SD = 0.26)* for the left submental muscles, and 0.06 seconds (*SD = 0.28*) for the right submental muscles. The margins to test equivalency were set to ±0.35 for the left and right side, based on our pilot data. Results showed that the mean duration of sEMG burst for the 5ml water trials obtained using both types of sensors were equivalent/comparable to each other for both the left [t_u = 9.48 and t_l = -7.25, overall *p-value <0.0001*], and the right channel [t_u = 9.03 and t_l = -6.35, overall p-value *<0.0001*]. Table 13 summarizes the results of the mean duration of sEMG burst values.



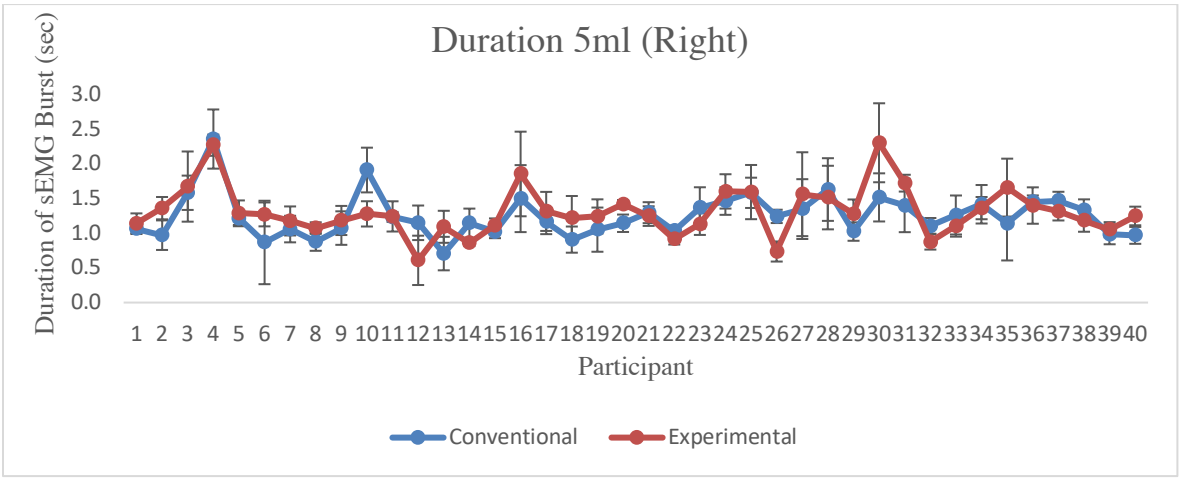


Figure 13. Mean Duration of sEMG Burst During 5ml Swallow Trials for Each Participant (Left and Right)

Duration 10ml water trials

For the 10ml water trials, the mean duration of sEMG burst values for each participant are shown in Figure 14 for both channels. For the **left** channel, the mean duration of sEMG burst obtained using the conventional sensors across subjects was 1.31 seconds (*SD = 0.3*), and the respective duration obtained using the experimental sensors was 1.34 seconds (*SD = 0.3*). For the **right** channel, the mean duration of sEMG burst obtained using the conventional sensors was 1.32 seconds (*SD = 0.4*), 1.33 seconds (*SD = 0.3*) using the experimental sensors. As usual, first, we calculated the mean difference of the values obtained using the two types of sensors and

assessed the distribution of the difference. The difference was normally distributed. The mean difference was 0.02 (*SD = 0.4*) for the left channel, and 0.01 (*SD = 0.41*) for the right channel. Equivalency margins were set to ±0.42 for the left and right channels, respectively. Once more, results indicated that the mean duration of sEMG burst for the 10ml water trials obtained using both types of sensors was equivalent/comparable to each other for both the left [t_u = 6.75 and t_l = -6.11, overall *p-value <0.0001*] and right channels [t_u = 6.58 and t_l = -6.23, overall *p-value < 0.0001*].

Taken together, these results on the sEMG burst duration variable fully support the last hypothesis of Aim 1, and show that the duration of the sEMG activity captured with both sensor types is comparable for all swallow trials tested. Table 13 summarizes the results on this variable of the 10ml swallow trials.

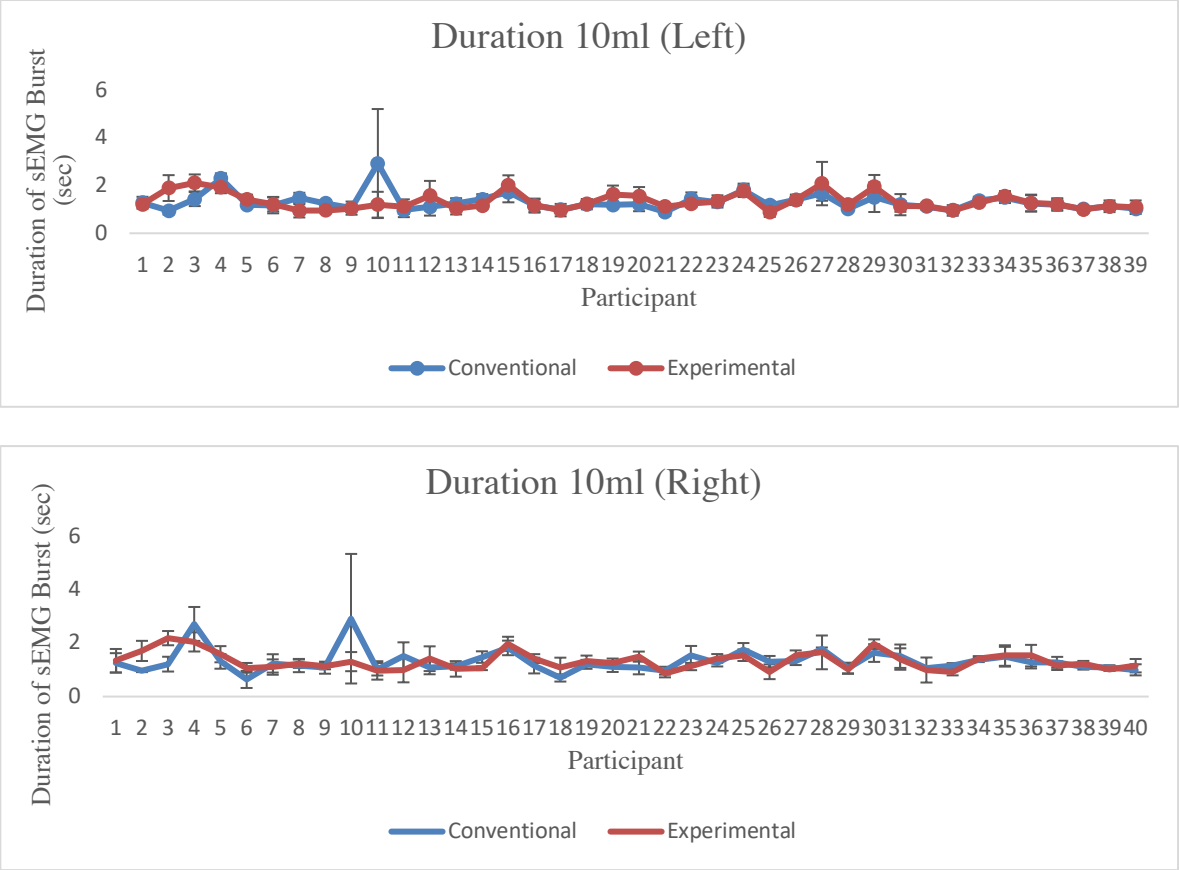


Figure 14. Mean Duration of sEMG Burst During 10ml Swallow Trials for Each Participant (Left and Right)

Table 13. Mean Duration of sEMG Burst During 5ml and 10ml Swallow Trials

		Experimental Sensors		**Conventional Sensors**		**Difference**	
		Left	**Right**	**Left**	**Right**	**Left**	**Right**
5ml	Mean	1.31	1.31	1.27	1.25	0.04**	0.06**
	SD	0.3	0.3	0.2	0.3	0.26	0.28
10ml	Mean	1.34	1.33	1.31	1.32	0.02**	0.01**
	SD	0.3	0.32	0.3	0.43	0.4	0.41

Note. These values are reported in seconds. **$p < 0.01$

4.1.d. Safety and Pre-Clinical Factors Results

Our second aim was to examine the safety/adverse effects, and efficiency and satisfaction/comfort with the use of the experimental sEMG sensors as compared to the conventional counterparts. Regarding safety, we hypothesized that no adverse effects would be reported during or after usage of either type of sEMG sensors. In terms of efficiency, we hypothesized that the amount of time it takes to place the experimental sensors will be shorter than the amount of time it takes to place the conventional sensors. Finally, in terms of level of satisfaction/comfort, we hypothesized that satisfaction expressed after using the experimental sensors would be higher that post usage of the conventional sensors.

4.1.d.i. Safety and Adverse Effects Results

Safety and adverse effects were recorded using the Visual Inspection Form (APPENDIX D).

Conventional Sensors

For the conventional sensors, none of the participants reported that their skin was itchy after removing the sensors. However, two subjects reported that their skin felt itchy 5 minutes after removing the sensors. Redness of the skin was observed in 3 participants after the removal of these sensors. All 3 reported having a sensitive skin. One participant's redness cleared within a few minutes. Mild redness was present 5 minutes after the removal of the conventional sensors in 2 out of these 3 participants. One of these participants was assigned to Group A, i.e., the experiment was completed with the conventional sensors first. The redness was cleared completely before the experimental sensors were placed on the skin (i.e., approximately 5 minutes later). The other participant was assigned to Group B, i.e., the conventional sensors were used during the second part of the experiment. This participant's redness was completely cleared before the end of the session. Aloe Vera lotion was offered to all participants; however, none

chose to apply it, as they were not concerned. Skin irritation was reported by one of the participants right after the removal of the sensors. However, no concerns were reported after 5 minutes.

Experimental Sensors

For the experimental sensors, one participant reported that her skin was itchy right after the removal of the sensors. However, this was resolved within 5 minutes. No redness or skin irritation was observed and/or reported after the removal of the experimental sensors by any of the participants.

4.1.d.ii. Pain

Pain was recorded using the Pain Screening Form (APPENDIX E).

Conventional Sensors

For the conventional sensors, one person reported experiencing mild pain after sensors' removal. The participant rated the pain level as 1 out of 10 (i.e., extremely mild pain). This participant did not report any pain after 5 minutes. In addition, one of the participants who did not report any pain initially reported that she was experiencing pain 5 minutes after the removal of the conventional sensors. The pain level was rated as 1 (i.e., extremely mild pain).

Experimental Sensors

For the experimental sensors, no pain was reported neither immediately after their removal from the skin, nor 5 minutes later.

Although we did not find any severe adverse effects, itchiness and redness of the skin were reported/observed after the removal of the experimental sensors in a small number of participants and in a higher number of participants after the removal of the conventional sensors (Table 14). Mild pain was reported by one participant after the removal of the conventional

sensors. These effects were more frequent with the conventional sensors. These findings suggest that the experimental sensors are safe to use.

Table 14. Occurrence of Safety and Adverse Effects

		Experimental Sensors		Conventional Sensors	
		Immediately	5-minutes after	Immediately	5-minutes after
Visual Inspection Form	Itchiness	1	-	-	2
	Redness	-	-	3	2
	Irritation	-	-	1	-
Pain Screen	Pain	-	-	1	1 (new)

4.1.d.iii. Efficiency of Electrode Placement

Electrode placement took approximately 2 minutes and 33 seconds on average (range: 1:43-4:22 minutes) for the conventional sensors, and 2 minutes and 44 seconds (range: 1:23-4:27 minutes) for the experimental sensors. A lower tail paired-samples t-test was used to determine whether it took significantly less time to place the experimental sensors. The average difference in time efficiency was 10.8 seconds, SD = 36.55), and this difference was not statistically significant $t(39) = 1.87$, $p = 0.9657$. Contrary to our hypothesis (Aim 2, hypothesis #2), we did not find a statistically significant difference in efficiency between the two sensor types. However as seen in Table 15, the difference was typically below 60 seconds.

Table 15. Duration of Electrode Placement for Each Participant for Both Sensor Types

Participant	Experimental	Conventional	Difference
1	191	229	-38
2	90	131	-41
3	83	137	-54
4	124	178	-54
5	191	197	-6
6	156	130	26
7	147	152	-5
8	137	171	-34
9	127	142	-15
10	156	144	12
11	201	151	50
12	178	131	47
13	178	118	60
14	133	117	16
15	156	103	53
16	132	126	6
17	201	183	18
18	197	145	52
19	142	120	22
20	192	202	-10
21	220	175	45
22	147	129	18
23	116	143	-27
24	169	146	23
25	155	106	49
26	105	145	-40
27	152	167	-15
28	143	143	0
29	130	152	-22
30	170	157	13
31	184	116	68
32	189	168	21

Table 15 continued

33	183	150	33
34	185	177	8
35	186	152	34
36	218	262	-44
37	267	159	108
38	156	132	24
39	163	150	13
40	194	175	19
Mean	**163.6**	**152.775**	**10.825**
Standard Deviation	**36.8759528**	**31.8847986**	**36.5568665**

Note. These values are reported in seconds.

4.1.d.iv Satisfaction/Comfort

High satisfaction/comfort was reported with both sensor types. An upper tail paired-samples t-test was used to determine whether there was a statistically significant difference in satisfaction. The average satisfaction/comfort rating was 48.06/50 for the conventional sensors, and 48.62/50 for the experimental sensors. This difference, albeit small (small effect size), was statistically significant $t(39) = 1.71$, $p = 0.0476$, $d = 0.226$. This result supports our third hypothesis of Aim 2 and indicates that the participants were more satisfied (slightly) with the experimental sensors. Table 16 provides the cumulative scores from the Satisfaction/Comfort Questionnaire for each participant.

Table 16. Results of the Satisfaction/Comfort Questionnaire for Each Participant for Both Sensor Types

Participant	Experimental	Conventional	Difference
1	50	49.9	0.1
2	49	49	0
3	50	50	0
4	50	50	0
5	50	43	7
6	50	50	0
7	50	50	0
8	50	50	0
9	50	49.5	0.5
10	50	49	1
11	49	49	0
12	50	50	0
13	48	50	-2
14	50	50	0
15	29	38	-9
16	50	50	0
17	48	49	-1
18	50	50	0
19	50	50	0
20	45	44	1
21	50	48	2
22	50	44.1	5.9
23	50	49	1
24	45	45	0
25	47	41	6
26	48	50	-2
27	50	48	2
28	50	50	0
29	50	49	1
30	50	49	1
31	50	50	0
32	50	49	1
33	42	38	4
34	50	49	1
35	45	45	0
36	50	49	1

Table 16 continued

37	50	49	1
38	50	50	0
39	50	50	0
40	50	50	0
Mean	**48.625**	**48.0625**	**0.5625**
Standard Deviation	**3.67728649**	**3.23408827**	**2.43064701**

CHAPTER 5. DISCUSSION

Despite emerging evidence that rehabilitation of swallowing disorders can be most beneficial when principles of exercise physiology and neuroplasticity are followed, in clinical practice several limitations preclude this from happening consistently. To begin with, it is not always possible to have frequent sessions with a speech-language pathologist given time constraints, limited resources, and restrictions in reimbursement. In addition, for people with mobility limitations and patients who live in underserved areas, it might not be feasible to see a speech-language pathologist every week (Wade, Karnon, Elshaug, & Hiller, 2010). As a result, patients usually complete their exercises at home without receiving feedback from their clinicians. In addition, due to lack of existing user-friendly and cost-effective biofeedback devices for swallowing, patients usually receive no extrinsic biofeedback when they complete their exercises at home.

To start addressing this need, our lab (Purdue I-EaT Swallowing Research Lab) (PI: Malandraki) in collaboration with the Purdue Bio Sticktronics Lab (PI: Lee) started developing inexpensive, portable, and comfortable to "wear" sensors for future use in home-based therapy. As a first step, we developed a first version wearable sEMG sensors specifically designed to conform to the anatomy of the submental area impeccably (patent pending, inventors: Lee & Malandraki). This dissertation study offers the first validation of this newly developed wearable sEMG sensors patch. Specifically, the present study aimed to compare these newly developed sEMG sensors to commercially available conventional ones in monitoring submental muscle activity during swallowing in healthy older adults. We focused on older adults because dysphagia is more prevalent in individuals who are over 50 years of age (Bhattacharyya, 2014).

Comparisons were made based on a) signal related factors (i.e., signal-to-noise ratio, baseline amplitude, normalized amplitude of the swallow trials, duration of sEMG burst during swallow trials); and b) safety and pre-clinical factors (safety/adverse effects, efficiency of electrode placement, satisfaction/comfort).

In terms of signal related factors (Aim 1), comparisons between the variables of signal-to-noise ratio and baseline amplitude were examined using non-inferiority tests, because we hypothesized that the experimental sensors would not perform inferiorly to the conventional ones. Comparisons between normalized amplitude and duration of sEMG burst during swallow trials were examined using an equivalency test, as we hypothesized that the values obtained using the experimental sensors would be comparable/equivalent to the values obtained using the conventional sensors.

Overall, the results of our experiments for Aim 1 supported our hypotheses. First, the experimental sensors did not perform inferiorly to the conventional sensors in signal-to-noise ratio or baseline amplitude, indicating our experimental sensors obtained very good signal quality. Furthermore, for most swallow trials examined, both the normalized amplitude and the duration of sEMG burst during swallow trials obtained with both sensor types were equivalent. We further discuss these findings in the following section.

In terms of safety and pre-clinical factors (Aim 2), we hypothesized that no adverse effects will be reported after using either type of sensors. We also hypothesized that sensor placement will be more efficient and satisfaction will be higher with the experimental sensors. Our primary goal was to examine whether the experimental sensors were safe to use, and whether older adults were comfortable using them. Most of our hypotheses for Aim 2 were also proven. Specifically, in terms of safety and adverse events, mild redness and itchiness occurred with the conventional sensors in six participants, whereas only one participant reported itchiness

with the experimental sensors. No redness or skin irritation was observed or reported by any of the participants after the removal of the experimental sensors. These results support that the experimental sensors are safe to use, and do not cause any skin irritation. In terms of time efficiency, our hypothesis was not proven, as there were no statistically significant differences in the efficiency of sensor placement. Both sensor types took a similar amount of time to place on the participants' skin. However, satisfaction/comfort level was significantly higher with the experimental sensors compared to the satisfaction reports with the conventional sensors.

Taken together, these findings indicate that the newly developed wearable sEMG sensors patch is safe, obtains comparable signal quality and signal parameters to widely used conventional sensors, and older adults prefer it to the latter ones. An in-depth discussion/interpretation of these findings follows, starting with the discussion of the results on signal related factors and followed by a discussion of the findings on the safety and preclinical factors.

5.1. Signal Related Factors

5.1.a. Signal Quality

Consistent with our hypotheses #1 and 2 of Aim 1, our results indicated that the quality of the signal recorded with the experimental sensors was not inferior to the quality of the signal obtained with the conventional ones. Both signal-to-noise ratio and baseline amplitude values were within the recommended values for both sensors' types. These findings can be explained in the light of SENIAM recommendations. The SENIAM project (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles) is a European group that developed guidelines for best practices in EMG data collection, and these practices are frequently adopted by EMG researchers (Hermens & Freriks, 2017; Disselhorst-Klug, & Rau, 2000). The current study also followed these guidelines to ensure the attainment of optimal signal quality.

One of the most important factors in obtaining high quality EMG recordings and signal is electrode-to-skin contact. Good electrode-to-skin contact results in more reliable amplitude values, a smaller common mode rejection ratio, and better signal-to-noise ratio (Hermens & Freriks, 2017). In this study we took several steps to accomplish decent skin contact. First, all male participants were asked to shave prior to coming into our laboratory. Furthermore, before placing the electrodes, we visually inspected the skin for the presence of facial hair and any potential skin problems including redness at baseline. We then cleaned the skin underneath the chin thoroughly with alcohol wipes following SENIAM recommendations. Similar practices have been reported in previous studies in our field (Huckabee, Low, & McAuliffe, 2012; P. M. Palmer et al., 1999; Reimers-Neils, Logemann, & Larson, 1994; Vaiman & Eviatar, 2009b; Wheeler et al., 2007). In addition, since the experimental sensors are specifically designed for the submental area using flexible materials, they have been designed to conform to the atypical anatomy of the area under the chin perfectly, resulting in very good electrode-to-skin contact.

The type of electrode used is also an important factor in signal quality. SENIAM recommends using bipolar or differential pair electrodes that are proportional to the muscles of interest (Hermens & Freriks, 2017; Hermens et al., 2000). In this study, both sensor types included bipolar electrodes that were able to selectively amplify the difference in the signal from the muscle action potentials while suppressing the common signal, i.e., the background noise and improving the signal-to-noise ratio. In addition, a ground electrode was attached to the mastoid process of the temporal bone during use of both types of submental sensors. This practice is commonly used in EMG studies (e.g., Crary et al., 2006; Reimers-Neils et al., 1994; Wheeler et al., 2007). A ground electrode should be placed on a bone that is closer to the EMG sensors' location, thus, for submental muscles bones of the head and neck are ideal locations for the

ground electrode (Stepp, 2012). In this study, the mastoid process was chosen as the location of the ground electrode because this location provided the best baseline signal.

Accurate placement of the sensors is another critical factor that influences the quality of the EMG signal. SENIAM recommends marking the location where the sensors will be attached and then placing the sensors on the belly of the muscle longitudinally (i.e., parallel to the muscle fibers) and away from the muscle tendons and other muscles to avoid crosstalk (Hermens & Freriks, 2017; Hermens et al., 2000; Stepp, 2012). Moreover, for submental muscles, the inter-electrode distance should not exceed ¼ of the muscle fiber length or 20mms depending on which one is smaller (Stepp, 2012). To ensure consistent placement with both sensors, we first asked the participants to push their tongue against the roof of their mouth and palpated the submental muscles to identify the location. Then, we marked the sensor attachment points on the skin using a marker. Both sensors were placed on the left and right submental muscles following the direction of the submental muscle fibers and the inter-electrode distance was 1.5 cm. While the conventional sensors were placed on the attachment points individually (left side front and back, right side front and back) by using four different stickers, on the contrary, the uniform nature of the experimental sensor patch allowed easy placement on the attachment points and stable interelectrode distance throughout the experiment. This could be one of the advantages of using the wearable sensors as opposed to the conventional ones for home-based treatment in the future, as their placement will include fewer steps (more discussion in future directions).

The location of the electrodes was also consistent with the location reported in prior EMG studies that investigated swallowing muscle activity. However, the majority of these studies report that the sensors were placed on the submental region lateral to each side of the midline (Crary et al., 2006; P. M. Palmer et al., 1999; Vaiman & Eviatar, 2009b) without

specifying inter-electrode distance which at times varied from 1 to 2 centimeters (Crary et al., 2006; P. M. Palmer et al., 1999; Vaiman & Eviatar, 2009b). The conventional sensors were designed mainly for the limb muscles, which are much larger than the submental muscles. They typically come with large adhesives that need to be trimmed to fit the submental area. However, since the experimental sensors were specifically designed for the submental area, the use of the wearable sensor patch could improve consistency in sensors' placement for both research and clinical practice.

Movement artifact is also an important factor to consider in signal quality. Although it is highly unlikely to eliminate movement artifacts completely during swallow trials, several steps were taken to minimize their effects. First, we asked our participants to stay as still as possible before, during, and right after swallow trials. The boluses were presented in small medicine cups; thus, participants did not have to tilt their head backwards to consume the liquid and were able to keep their head straight throughout the trial. Participants were also instructed to stay silent right after each swallow trial, which eliminated any muscle activity related to speech. One exception was made for coughing. Unlike the Gupta and colleagues (1996) study that restricted their participants from coughing during swallow trials, we did not ask our participants to suppress their cough. Studies that have examined the effects of aging on swallowing have showed that the frequency of penetration increases significantly in healthy adults over 50 (Daggett, Logemann, Rademaker, & Pauloski, 2007; Robbins et al., 1992; Tracy et al., 1989), hence occasional couching or throat clearing during swallow trials is considered normal in this age group. This was also observed occasionally in this cohort of older adults. When coughing was present, we encouraged our participants to clear their throat and did not move on to the next trial until their

urge-to-cough was eliminated. If significant movement artifact was observed at any point, we disregarded that trial and completed an additional trial.

Lastly, data acquisition parameters also play a significant role in the quality of the EMG signal. The frequency range of the EMG signal mainly ranges between 0 and 450 Hz because the majority of muscle activity occurs in these frequencies (Hermens & Freriks, 2017). However, it is recommended to add a high-pass filter with a cutoff point around 20Hz to remove all movement artifact that can be present in the signal (Stepp, 2012). In addition, a low-pass filter around 500Hz is also recommended to remove the high-frequency noise that is caused by the equipment (e.g., computer, EMG device) (Stepp, 2012). Thus, the sampling rate should be at least 1000 Hz (i.e., double the highest frequency) (Stepp, 2012). In the current study, we used a 20Hz high pass and 500Hz low pass filter as well as a 60Hz notch filter. Our sampling rate was 1000Hz. However, the vast majority of EMG studies in the field of dysphagia have not used these filters or sampling rate. For example, Ding and her colleagues used a low-pass filter at 300Hz and high-pass filter at 100 Hz (Ding et al., 2002). Similarly, Crary and colleagues (2006), used a narrower bandpass filter (50 to 250Hz) with a sampling rate of 500 Hz (Crary et al., 2006). Therefore, these investigators most likely lost some of the EMG activity at lower and higher frequencies. Our data acquisition parameters allowed us to be able to make valid comparisons between our two systems of interest.

5.1.b. Signal Amplitude and Duration During Tasks

Supporting our hypotheses # 3 & 4 (Aim 1), the results of the current study also showed that the normalized amplitude values and the duration of sEMG burst during swallows obtained using both types of sensors were equivalent for most variables examined.

EMG amplitude depends on factors, such as electrode-to-skin impedance and location of the electrode; thus, it differs between individuals and within the same individual over different sessions. Because of this reason, it is not possible to compare the raw EMG signal or raw amplitude values within or between subjects (Mathiassen, Winkel, & Hägg, 1995). Therefore, to compare two EMG amplitude values, normalization of the EMG is necessary. Normalization allows us to convert the amplitude values obtained from different individuals or from the same individual over time to a common scale (e.g., 0-100%) to make comparisons between two different sessions. Typically, the EMG signal is normalized in reference to maximal voluntary contraction (MVC) or some percentage of the MVC of the muscles of interest. For anterior neck musculature, the MVC has been found to be more reliable in multiple trials (Netto & Burnett, 2006) because of its complex musculature. In the current study, the EMG amplitude values were normalized using MVC of the submental muscles. This allowed us to make comparisons within individuals across different trials. This step is rarely reported in swallowing research making it harder to make comparisons between the amplitude values reported in different studies.

Amplitude and duration during swallow trials are two parameters that are frequently used clinically to provide evaluative and therapeutic goals. Therefore, they are important to examine. Our results revealed that both types of sEMG sensors exhibited similar patterns in detecting muscle activity in terms of amplitude and duration during most swallow trials. Specifically, our results showed that the normalized mean amplitude values were equivalent for the 5ml and 10ml water swallows on the left and right channels. Duration of sEMG muscle activity was deemed equivalent for all bolus types across all channels.

In terms of amplitude during swallow trials, a recent study also compared a set of new epidermal electrodes with conventional snap-on EMG electrodes and showed that the mean

amplitude values obtained using their epidermal electrodes were similar to the values obtained using the conventional counterpart (i.e., mean = 0.433 vs. 0.414 mV respectively) across different swallow trials (Constantinescu et al., 2016). However, several limitations of this work make any direct comparisons with the current study challenging. First, the boluses that were consumed in the Constantinescu et al., (2016) study were not standardized. Instead, participants were asked to take a small sip of water or swallow their saliva. Given the well documented effects of volume on EMG amplitude of the swallows (Dantas & Dodds, 1990; Perlman et al., 1999), keeping the bolus volumes consistent across trials is critical when making comparisons between swallows. In addition, the authors reported and compared raw amplitude values, however, as discussed earlier, the raw EMG signal cannot be used to make these types of comparisons because impedance changes as the skin-electrode contact changes making normalization essential (Mathiassen et al., 1995; Sousa & Tavares, 2012).

The duration of sEMG burst during swallow trials was also comparable between the two sensor types. To our knowledge, there have been no studies that have compared the duration of sEMG burst for submental muscles between two sensor types. Previous studies that have compared duration of sEMG burst using conventional sensors have showed a bolus-volume effect, i.e., the duration of sEMG burst increases with larger boluses (Hrycyshyn & Basmajian, 1972; Perlman et al., 1999). In the current study, the boluses were measured precisely, and participants were instructed to consume the full amount in one swallow. In addition, participants were asked to hold the bolus in their mouth for a few seconds until the sEMG signal was noise free to prevent any artifacts that could potentially increase the duration of sEMG burst (Perlman et al., 1999). Using these techniques allowed us to obtain a robust signal. The duration of sEMG burst during swallow trials obtained by using both sensor types was comparable to the duration

of sEMG burst reported in the literature. Similarly, the mean duration of sEMG burst during the 10ml swallow trials was longer than the mean duration of sEMG burst during the 5ml swallow trials, also supporting a bolus volume effect (Crary et al., 2006; Hrycyshyn & Basmajian, 1972; Perlman et al., 1999)

From a theoretical standpoint, using a strict and high-fidelity data collection protocol by carefully following SENIAM guidelines, training the subjects, controlling for motion, and completing 5 repetitions per task afforded the opportunity to compare signal related factors obtained using two different sensor types and provided equivalent values between two different systems. Since even minor movements can change the EMG signal significantly, completing one repetition is not enough to account for the potential variability in muscle activation during swallowing. In addition, any additional head or tongue movement can result in increased amplitude values or duration of the sEMG burst. For these reasons, completing several repetitions of the same trials and using average values obtained from the repeated trials are important when examining signal-related values. Moreover, this study is among the few studies that used normalized amplitude values instead of the raw EMG signal. As mentioned earlier, normalization of the EMG signal is necessary in order to compare two EMG amplitude values between two different sessions or individuals. Following this method may help swallowing researchers to design better studies that examine the use of sEMG in swallowing treatment and potentially improve the use of sEMG for patient care. Lastly, intra and inter subject reliability is not commonly examined in sEMG studies. This study proved that high level of intra- and inter-rater reliability is achievable when high quality protocols are followed.

5.2. Safety and Pre-Clinical Factors

Regarding the safety of the electrodes, we hypothesized that no safety or adverse effects will be reported during or after using either type of sEMG sensors, and this hypothesis was

partially proven. Contrary to our expectations, some participants experienced itchiness (n=2/40) and redness of the skin (n=3/40) after the removal of the conventional sensors. Mild redness was still present 5 minutes after the removal of these sensors in 2 out of those 3 participants. Only one participant reported feeling itchy right after the removal of the experimental sensors. No other skin problems were observed or reported. Regarding pain, mild pain (1/10 points) was reported by two participants after the removal of the conventional sensors. None of the participants reported any pain after the removal of the experimental sensors.

These findings are in agreement with previous studies that have showed that using biocompatible wearable sensors is less irritating to the skin, because they allow more air permeability and ventilation of moisture and residue from the skin than traditional sensors do (Kwak, Jeong, & Suh, 2011; Pang, Lee, & Suh, 2013). Indeed, the use of conventional sensors required four stickers which enabled strong adhesion. Although both sensor types were adhering to the skin very well, at the end of the experiment it was more difficult to remove the conventional sensors compared to the experimental sensors, hence more skin irritation was observed with the conventional sensors.

Regarding efficiency of electrode placement, the duration of electrode placement was clinically similar between the two sensors. Contrary to our hypothesis, we did not find any statistically significant differences between the two sensors based on efficiency, indicating that at this time and with the current version of the sensors, time efficiency remains the same. This was likely due to the need to apply more body adhesive to the experimental sensors during sensor placement to increase skin-electrode contact. However, it is important to note that the difference was typically below 60 seconds. This difference is likely not clinically significant.

Finally, in terms of satisfaction/comfort level, there was a statistically significant difference between the two sensor types, however, the effect size was small, and results have to

be interpreted with caution. Specifically, participants consistently rated their satisfaction level with the experimental sensors higher than their satisfaction level with the conventional sensors. Some anecdotal feedback while using the experimental sensors included: “I don’t feel anything.” “These were lighter than the other ones.” “It is hardly noticeable.” This higher satisfaction rate is in agreement with prior studies reporting overall high user satisfaction with wearable devices (e.g., Botella et al., 2016; Fensli et al., 2010). Moreover, studies that have examined patient satisfaction with the use of telehealth in the treatment of dysphagia have consistently reported high satisfaction rates and preference towards telehealth versus face to face practices (Kantarcigil & Malandraki, 2017; Malandraki, Roth, & Sheppard, 2014; Sharma, Ward, Burns, Theodoros, & Russell, 2013).

Overall, the results of this validation study support that the newly developed wearable sensors are equivalent or superior to the conventional EMG sensors in most variables examined. However, it has to be acknowledged that this study is not without limitations. The next section provides a detailed summary of these limitations and discusses future directions.

5.3. Limitations and Future Directions

As mentioned earlier, the present study is the first in a series of studies that will be conducted to ensure the validity and effectiveness of the newly developed patch, before its use in the management of swallowing disorders is examined. Therefore, several aspects of the study and the sensors need to be carefully assessed and improved for future research.

5.3.a. Technical Considerations

Regarding sensor related factors, the first limitation of the current version is related to adhesion/skin contact. While the adherence of the specific tested version in this study has improved vastly from previous versions, skin adherence was still dependent on the use of a

special body adhesive. Specifically to achieve excellent skin adhesion, a commercially available body adhesive was applied on the sensor patch, in the area surrounding the sensors, approximately 30 minutes prior to the application of the sensors on the skin. Although in a research setting, this did not cause any major issues, it would be much harder for patients to comply with this demand at home or in the clinic. In addition, the application of this adhesive requires precision, because while the area around the sensors needs to be covered, the adhesive should not be applied to the actual sensors, as it may decrease conduction. This was challenging even for the leading researcher (doctoral student) at times. It would be exceedingly difficult, if not impossible, for some patients with dysphagia to do this accurately. Most likely, they would need to depend on someone else to complete this part, which could create another burden on the patient. In addition, there were 17 instances where the experimental sensors started coming off in the middle of data collection, and required more adhesive to be applied. In summary, although excellent adhesion was achieved with the use of an external body adhesive, stable adhesion remains as one of the limitations of the current version of the wearable sensors patch. The future version of the patch should not require application of body adhesive and should aim for consistent adherence to the skin for at least 30-60 minutes, i.e., the duration of a typical swallowing therapy session.

Regarding durability, in 7 out of 40 trials, the experimental sensors tore while being removed from the subject's skin at the end of the experimental session. While the electrodes and the connections remained intact at all times during the experiment, the honeycomb mesh structure was prone to tear upon removal of the sensors, even though the leading researcher was very experienced in handling the sensors and did so with much care. Currently our team is starting to incorporate more durable materials that will allow patients to use the new sensors patch several times.

In addition, there were three instances where the EMG electrode discs did not work properly, i.e., there was either no signal detected or the signal displayed on the screen was not a typical EMG signal. In these cases, the problem was resolved once the experimenter replaced the cable that connects the sensors to the BioRadio device. Creating a wireless version of the sensors, which is also a current goal of the team, will eliminate the need for the use of connecting cables between the sensors and the BioRadio device. If the sensors connect to the BioRadio device or another device (e.g., an app on a smartphone) via Bluetooth, the system could potentially become more reliable and less prone to connection issues.

Moreover, as mentioned earlier, the sensors were placed by the experimenter on the participants' submental area. This option was chosen because the primary goal of this first study was to validate the signal obtained using the wearable patch against the signal obtained using conventional sensors. This requires accurate and reliable placement of the sensors both within and between subjects. Thus, the same researcher was responsible for placement of all sensors and for all participants. Currently, it is not clear how older adults will manage the placement on the sensors on the submental area and how open they will be in doing this independently. This remains to be further explored. Future studies should also explore the placement of the sensors by several potential users (patients and clinicians) across several attempts to examine whether the sensors can be placed on the submental muscles accurately and reliably across individuals and trials.

In addition, efficiency of electrode placement was timed by the doctoral student who was also in charge of applying the sensors to the skin. Although a strict protocol was followed to start and end the timer, there could be an inherent bias towards the experimental sensors. However, it is noteworthy to mention that the results showed slightly increased duration of electrode placement for the experimental sensors, albeit not statistically significant.

5.3.b. Clinical Considerations

In addition to the technical considerations, there are also clinical issues to consider. First of all, this study was conducted with healthy older adults. It will be important to continue testing further iterations of these sensors with older adults until the aforementioned limitations can be improved (e.g., durability) and the wearable sensors' patch is optimized. It would also be beneficial to start receiving feedback from clinicians who specialize in dysphagia during this process. Since they will be main individuals who will use these sensors and train their patients on how to use them, their input on sensor placement, data visualization, and acquisition would be invaluable (Leonard-Barton & Sinha, 1993).

Another limitation of the current study is testing the sensors with a single consistency, i.e., water, however swallowing treatment includes other consistencies such as pudding as well. Other consistencies were not included in this study due to high variability in amplitude values obtained across trials, but future studies should examine different swallow trials including dry swallows, pudding, and cookie. In the long run, it would be important to examine the use of the newly developed sEMG sensors as a biofeedback tool for different exercises such as the Mendelsohn maneuver or the effortful swallows, as the typical use of sEMG to teach such approaches has been shown to be beneficial (Azola et al., 2017; Carnaby-Mann & Crary, 2010). Upon sensors' optimization, the next step would be to examine the utility of the sensors on patients with dysphagia through randomized controlled trials.

In addition, while we calculated the BMI of the participants, we did not collect data on the adipose tissue density of the participants, especially under the chin area. On a post-hoc analysis we found a moderate negative correlation between signal-to-noise ratio and BMI in our participants, suggesting that as BMI increases, the voltage of the signal moderately decreases.

Future studies should collect data on adipose tissue density by using devices such as a handheld body fat analyzer to explore the relationship between adipose tissue density and the EMG signal.

Regarding safety/adverse effects and pre-clinical factors, as mentioned in the method sections, a research assistant helped with this part of data collection. The research assistants were blinded to the type of sensors used when examining the skin for adverse effects in all but 6 subjects. In these 6 instances, an undergraduate research assistant was present in the room to get trained on data collection parameters. Thus, she was not blinded for these 6 subjects. Future studies should aim for complete blindness to prevent any bias.

5.4. Potential Clinical Implications

Since this is the first study that examined the use of this newly developed wearable sEMG sensors patch in swallowing, one can only speculate about the clinical implications of using this device in clinical practice. First, after some of the limitations have been addressed (e.g., making the sensors wireless and more durable), they could potentially replace the bulky and expensive EMG equipment used today in several clinical settings. This could allow more clinicians to have access to this type of technology and could enable them to use sEMG biofeedback more often in clinical practice.

Furthermore, currently speech-language pathologists have limited evidence-based tools that enable them to remotely monitor their patients' progress, adjust their exercise intensity, and track their exercise adherence. Telehealth can be used as an alternative service delivery model to overcome these issues and can be beneficial to patients and clinicians with mobility limitations, and to patients who live in rural or underserved areas. The use of telehealth has been at the forefront of recent medical advancements and there has been substantial growth in telehealth dysphagia research during the last 15 years. Most of the telehealth research in dysphagia has

focused on the remote evaluation of dysphagia (Burns, Ward, Hill, Phillips, & Porter, 2016; Kantarcigil & Malandraki, 2017; Kantarcigil, Sheppard, Gordon, Friel, & Malandraki, 2016; Malandraki et al., 2013; Malandraki, McCullough, He, McWeeny, & Perlman, 2011; Sharma, Ward, Burns, Theodoros, & Russell, 2011; Ward, Sharma, Burns, Theodoros, & Russell, 2012); however, there are a few studies that provide initial support on the effectiveness of center-based and home-based dysphagia treatment (Burns et al., 2012; Burns & Wall, 2017; Malandraki et al., 2014; Wall, Ward, Cartmill, Hill, & Porceddu, 2017).

Current research evidence includes one randomized controlled trial which evaluated the service outcomes of a telehealth service delivery model (Burns et al., 2017), one case study in pediatric dysphagia (Malandraki et al., 2014), and a satisfaction study which examined the use of dysphagia apps in home-based therapy (Wall et al., 2017). These studies provided initial research support on the feasibility and effectiveness of using telehealth for dysphagia treatment. However, they also have limitations as they were small cohort or case studies. In addition, none of these studies investigated ways to record and adjust quantitative data remotely. In current clinical practice, there is an urgent need for developing tools that can easily and reliably monitor patients' swallowing function remotely. Thus, this work is timely and leads the way for future trials that will examine the effectiveness of optimized versions of these new wearable sEMG sensors in dysphagia rehabilitation. This contribution to the current evidence and clinical practice can be substantial.

5.5. Conclusion

We validated a set of newly developed wearable ultrathin surface electromyography sensors specifically designed to record submental muscle activity during swallowing. Our findings suggest that these sensors conform to the submental area seamlessly using an external adhesive, and allow for high quality recording of the electromyography signal during swallow

trials. Regarding signal related factors, our results showed that signal quality of the experimental sensors is not inferior to the signal quality obtained using conventional sensors, and that the normalized amplitude and duration of sEMG burst during swallows acquired with both sensor types are comparable. Taken together, these findings indicate that the experimental sensors' technical performance is similar to the performance of widely used conventional sEMG electrodes. Results of the safety and pre-clinical factors comparisons further supported that the wearable sEMG sensors are safe to use and healthy older adults are satisfied with them. While this study provides valuable validation data for the hardware pieces of this newly developed patch, further research is warranted to optimize peripheral and central components of this innovative technology, before clinical trials examining the effectiveness of these sensors in the treatment of dysphagia can be initiated.

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APPENDIX A. RESULTS OF THE PILOT STUDY

Appendix A.1. Preliminary Study – Basis for Power Analysis and Determining Margins

Appendix A.1.a. Participants

Five healthy adults were recruited from the Greater Lafayette area of Indiana to participate in the preliminary study, which formed the basis for the power analysis for the larger study. Table 17 contains details on the five participants' demographics and screenings results. Three older females and two older males completed the preliminary study. The mean age was 69. All participants received a score of zero on the EAT-10. The mean MoCA score was 28.6 (cut-off score is 25). However, it is important to note that one participant (subject 2) presented with low tongue strength values as this participant's average tongue strength was 23. Based on a systematic review and meta-analysis of 38 studies investigating normative data on tongue strength, this value is below the normal limits of 47-69 reported in healthy adults (Adams, Mathisen, Baines, Lazarus, & Callister, 2013). In our study, the maximal lingual press values are used to normalize the EMG data and not to screen participants for eligibility. However, this participant had more variable normalized EMG amplitude values. Therefore, power calculations for amplitude values were completed without this participant.

Table 17. Preliminary Study - Participant Demographics and Characteristics

ID	Sex	Age	EAT-10	MoCA	OPSES	Mean Tongue Strength
1	Female	71	0	30	No abnormal findings	44
2	Female	75	0	29	No abnormal findings	23
3	Male	67	0	26	No abnormal findings	59
4	Male	67	0	29	No abnormal findings	47
5	Female	65	0	29	No abnormal findings	54

Note. EAT-10: Eating Assessment Tool-10, MoCA: Montreal Cognitive Assessment, OPSES: Oropharyngeal Sensorimotor Examination of Swallowing

Appendix A.1.b. Results of the Pilot Study

Signal Related Factors

Signal Quality

Table 18 presents the signal-to-noise ratio values for the left and right channels of submental muscle activity and the within subject differences between the experimental and conventional sensors for each participant. As can be seen, the mean signal-to-noise ratio was 17.12 for the left conventional sensors, and 18.41 for the left experimental sensors (mean difference = 1.29 and SD of the difference =2.05). The mean signal-to-noise ratio was 17.38 for the right conventional sensors, and 17.73 for the right experimental sensors (mean difference = 0.34 and SD of the difference = 2.03). Both of these values are above 1.2, which is the minimum acceptable value for signal-to-noise ratio (Delsys, 2018). Table 19 presents the baseline amplitude values for the left and right channels and the within subject differences across the two sensor types. The mean amplitude of the baseline signal for the left conventional and experimental sensors was 4.18 μV and 3.73 μV, respectively (mean difference = -0.44 and SD of

the difference 0.2). The mean amplitude of the baseline signal was 4.20 μV for the right conventional sensors, and 3.85 μV for the right experimental sensors (mean difference =-0.34 and SD of the difference = 0.55). Less than 20μV is considered to be a good baseline value (Konrad, 2005), thus a good baseline value was obtained with both types of sensors during this pilot study.

Table 18. Preliminary Study - Signal-to-Noise Ratio Results for Submental Muscles

	Experimental Sensors		**Conventional Sensors**		**Difference**	
ID	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**
1	9.81	9.79	9.37	9.30	0.43	0.49
2	21.55	19.75	22.15	22.49	-0.60	-2.74
3	20.04	15.02	15.35	15.24	4.69	-0.21
4	27.23	28.07	25.62	26.53	1.60	1.54
5	13.45	16.02	13.10	13.36	0.34	2.65
Mean	**18.41**	**17.73**	**17.12**	**17.38**	**1.29**	**0.34**
SD	**6.87**	**6.78**	**6.65**	**6.99**	**2.05**	**2.03**

Table 19. Preliminary Study – Baseline Amplitude Results for Submental Muscles

	Experimental Sensors		Conventional Sensors		Difference	
ID	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**
1	13.60	13.92	13.99	14.25	-0.39	-0.32
2	1.11	1.20	1.30	1.26	-0.19	-0.06
3	1.07	1.84	1.39	1.45	-0.32	0.39
4	0.99	0.90	1.64	1.54	-0.65	-0.64
5	1.89	1.41	2.56	2.49	-0.66	-1.07
Mean	**3.73**	**3.85**	**4.18**	**4.20**	**-0.44**	**-0.34**
SD	**5.52**	**5.63**	**5.50**	**5.63**	**0.20**	**0.55**

Signal Amplitude and Duration During Tasks

Normalized Amplitude of the Swallow Trials

Table 20 and

Table 21 present in detail the normalized mean EMG amplitude values (area under the curve) for the left and right submental muscles during the 5ml and 10ml swallow trials for each participant and the within subject differences between the two types of sensors. In summary, for the 5ml swallows, the normalized EMG amplitude values of the left submental muscles ranged from 5.67% to 33.26% with the conventional sensors, and from 5.4% to 25.47% with the experimental sensors. For the 10ml swallows, the normalized EMG amplitude values of the left submental muscles ranged from 7.62% to 33.22% with the conventional sensors, and from 7.42% to 26.87% with the experimental sensors. The normalized EMG amplitude values of the right submental muscles ranged from 5.72% to 22.71% with the conventional sensors, and from 4.78% to 23.63% with the experimental sensors during the 5ml swallow trials. The normalized EMG amplitude values of the right submental muscles ranged from 7.98% to 25.97% with the conventional sensors, and from 7.55% to 26.78% with the experimental sensors during the 10ml swallow trials.

Table 20. Preliminary Study - Normalized Mean Amplitude Values for the **LEFT** Submental Muscles During Swallow Trials

	Experimental Sensors		**Conventional Sensors**		**Difference**	
ID	**5ml Liquid (%)**	**10ml Liquid (%)**	**5ml Liquid (%)**	**10ml Liquid (%)**	**5ml Liquid (%)**	**10ml Liquid (%)**
1	25.47	26.87	24.61	28.24	0.85	-1.36
2	13.00	9.34	33.26	33.22	-20.25	-23.87
3	10.36	14.58	11.63	13.30	-1.26	1.27
4	12.45	10.54	17.89	20.17	-5.44	-9.63
5	5.40	7.42	5.67	7.62	-0.26	-0.20

Mean	**13.34**	**13.75**	**18.61**	**20.51**	**-5.27**	**-6.75**
SD	**7.41**	**7.78**	**10.80**	**10.48**	**8.70**	**10.46**

Note. These values are reported in percentages, as they are normalized.

Table 21. Preliminary Study - Normalized Mean Amplitude Values for the **RIGHT** Submental Muscles During Swallow Trials

	Experimental Sensors		**Conventional Sensors**		**Difference**	
ID	**5ml Liquid (%)**	**10ml Liquid (%)**	**5ml Liquid (%)**	**10ml Liquid (%)**	**5ml Liquid (%)**	**10ml Liquid (%)**
1	23.63	26.78	22.71	25.97	0.92	0.80
2	11.42	9.78	21.31	22.00	-9.88	-12.22
3	9.20	14.63	12.98	12.59	-3.78	2.03
4	12.65	10.69	17.92	21.43	-5.27	-10.73
5	4.78	7.55	5.72	7.98	-0.93	-0.42
Mean	**12.34**	**13.89**	**16.13**	**17.99**	**-3.79**	**-4.10**
SD	**6.98**	**7.65**	**6.92**	**7.43**	**4.17**	**6.80**

Note. These values are reported in percentages, as they are normalized.

Duration of sEMG Burst During Swallow Trials

Table 22 and Table 23 present mean duration of EMG burst during the 5ml and 10ml swallow trials for the left and right submental muscles for each participant, and the within subject differences between the two types of sensors. For the left submental muscles, the mean duration of the 5ml swallow trials was 1.38 seconds for the conventional sensors, and 1.73 seconds for the experimental sensors. The mean duration of the 10ml swallow trials was 1.43 seconds for the conventional sensors, and 1.71 seconds for the experimental sensors. For the right submental muscles, the mean duration of the 5ml swallow trials was 1.43 seconds for the

conventional sensors, and 1.54 seconds for the experimental sensors. The mean duration of the 10ml swallow trials was 1.49 seconds for the conventional sensors, and 1.77 seconds for the experimental sensors.

Table 22. Preliminary Study - Mean Duration Values for the **LEFT** Submental Muscles During Swallow Trials

	Experimental Sensors		**Conventional Sensors**		**Difference**	
ID	**5ml Liquid**	**10ml Liquid**	**5ml Liquid**	**10ml Liquid**	**5ml Liquid**	**10ml Liquid**
1	1.17	1.22	1.08	1.28	0.09	-0.06
2	1.91	1.90	1.03	0.94	0.88	0.95
3	1.98	2.11	1.29	1.43	0.68	0.68
4	2.18	1.92	2.32	2.31	-0.14	-0.38
5	1.43	1.42	1.19	1.19	0.23	0.23
Mean	**1.73**	**1.71**	**1.38**	**1.43**	**0.35**	**0.28**
SD	**0.41**	**0.37**	**0.53**	**0.52**	**0.42**	**0.54**

Note. These values are reported in seconds.

Table 23. Preliminary Study - Mean Duration Values for the **RIGHT** Submental Muscles During Swallow Trials

	Experimental Sensors		**Conventional Sensors**		**Difference**	
ID	**5ml Liquid**	**10ml Liquid**	**5ml Liquid**	**10ml Liquid**	**5ml Liquid**	**10ml Liquid**
1	1.14	1.34	1.06	1.26	0.08	0.08
2	1.36	1.71	0.97	0.96	0.38	0.74
3	1.67	2.19	1.58	1.21	0.08	0.97
4	2.27	2.05	2.36	2.72	-0.08	-0.67
5	1.28	1.59	1.21	1.32	0.07	0.26
Mean	**1.54**	**1.77**	**1.43**	**1.49**	**0.10**	**0.27**
SD	**0.44**	**0.34**	**0.56**	**0.69**	**0.17**	**0.64**

Note. These values are reported in seconds.

3.8.b.ii. Safety and Pre-Clinical Factors

Safety and Adverse Effects

No discomfort, adverse effects or pain were observed or reported by the participants for either type of sensors. All participants rated their pain level as zero.

Efficiency

Electrode placement lasted approximately 2 minutes and 54 seconds on average (2:11-3:49 minutes) for the conventional sensors, and 2 minutes and 16 seconds (1:23-3:11 minutes) for the experimental sensors.

Satisfaction

High satisfaction was reported with both sensor types. The average satisfaction rating was 48.38/50 for the conventional sensors and 49.8/50 for the experimental sensors. Ratings and standard deviations are provided in Table 24.

Table 24. Results of the Satisfaction /Comfort Questionnaire

ID	Experimental Sensors	Conventional Sensors	Difference
1	50	49.9	0.1
2	49	49	0
3	50	50	0
4	50	50	0
5	50	43	7
Mean	**49.8**	**48.38**	**1.42**
SD	**0.44**	**3.03**	**3.11**

APPENDIX B. PHONE SCREENING QUESTIONNAIRE

Researcher will query: "Do you give verbal consent to be asked questions that are relevant to determining your appropriateness to participate in this study, including questions about your personal information, general health and medical status and swallowing/eating? You may decline to answer any question. If you do not qualify for this study (based on this screening), the data we collect will be shredded."

❑ YES, I give consent ❑ NO, I do not give consent ❑

Screening Questions

1. **Are you between the ages of 50-90?** **Yes** No
2. **Do you have any concerns about your swallowing?** Yes **No**
3. **Do you have a history of a neurological disorder?** Yes **No**
4. **Do you have a history of head and neck cancer or surgery, or radiation exposure to the head and neck area?** Yes **No**
5. **Do you have a history of gastrointestinal disease?** Yes **No**
6. **Do you have a history of respiratory disease?** Yes **No**
7. **Is there any chance that you are pregnant?** *(only for young females)* Yes **No**
8. **Would you be willing to take a pregnancy test to confirm this?** *(only for young females)* **Yes** No

If the participant passes the screening questions (i.e., all bolded words are circled), please obtain the following information:

Contact Information:

Name:_____

Date:_____

Address:_____

Phone number:_____

Email address:_____

How do you prefer to be contacted? Phone Email

Would you like to schedule your appointment now? Yes No

Date/Time of Visit:_____

APPENDIX C. EATING ASSESSMENT TOOL-10

Pt ID: _____ _____ Date: _____
Height: _____ _____ Weight: _____

Directions: Now, I am going to read you some statements to learn more about how your swallowing interferes with your quality of life. I want to you rate each statement from 0 to 4, 0 being no problem and 4 being a severe problem.

Circle the appropriate response	**0 = No problem**				**4 = Severe problem**
1. My swallowing problem has caused me to lose weight.	0	1	2	3	4
2. My swallowing problem interferes with my ability to go out for meals.	0	1	2	3	4
3. Swallowing liquids takes extra effort.	0	1	2	3	4
4. Swallowing solids takes extra effort.	0	1	2	3	4
5. Swallowing pills takes extra effort.	0	1	2	3	4
6. Swallowing is painful.	0	1	2	3	4
7. The pleasure of eating is affected by my swallowing.	0	1	2	3	4
8. When I swallow, food sticks in my throat.	0	1	2	3	4
9. I cough when I eat.	0	1	2	3	4
10. Swallowing is stressful.	0	1	2	3	4
Total EAT-10:					

Belafsky, P.C., Mouadeb, D.A., Rees, C.J., Pryor, J.C., Postma, G.N., Allen, J.A., and Leonard, R.J. (2008). Validity and reliability of the Eating Assessment Tool (EAT-10). *Annals of Otology, Rhinology, & Laryngology, 117 (12)*: 919-924.

APPENDIX D. THE VISUAL INSPECTION FORM

Directions: This form will be completed twice, once right after the experiment (left side of the table) and once 5 minutes after the experiment (right side of the table). Check skin for any adverse effects. Tell the participants, "*Now I will check your neck for any redness or skin irritation. Does your skin feel itchy*?" Mark their answer as "yes or no." At the end, ask: "*Do you have any comments about how the sensors feel on your skin*?" If you have any additional observations or they make any additional comments, write it below.

	Right after the experiment		**5 minutes after the experiment**	
Skin or mouth is itchy	❑ Yes	❑ No	❑ Yes	❑ No
Skin is red	❑ Yes	❑ No	❑ Yes	❑ No
Skin or mouth is irritated	❑ Yes	❑ No	❑ Yes	❑ No

Any additional observations:

_____

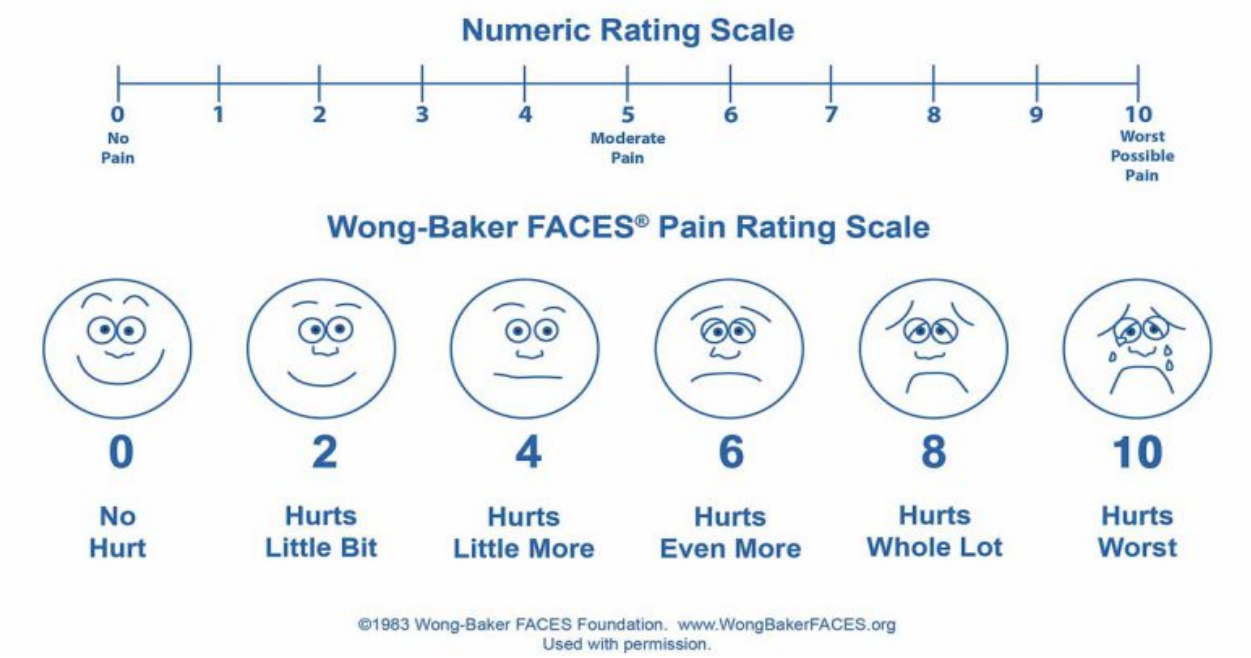
_____

_____

_____

APPENDIX E. THE PAIN SCREENING FORM

Directions: Complete this form right after the experiment. Ask the participants, "*Do you have any pain in the neck area*?" If they say no, mark zero (0). If they say yes, ask: "*please rate your pain on a scale of 0 to 10, where zero is having no pain and 10 is having the worst possible pain and describe the pain. You can look at these faces and choose the one that fits your pain level the most*" Mark their answer and write down their description.



Any additional information:

_____

_____

VITA

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EDUCATION

Expected May 2019	**Ph.D. in Speech, Language, & Hearing Sciences** Purdue University, West Lafayette, IN Dissertation: Validation of a Novel Ultra-Thin Wearable Electromyography Sensor Patch for Monitoring Submental Muscle Activity during Swallowing Committee members: Dr. Georgia A. Malandraki (chair), Dr. Chi Hwan Lee (Schools of Biomedical and Mechanical Engineering), Dr. Bruce A. Craig (Department of Statistics), Dr. Preeti Sivasankar, & Dr. Jessica Huber
Dec. 2013	**M.S. in Speech and Language Pathology** Teachers College, Columbia University, New York, NY
May 2010	**M.S. in Child Development with Early Intervention Specialization** Erikson Institute, Chicago, IL
Jun. 2006	**B.A. in Early Childhood Education** Marmara University, Istanbul, Turkey

RESEARCH INTERESTS

The application of telehealth in dysphagia diagnosis, rehabilitation, and consultation
Creating evidence-based protocols for dysphagia rehabilitation

RESEARCH EXPERIENCE AND POSITIONS

Aug. 2014 – Present	**Graduate Research Assistant** Imaging, Evaluation, and Treatment of Swallowing Laboratory at Purdue University, West Lafayette, IN Principal Investigator/Advisor: Georgia A. Malandraki, PhD, CCC-SLP, BCS-S – Examining the use of telehealth in dysphagia evaluation and treatment to create evidence-based protocols for dysphagia management – Collecting and analyzing electromyography data from children and adults using LabChart, BioCapture, and MATLAB – Conducting statistical analyses using SAS, R, and SPSS and interpreting findings – Collaborating with faculty members and research assistants from the Department of Biomedical Engineering to create wireless electromyography sensors – Mentoring undergraduate research assistants in data collection and analyses
Jan. 2013 – Aug. 2014	**Graduate Research Assistant** Swallowing, Voice and Neuroimaging Laboratory at Teachers College, Columbia University, New York, NY Principal Investigator: Georgia Malandraki, PhD, CCC-SLP, BCS-S – Performed comprehensive diagnostic evaluations of swallowing in children and adults to determine eligibility and design treatment plans

- Implemented treatment research protocols using principles of neuroplasticity and evidence-based methodologies including electromyography and strength training
- Coordinated subject recruitment, scheduling, and research activities
- Conducted literature reviews to assist in manuscript preparation

Sept. 2009 – Apr. 2010 **Research Intern**
Fussy Baby Network, Chicago, IL
Supervisors: Drs. Linda Gilkerson and Leslie Katch Dobos

- Designed a qualitative research study and conducted thematic analysis of qualitative data on multicultural parenting practices and feeding disorders using NVivo software
- Analyzed data from quantitative studies using SPSS to assist in manuscript preparation

Jul. 2009 – Jan. 2010 **Research Assistant**
University of Chicago Developmental Psychology Department, Chicago, IL
Principal Investigator: Dr. Susan Goldin-Meadow

- Analyzed hand gestures of twenty Turkish hearing and deaf children and their mothers to assess inter-rater reliability

SCHOLARSHIPS, HONORS, AND AWARDS

2018	Purdue Graduate Student Government's Travel Grant
2017	Council of Academic Programs in Communication Sciences and Disorders (CAPCSD) PhD Scholarship ($20,000)
2017	Ruth and M. D. Steer Outstanding Teaching Assistant Award (voted by students and awarded annually to one TA)
2016	ASHA Foundation's New Century Scholars Doctoral Scholarship ($10,000)
2016	Department of Speech, Language, & Hearing Sciences' Travel Award
2016	Purdue Graduate Student Government's Travel Grant
2016	Ruth and M. D. Steer Outstanding Teaching Assistant Award (voted by students and awarded annually to one TA)
2015	Compton Graduate Research Travel Award
2015	Lions McKinney Outreach Program's Research Award for project entitled "Teledynamic asynchronous pediatric dysphagia evaluations are feasible and reliable."
2014 – 2017	Wilson Graduate Scholarship, additional stipend for $2,339 per semester
2014	Telepractice Research Scholarship
2014	Speech Pathology and Audiology Scholarship
2012 – 2013	Teachers College, Columbia University International Student Scholarship
2012 – 2013	J. Schwartz Scholarship
2012	Carol N. Wilder Stipend Award
2008 – 2010	Harris Excellence Scholarship, covering 75% of tuition

RESEARCH GRANTS

June 2016 – June 2017	Purdue Institute for Integrative Neuroscience Research Grant for project entitled "The S.M.A.R.T. (Swallowing Muscle Activation Recorded via Telehealth) sensors validation study." Role: Principal Investigator, Co-PI: Georgia Malandraki, Co-I: Chi Hwan Lee ($9,000)
June 2016	Purdue Graduate Student Government's Research Grant for project entitled "The S.M.A.R.T. (Swallowing Muscle Activation Recorded via Telehealth) sensors validation study." Role: Principal Investigator ($500)
April 2015	10th Annual Robert L. Ringel Graduate Student Research Award for project entitled "A head start to the clinical swallowing exam using an electronic case history form." Role: Principal Investigator (awarded annually to one doctoral student; $1,800)

PUBLICATIONS

Refereed Publications

1. Mishra, A., Sheppard, J.J., **Kantarcigil, C**., & Malandraki G.A. (2017). New measures of mealtime duration: associations with swallowing and feeding performance in children with cerebral palsy. *American Journal of Speech Language Pathology,* 1-9.

2. Malandraki, G.A., & **Kantarcigil, C.** (2017). Telehealth for dysphagia rehabilitation: the present and the future. *Perspectives of the ASHA Special Interest Groups, 2*(18), 42-48.

3. **Kantarcigil, C.**, & Malandraki, G.A. (2017). First step in telehealth assessment: development and validation of an electronic case history form for dysphagia. *Dysphagia, 32*(4), 548-558.

4. **Kantarcigil, C.**, Sheppard, J.J., Gordon, A., Friel, K., & Malandraki, G.A. (2016). A telehealth approach to conducting clinical swallowing evaluations in children with cerebral palsy. *Research in Developmental Disabilities, 55*, 207-217.

5. Malandraki, G.A., Rajappa, A., **Kantarcigil, C.,** Wagner, E., Ivey, C., & Youse, K. (2016). The Intensive Dysphagia Rehabilitation approach applied to patients with neurogenic dysphagia: a case series design study. *Archives of Physical Medicine and Rehabilitation*, 97*(4),* 567-574.

Non-Refereed Publications

1. **Kantarcigil, C.,** & Malandraki, G.A. (2016). The rise of telehealth in the United States: the present and the future of dysphagia telerehabilitation. *Dysphagiacafe.com*, Spring 2016.

2. **Kantarcigil, C.** (2015). Remote evaluation of dysphagia. *The annual newsletter of ASHA's Asian-Indian Caucus: ASHA KIRAN*, November 2015.

CONFERENCE PRESENTATIONS

Oral Presentations

1. Malandraki, G.A., Bauer Malandraki, J. L., Rajappa, A., & **Kantarcigil, C.** (2018*). Four years of applying the Intensive Dysphagia Rehabilitation (IDR) approach: A Personalized Neuroplasticity-Driven Swallowing Training*. American Speech-Hearing-Language Association Convention, Boston, MA.

2. Malandraki, G.A., **Kantarcigil, C**. DelPrete, N., & Jones, A. (2016, November). *Variability of dysphagia and mealtime duration in children with unilateral cerebral palsy: a pilot study*. Paper presented at the American Speech-Language and Hearing Association's Annual Convention, Philadelphia, PA.

3. Mourão, L.F., Friel, K.M., **Kantarcigil, C.,** Luchesi, K.F., Gordon, A.M., & Malandraki, G.A. (2016, March). *The role of the corpus callosum in pediatric dysphagia: preliminary findings from a Diffusion Tensor Imaging (DTI) study in children with congenital left-hemisphere lesions*. Paper presented at the Dysphagia Research Society's Annual Convention, Tuscan, AZ.

4. **Kantarcigil, C.**, Sheppard, J.J., Gordon, A., Friel, K., & Malandraki, G.A. (2015, May). *Face-to-face versus asynchronous clinical swallowing evaluations in pediatric dysphagia*. Paper presented at the American Telemedicine Association's Annual Conference, Los Angeles, LA.

5. Rajappa, A., **Kantarcigil, C.,** Wagner, E., Youse, K., & Malandraki, G.A. (2014, November). *Boot camp for swallowing treatment: a new service delivery model*. Paper presented at the American Speech-Language and Hearing Association's Annual Convention, Orlando, FL.

Scientific Posters

1. Malandraki, G.A., **Kantarcigil, C**., Sheppard, J.J., & Gordon, A. (2018, March). *The day-to-day variability of dysphagia and mealtime duration in children with cerebral palsy*. Poster presented at the Dysphagia Research Society's 2018 Annual Meeting, Baltimore, MD.

2. **Kantarcigil, C.,** & Malandraki, G.A. (2017, May). *Development of the e-HiT for patients with dysphagia and comparison with a traditional case-history form.* Poster presented at the American Telemedicine Association's Annual Conference, Orlando, FL.

3. **Kantarcigil, C.,** & Malandraki, G.A. (2016, November). *Development and comparisons of an electronic dysphagia case history form with a paper-based version.* Poster presented the American Speech-Language and Hearing Association's Annual Convention, Philadelphia, PA.

4. **Kantarcigil, C.**, Sheppard, J.J., Gordon, A., Friel, K., & Malandraki, G.A. (2015, April). *Asynchronous pediatric swallowing evaluations using telepractice*. Poster presented at the Indiana State Speech-Language, and Hearing Association's Annual Convention, Indianapolis, IN.

5. **Kantarcigil, C.**, Sheppard, J.J., Gordon, A., Friel, K., & Malandraki, G.A. (2015, March). *Teledynamic asynchronous pediatric dysphagia evaluations are feasible and reliable.* Poster presented at the Dysphagia Research Society's 2015 Annual Meeting, Chicago, IL.

6. Malandraki, G.A., Friel, K., Mishra, A., **Kantarcigil, C**., Gordon, A., & Sheppard J.J. (2015, March). *Swallowing disorders in pediatric hemiplegia: frequency, types and associations with neurological findings*. Poster presented at the Dysphagia Research Society's 2015 Annual Meeting, Chicago, IL.

7. **Kantarcigil, C.**, Park, C., Conklin, A., Del Sol, A., Dikeman, K., Kazandjian, M., & Malandraki, G.A. (2014, April). *Two successive swallowing interventions effective in feeding tube weaning in chronic stroke: a single subject research design study.* Poster presented at the New York State Speech-Language, and Hearing Association's 54th Annual Convention, Saratoga Springs, NY.

TEACHING EXPERIENCE

Teaching Assistant - Purdue University

Term	Course Number	Course Title	Course Lead	Size	Responsibilities	Evaluation*
Fall 2014	SLHS 419	Anatomy & Physiology of the Speech Mechanism	Preeti Sivasankar, PhD	117 students	Teaching two labs/week, assisting in exam preparation and grading	4.7/5
Spring 2015	SLHS 115	Introduction to Communication Disorders	Françoise Brosseau-Lapré, PhD	65 students	Teaching three lectures, assisting in exam preparation and grading	NA
Spring 2016	SLHS 303	Anatomy & Physiology of the Speech Mechanism	Georgia A. Malandraki, PhD	37 students	Teaching two labs/week, assisting in exam preparation and grading	4.9/5
Spring 2017	SLHS 303	Anatomy & Physiology of the Speech Mechanism	Georgia A. Malandraki, PhD	46 students	Teaching three labs/week, assisting in exam preparation and grading	5/5

***Evaluation:** 1 = Very poor, 2 = Poor, 3 = Fair, 4 = Good, 5 = Excellent

Guest Lectures - Purdue University

1. **Kantarcigil, C.** (2017, October 25). "Speech Breathing." Anatomy & Physiology of the Speech Mechanism.
2. **Kantarcigil, C.** (2017, October 19). "Assessment and Treatment of Dysphagia." Introduction to Communication Disorders.
3. **Kantarcigil, C.** (2016, April 4). "The Remote Management of Dysphagia." Introduction to Communication Disorders.
4. **Kantarcigil, C.** (2015, November 17). "Lab: Dysphagia Treatment." Speech-Language Disorders in Healthcare Setting.
5. **Kantarcigil, C.** (2015, April 27). "Lab: Dysphagia Treatment." Dysphagia.
6. **Kantarcigil, C.** (2015, March 11). "Physiology of the Respiratory System." Anatomy & Physiology of the Speech Mechanism.
7. **Kantarcigil, C.** (2015, March 11). "Videofluoroscopic Evaluation of Swallowing: Case Studies." Dysphagia.
8. **Kantarcigil, C.** (2015, March 4). "Videofluoroscopic Evaluation of Swallowing." Dysphagia.
9. **Kantarcigil, C.** (2015, March 2). "Anatomy of the Respiratory System." Anatomy & Physiology of the Speech Mechanism.

MENTORING EXPERIENCE

2014 – Present	Mentor (under the guidance of Dr. Malandraki) for undergraduate research assistants at Purdue University (Katy Baar, Abby Oliver, Katie Bolte, and Jasmine Anguiano)
2014	Mentor (under the guidance of Dr. Malandraki) for research assistants at Teachers College, Columbia University (Chad Grossman, Aditi Valada, and Manushree Karthik)

CLINICAL EXPERIENCE

Jun. 2013 – Aug. 2013	**Graduate Clinician** Kingsbrook Jewish Medical Center, New York, NY
Jan. 2013 – May 2014	**Graduate Clinician** Dysphagia Research Clinic at Columbia University, New York, NY
May 2012 – Dec. 2013	**Graduate Clinician** Edward. D. Mysak Clinic for Communication Disorders at Columbia University, New York, NY
Jan. 2013 – May 2013	**Graduate Clinician** New York Department of Education Pubic School 111, New York, NY
Aug. 2010 – Aug. 2011	**Early Intervention Specialist** Project Match, Altgeld Gardens, Chicago, IL
May 2010 – May 2011	**Early Intervention Specialist** EB Pediatric Resources, Chicago IL
Oct. 2007 – Jul. 2008	**Early Intervention Specialist** Franklin County Board of Developmental Delays Early Childhood Education and Family Center, Columbus, OH

LEADERSHIP EXPERIENCE

Aug. 2014 – Present	**Senior PhD Research Assistant** Imaging, Evaluation, and Treatment of Swallowing (I-EaT) Laboratory at Purdue University, West Lafayette, IN
Jan. 2013 – May 2014	**Lab Manager** Swallowing, Voice and Neuroimaging Laboratory at Teachers College, Columbia University, New York, NY
Aug. 2004 – May 2006	**Student Support Project Coordinator** Foundation for Advancement of Counseling in Education, Istanbul, TR

PROFESSIONAL SERVICE AND OUTREACH

April 2018 – Present	**Councilor-in-Training & Chair of the Student Advisory Council** Dysphagia Research Society Board of Directors
Apr. 2016 & Apr. 2017	**Community Outreach Event Planner and Facilitator** – *Purdue University's Undergraduate Research Symposium* (~150 participants)
Apr. 2015	– *Pals of Cerebral Palsy: An afternoon on Swallowing Disorders and Cerebral Palsy* at Purdue University (~200 participants)
Apr. 2014	– *Join the Conversation: Uniting People with Swallowing Disorders and their Supporters* at Teachers College, Columbia University (~200 participants) ○ Assisted with applying for the "Diversity and Community Initiative Grant" from Teachers College, Columbia University and received funding ($1,500) to organize this event
Apr. 2013	– *Raising Dysphagia Awareness within the Community* at Teachers College, Columbia University (~300 participants)
Jan. 2007 – Oct. 2007	**Volunteer** Ohio Youth Advocate Program Emergency Shelter Care (group home for children with intellectual disabilities)
Oct. 2005 – June 2006	**Early Intervention Specialist** Small Steps Early Intervention Program (weekly intervention program for children with special needs who live in low-income neighborhoods)
Oct. 2002 – June 2006	**Volunteer** Foundation for Advancement of Counseling in Education

REVIEWER ACTIVITIES

Ad Hoc Journal Reviewer (co-reviewer with Dr. Georgia Malandraki): Dysphagia, Head & Neck, Journal of Telemedicine and Telecare

Grant Reviewer: Purdue Graduate Student Organization Grant Allocation Committee

SELECTED TRAININGS AND CERTIFICATIONS

Sept. 2017	Purdue Center for Instructional Excellence's Graduate Teaching Certificate (Tier 2)
May 2017	BioRadio and BioCapture electromyography data collection training
Apr. 2016	Purdue Center for Instructional Excellence's Graduate Instructional Development Certificate (Tier 1)
Mar. 2016	Electromyography analysis training by Dr. Anne Smith (Purdue University)
May 2015	PowerLab and LabChart (AD Instruments) electromyography and respiratory data collection and analyses training
May 2014	Telemedicine 101: Building Your Telemedicine Program
Mar. 2014	Modified Barium Swallow Impairment Profile® (MBSImP) Training
May 2012	Lee Silverman Voice Treatment (LSVT®) Certification

PROFESSIONAL MEMBERSHIP

2015 – Present	Dysphagia Research Society
2015 – Present	Indiana State Speech-Language, and Hearing Association
2014 – Present	ASHA Special Interest Group 18: Telepractice
2014 – Present	American Telemedicine Association
2012 – Present	National Student Speech, Language Hearing Association (NSSLHA)