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Research Article

Validation of a Novel Wearable Electromyography Patch for Monitoring Submental Muscle Activity During Swallowing: A Randomized Crossover Trial

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Purpose: Surface electromyography (sEMG) is often used for biofeedback during swallowing rehabilitation. However, commercially available sEMG electrodes are not optimized for the head and neck area, have rigid form, and are mostly available in large medical centers. We developed an ultrathin, soft, and flexible sEMG patch, specifically designed to conform to the submental anatomy and which will be ultimately incorporated into a telehealth system. To validate this first-generation sEMG patch, we compared its safety, efficiency, and signal quality in monitoring submental muscle activity with that of widely used conventional sEMG electrodes.
Method: A randomized crossover design was used to compare the experimental sEMG patch with conventional (snap-on) sEMG electrodes. Participants completed the same experimental protocol with both electrodes in counterbalanced order. Swallow trials included five trials of 5- and 10-ml water. Comparisons were made on (a) signal-related factors: signal-to-noise ratio (SNR), baseline amplitude, normalized mean amplitude, and sEMG burst duration and (b) safety/preclinical factors: safety/adverse effects, efficiency of electrode placement, and satisfaction/comfort. Noninferiority and equivalence tests were used to examine signal-related factors. Paired *t* tests and descriptive statistics were used to examine safety/preclinical factors.
Results: Forty healthy adults participated (24 women, M_{age} = 67.5 years). Signal-related factors: SNR of the experimental patch was not inferior to the SNR of the conventional electrodes ($p < .0056$). Similarly, baseline amplitude obtained with the experimental patch was not inferior to that obtained with conventional electrodes ($p < .0001$). Finally, normalized amplitude values were equivalent across swallows (5 ml: $p < .025$; 10 ml: $p < .0012$), and sEMG burst duration was also equivalent (5 ml: $p < .0001$; 10 ml: $p < .0001$). Safety/preclinical factors: The experimental patch resulted in fewer mild adverse effects. Participant satisfaction was higher with the experimental patch ($p = .0476$, $d = 0.226$).
Conclusions: Our new wearable sEMG patch is equivalent with widely used conventional sEMG electrodes in terms of technical performance. In addition, our patch is safe, and healthy older adults are satisfied with it. With lessons learned from the current COVID-19 pandemic, efforts to develop optimal swallowing telerehabilitation devices are more urgent than ever. Upon further validation, this new technology has the potential to improve rehabilitation and telerehabilitation efforts for patients with dysphagia.
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Swallowing requires the complex involvement and sequencing of several sensorimotor events. One such event is hyolaryngeal excursion occurring during the pharyngeal phase of swallowing. This action involves the anterior and superior movement of the hyolaryngeal

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complex and occurs by the contraction of the suprahyoid muscle group (mylohyoid, geniohyoid, and anterior belly of the digastric), with partial contribution from the long pharyngeal muscles (i.e., stylopharyngeus, palatopharyngeus, and salpingopharyngeus; Dodds et al., 1988; J. B. Palmer et al., 1992; Pearson et al., 2013; Schwertner et al., 2016; Spiro et al., 1994). The contraction of these muscles during swallowing is critical for airway protection, as it directs the bolus away from the airway by facilitating laryngeal inlet closure (Logemann et al., 1992). It also enables pharyngeal clearance by facilitating the opening of the pharyngoesophageal segment (Cook et al., 1989; Perlman et al., 1999).

Deficits associated with decreased hyolaryngeal excursion can have significant negative effects on the safety and efficiency of the swallow. Thus, treating such deficits has been of high priority for clinicians for years. Historically, these deficits have been treated using swallowing exercises that target the strength and timing of suprahyoid muscle activation (e.g., Athukorala et al., 2014; Wheeler-Hegland et al., 2008). In recent years, we have been learning that, in order for these exercises to be effective, specific principles need to be followed. Both animal and human studies have shown that therapies that incorporate principles of exercise physiology (e.g., overload principle, specificity) and neuroplasticity lead to neural adaptations and long-term improvements in function (Adkins et al., 2006; Bayona et al., 2005; Burkhead et al., 2007; Kleim & Jones, 2008). In dysphagia rehabilitation, these principles have started to be utilized for both the development of strength-training programs that aim to change the structural properties of muscle fibers (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 et al., 2007) and, more recently, for the development of skill-based learning paradigms that aim to improve the coordination or timing of swallowing (e.g., Athukorala et al., 2014; Huckabee & Macrae, 2014). For example, according to these principles, for optimum muscle and skill gains, swallowing exercises need to be completed with high intensity and frequency (Kleim & Jones, 2008). As a result, we often instruct patients to complete their exercises many times per day or week in the clinic and independently at home. However, recent research has shown that adherence to treatment recommendations for dysphagia rehabilitation is not optimal (Krekeler et al., 2018). Although many reasons may explain this reduced adherence, one reason often reported by clinicians is the lack of biofeedback devices (M. K. Kim et al., 2019) that can be used both in clinic and at home.

Due to the complex nature of swallowing, it is often difficult to provide accurate feedback on the strength or timing of the swallows or on muscle coordination without some type of augmentative or visual biofeedback device. For exercises involving the submental muscles, specifically, the main type of biofeedback used is feedback provided via surface electromyography (sEMG). sEMG is a noninvasive, practical, and radiation-free tool and is frequently used during swallowing treatment, as it provides user-friendly visual feedback—a key component of motor learning (Winstein, 1991)—to patients during their rehabilitation.

To date, several studies have examined the utility of sEMG of the submental muscles as a biofeedback tool in swallowing rehabilitation. Specifically, sEMG has been used to identify the presence of a swallowing event; examine the strength and duration of hyolaryngeal excursion, premotor time, and preswallow time; and monitor and gradually increase the intensity, duration, and frequency of exercise (e.g., Athukorala et al., 2014; Azola et al., 2017; Crary et al., 2006; Ding et al., 2002; Gupta et al., 1996; Wheeler et al., 2007). Utilizing extrinsic feedback during training has been linked not only to functional improvements but also to cortical reorganization (Athukorala et al., 2014; Bayona et al., 2005; Logemann et al., 2009; Malandraki et al., 2011, 2012; Pitts et al., 2009; Robbins et al., 2007; Schmidt & Lee, 2005). Specifically, results of these studies indicated that the use of sEMG as a biofeedback tool has resulted in significant improvements in maximum hyoid movement, duration of hyoid elevation, duration of upper esophageal sphincter opening, pharyngeal transit time, premotor and preswallow time, as well as swallowing-related quality of life (McCullough et al., 2012; McCullough & Kim, 2013; Zhu et al., 2015).

Despite these potential benefits, sEMG recording devices are not available in all settings. In fact, currently, most of the high-quality sEMG recording devices are bulky, expensive, and mainly used in research laboratories or large clinical centers. In recent years, portable and even wireless sEMG devices have started to emerge (e.g., Mobili-T: Constantinescu et al., 2018; Delsys: C. J. De Luca, 2002). However, to our knowledge, these systems use rigid or semiflexible platforms that are suboptimal for recording muscle activity from the curvilinear surface of the submental area during swallowing. In addition, some of the newer, state-of-the-art, flexible wearable sensors that have emerged are designed for flat or large areas of the body (e.g., chest or legs; K. H. Lee et al., 2020) and are currently not available to clinicians. To address this gap, our team developed a user-friendly, ultrathin wearable sEMG patch with cost-effective materials and fabrication techniques (M. K. Kim et al., 2019). This sEMG patch was specifically designed for recording sEMG activity of the suprahyoid muscles, and it will ultimately be integrated within a wireless sEMG system that will allow for both real-time biofeedback to patients and remote monitoring of patients by clinicians, allowing for swallowing telerehabilitation. In today's world and with lessons learned from the COVID-19 pandemic, efforts to develop optimal swallowing telerehabilitation devices are more urgent than ever.

As a first step, the purpose of this study was to validate this novel patch by comparing its performance with commercially available and widely used conventional sEMG (snap-on) electrodes in a sample of healthy older adults. We began this validation with a group of healthy older adults for several reasons. First, the prevalence of dysphagia increases in adults over 50 years old (Bhattacharyya, 2014);

thus, this study provided comparison data for future studies including patient populations. Second, as people age, skin loses its elasticity, resulting in structural and functional changes (Farage et al., 2008, 2013); therefore, examining the skin adherence of the sEMG patch in older adults is important. Testing healthy adults first is critical for initial evidence on device safety and signal quality.

Our first specific aim was to compare the signal quality of the new flexible sEMG patch (from here on, experimental patch) with the signal quality of commercially available sEMG electrodes (from here on, conventional electrodes). Signal quality parameters compared between the two included signal-to-noise ratio (SNR), baseline amplitude, as well as normalized mean amplitude during swallow trials, and burst duration of the smoothed sEMG signal during swallow trials. Higher values indicate better SNR, and lower values indicate better baseline amplitude values. As such, noninferiority tests (directional hypothesis) were used to compare the SNR and baseline amplitude values. We hypothesized (a) the average SNRs acquired using the experimental patch will not be inferior to SNRs acquired using the conventional electrodes and (b) the average baseline amplitude obtained at rest using the experimental patch will not be inferior to the same amplitude obtained using the conventional electrodes. In addition, given that there are no established norms for amplitude or duration of the sEMG signal during swallow trials, equivalency tests (nondirectional hypothesis) were used to compare the normalized mean amplitude values (i.e., area under the curve) of swallow trials and the burst duration of the smoothed sEMG signal during swallow trials. We hypothesized that both normalized mean amplitude during swallows and mean burst sEMG swallow duration obtained using conventional electrodes and the experimental patch will be equivalent.

Our second specific aim was to examine safety/adverse effects, efficiency of electrode placement, and satisfaction/comfort with the experimental patch as compared to conventional electrodes. In terms of safety, we did not expect to observe any adverse effects during or after using either type of electrodes. Furthermore, we hypothesized that (a) the time it takes to place the experimental patch will be shorter than the time it takes to place the conventional electrodes and (b) satisfaction expressed after using the experimental patch will be higher than the one reported using the conventional electrodes. Lastly, because body mass index (BMI) may affect sEMG signal quality, as a secondary exploratory aim, we sought to examine the effect of BMI on signal quality. We hypothesized that BMI will be correlated with signal-related factors.

Method

Participants

Participants were recruited from the Greater Lafayette–West Lafayette and Indianapolis areas between September 2018 and November 2018. Participants were included in the study if they were between the ages of 50 and 90 years and had no swallowing complaints or neurological disorders. Participants with impaired cognition identified on a standardized screening test (Montreal Cognitive Assessment; Nasreddine et al., 2005) and those who received a score of 3 or higher on the Eating Assessment Tool-10 (Belafsky et al., 2008) were excluded from the study. Exclusion criteria also included a known history of head and neck cancer, surgery, or radiation exposure to the head and neck area, gastrointestinal disease, or chronic respiratory disease. This study was approved by the institutional review board of our university. Written informed consent was obtained from all participants.

Design

A randomized crossover design was used. The order of the experimental conditions differed across groups. Group A participants completed the experimental protocol with the conventional electrodes first, and Group B participants completed the protocol with the experimental patch first. There was a 10-min rest period between the two experimental conditions (see Table 1).

Instrumentation

sEMG Recording

Experimental patch. The experimental patch (see Figure 1, patent pending) was specifically designed to conform to the curvilinear surface of the submental area. A detailed description of the main components of the patch is available in M. K. Kim et al. (2019). In short, the experimental patch was created using 13-μm-thick polyimide film and was cut in honeycomb layout to increase flexibility and stretchability (M. K. Kim et al., 2019). The mesh structure allowed breathability of the skin for prolonged use (M. K. Kim et al., 2019). The four electrodes (left and right differential pairs) were created from 9-μm-thick copper and electroplated with gold for biocompatibility. The interelectrode distance was 1.5 cm from edge to edge, and the electrodes are aligned with the fibers of the submental muscles (Konrad, 2005; J. B. Palmer, 1989; Stepp, 2012). Silbione (i.e., a biocompatible skin adhesive) was incorporated onto the experimental patch as an adhesive and passivation layer. A water-soluble body adhesive (i.e., JOBST It Stays! Roll-On Body Fixative) was also applied on the experimental patch 30 min prior to data collection to increase adhesion.

Conventional EMG electrodes. Commercially available, reusable, Ag/AgCI snap-on bipolar electrodes (Great Lakes NeuroTechnologies) were used as the comparison recording method. The diameter of the electrodes was 1.5 mm (Konrad, 2005; Stepp, 2012). These electrodes were chosen for comparison, because these snap-on bipolar electrodes are the most commonly used in prior swallowing research (e.g., Athukorala et al., 2014; Carnaby-Mann & Crary, 2010; Vaiman & Eviatar, 2009; Wheeler-Hegland et al., 2008) and in clinics that manage dysphagia.

Table 1. Study design.

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

Physiological Data Acquisition Devices

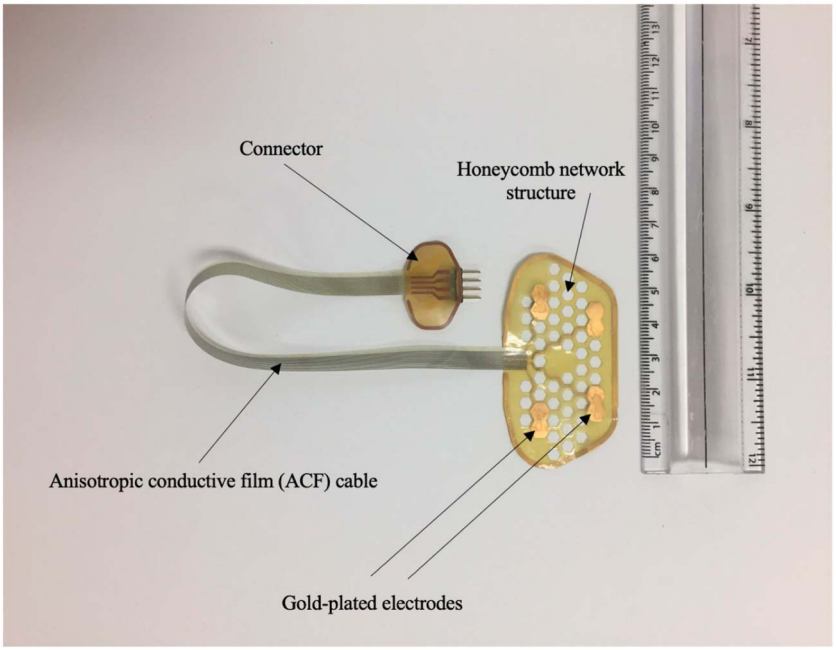
Changes in thoracic circumference during respiration and swallowing were recorded using a respiratory inductance plethysmography (RIP) band with piezoelectric sensors (Great Lakes NeuroTechnologies). Nasal respiratory flow was captured using a 2-ft nasal airflow cannula (Great Lakes NeuroTechnologies). The sEMG signals, as well as the RIP band and the nasal cannula, were coupled to the BioRadio (Great Lakes NeuroTechnologies), a peripheral wireless data acquisition device. BioRadio's data acquisition software BioCapture was used to digitally display the EMG signal, the respiratory phase, and the swallow apnea period. Output was displayed on a Dell laptop. The Iowa Oral Performance Instrument (IOPI Medical), a handheld pneumatic pressure sensor, was used to elicit the maximum voluntary contraction (MVC) of the submental muscles during sEMG (Stepp, 2012). EMG amplitude was normalized to MVC and was reported as %MVC (Smith et al., 1996).

Procedure

sEMG Data Acquisition

Data acquisition was completed by the first author (C. K.) who was trained extensively by her mentors (G. M. and C. H. L.) in the process and had completed sEMG data acquisition for more than 100 subjects prior to the initiation of this study. Surface EMG data acquisition followed the same protocol for both experimental conditions. The submental area was visually examined to assess the appearance of the skin at baseline. All male participants were clean-shaven. Skin surface was cleaned with alcohol wipes to reduce the skin–electrode impedance (Hermens & Freriks, 2017; Hermens et al., 2000). The elastic RIP band was placed around the rib cage under the axilla to record the movement of the rib cage. The nasal airflow cannula was placed in the nares to capture pressure-based airflow at rest and during swallowing (Hirst et al., 2002; J. Lee et al., 2011). The respiratory signals obtained from the RIP band and nasal airflow

Figure 1. Experimental patch (patent pending).



cannula were used as complementary tools to verify the inhalation/exhalation patterns and the swallow apnea period to guide in the identification of the swallows (J. Lee et al., 2011; Martin et al., 1994; Moreau-Gaudry et al., 2005; J. B. Palmer & Hiiemae, 2003).

The approximate location of the submental muscles was identified by palpating the submental area and asking participants to push their tongue against the roof of the mouth. The experimenter marked the location using a skin marker to ensure electrode placement was consistent. The conventional electrodes were affixed to the surface of the left and right submental muscles over the platysma and were aligned with the fibers of the submental muscles (see Figure 2b). Similarly, the experimental patch was placed on the surface of the left and right submental muscles over the platysma (see Figure 2a). To verify the location of the electrodes, the participants were asked to open their jaw wide and push hard against the roof of their mouth with their tongue to visualize the signal showing activation of the submental muscles. The electrodes were centered to the midline, and the interelectrode distance was approximately 1.5 cm from the medial edge of the left electrode to the medial edge of the right electrode (Hermens & Freriks, 2017; Hermens et al., 2000). This placement was chosen to measure the combined activations of the anterior belly of the digastric, mylohyoid, and geniohyoid muscles (P. M. Palmer et al., 1999). The ground electrode was placed on the mastoid process of the temporal bone. The time it takes to place the electrodes on the submental muscles was measured to examine the efficiency of electrode placement. The sEMG signal was pre-amplified with a gain of 1000 and fourth-order Butterworth bandpass filtered with low and high cutoff frequencies of 20 and 500 Hz, respectively (Stepp, 2012). A 60-Hz notch filter was used to eliminate powerline interference (Hermens et al., 2000). The sampling rate was 1000 Hz.

Participants were asked to sit as still as possible and breathe normally for 30 s to obtain a baseline, resting sEMG amplitude. Subsequently, a criterion-reference task comprising MVC of the submental muscles using the Iowa Oral Performance Instrument was completed (Konrad, 2005; Stepp, 2012). An air-filled bulb was placed on the anterior portion of the tongue. Participants pushed the air-filled bulb against the roof of their mouth with maximum effort. Three maximum anterior lingual pressure values (in kilopascals) that differed by less than 5% were obtained and recorded (Robbins et al., 2005). The average of these three trials was used to normalize the sEMG signal. After a short 2- to 3-min break, participants self-administered 5- and 10-ml thin liquid boluses from a medicine cup for a total of 10 trials. The order of swallow trials was randomized to control for an order effect or fatigue. The experimenter marked the approximate timing of the swallow by visually inspecting the thyroid notch and closely monitoring the raw sEMG and nasal signals.

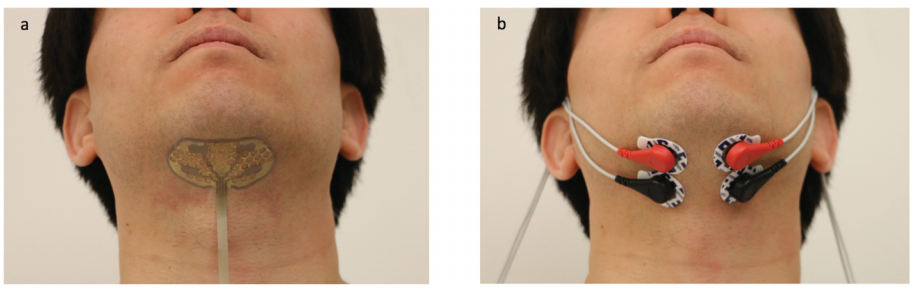
Post-Experiment

After the completion of the experimental protocol, a trained research assistant (RA), who was blinded to the type of electrode assessed, completed or assisted each participant to complete the Visual Inspection Form, the Pain Screening Form, and the Satisfaction/Comfort Questionnaire. The Visual Inspection Form and the Pain Screening Form were completed twice, once right after the removal of the electrodes and then 5 min after the removal of the electrodes. This delayed input was planned to investigate whether any allergic reactions or discomfort was occurring or still present 5 min after the experiment. The Satisfaction/Comfort Questionnaire was completed only once. The same procedure was followed after the removal of both types of electrodes.

The Visual Inspection Form. A Visual Inspection Form was designed to help the experimenters screen for potential adverse effects related to the skin. It consisted of three items related to the appearance of the skin (redness, skin irritation, and itchiness) and an open-ended question ("Do you have any other observations? If yes, please describe") to document any other potential skin-related adverse effects. Observations were rated on a binary scale (presence/absence of symptoms). The skin in the submental region was examined visually for any signs of adverse effects. Participants were also asked whether they experienced any discomfort or unpleasant sensations while the electrodes were attached to their skin. Their responses were recorded by the RA.

The Pain Screening Form. A Pain Screening Form was used to assess pain after removal of the electrodes. This quick screening tool included one polar question "Do you experience pain?" and the Wong–Baker FACES Pain Rating Scale, a well-known and validated 11-point pain severity scale (i.e., 0 = *no hurt*, 10 = *hurts worst*; E. J. Kim & Buschmann, 2006). If the pain level was rated as 1 or

Figure 2. Experimental patch (a) and conventional electromyography electrode montage (b).



higher, participants were asked to describe the pain. Responses were recorded by the RA.

Satisfaction/Comfort Questionnaire. Lastly, a five-item Satisfaction/Comfort Questionnaire was used to examine perceptions regarding level of comfort with the electrodes and general considerations regarding the use of sEMG electrodes in the future. Responses were rated on a 10-point scale (i.e., 1 = *extremely uncomfortable*, 10 = *extremely comfortable*). Participants were asked to rate their satisfaction and comfort level based on their experience with the electrodes following each experimental condition. Participants also had the opportunity to provide verbal feedback. Additional comments were documented by the RA.

Outcome Measures and Data Analyses

Comparisons between the experimental and conventional EMG recordings were made on signal-related factors (SNR, baseline amplitude, normalized mean amplitude of swallows, and burst sEMG swallow duration) and on safety and preclinical factors (safety/adverse effects, efficiency of electrode placement, and satisfaction/comfort level).

Signal-Related Factors

Signal-related factors were examined by investigating the signal characteristics at rest and during swallow trials and included SNR, baseline amplitude at rest, normalized mean amplitude of swallow trials, and the burst duration of the smoothed sEMG signal during swallow trials. EMG signals obtained from the left and right submental muscles were analyzed separately. Signal-related factors were analyzed by the first author (C. K.) using the sEMG data. Ten percent of the data were reanalyzed by the same rater and a different rater (last author, G. M.) to establish inter- and intrarater reliability. All EMG data were de-identified before the analysis, and analyzers were blinded to subject ID and electrode type.

SNR. The sEMG data were analyzed using a custom-written MATLAB script (MATLAB Inc.) that includes all necessary pre- and postprocessing steps (Smith et al., 1996; Stepp, 2012; Walsh & Smith, 2013). The raw sEMG signal was first visually inspected for contamination and motion artifacts. Any artifact that occurred during the rest periods was removed. The raw signal was filtered, demeaned, full-wave rectified, and smoothed. SNR was calculated using the following equation:

$$SNR = 20\log_{10}\frac{Signal}{Noise}. \quad (1)$$

Signal at rest. Baseline amplitude at rest was examined using the 30-s baseline measurement obtained at the beginning of the experiment. The average noise level was measured by calculating the mean amplitude of the signal for 5 s.

Signal during task performance. Two measures were derived from the sEMG signal during task performance: normalized mean amplitude (i.e., area under the curve) of swallow trials and the burst duration of the smoothed sEMG signal during swallow trials. First, each swallow trial was examined visually. Onset and offset of muscle activity were defined as a change greater than 2 *SD*s from the baseline of the sEMG signal and were selected using the custom-written MATLAB script. An algorithm searched for a change in baseline that was greater than 2 *SD*s within the user-identified window and marked the onset and offset of sEMG activity. If the algorithm did not identify the onset and offset of the swallow trial (most likely due to noise), these were marked manually. This, however, was infrequent and occurred in approximately 15% of trials.

Due to well-known intersubject variability in EMG recordings, for each participant, the EMG amplitude was normalized to the amplitude of MVC. This allowed comparisons across conditions and participants to examine the normalized mean amplitude of the swallow trials. sEMG amplitudes were reported as %MVC.

Safety and Preclinical Factors

Safety/adverse effects. Safety and adverse effects were defined as the presence of any adverse skin irritations or pain and were examined by the Visual Inspection and Pain Screening Forms. Data were collected by a blinded RA and were de-identified, so that the researcher who completed the statistical analysis was blinded to electrode type during analysis.

Efficiency of electrode placement. Efficiency of electrode placement was operationally defined as the length of time it takes to affix the electrodes on the surface of the submental muscles. It was measured from the time the electrodes were picked up by the researcher to the time when all electrodes were coupled to the BioRadio. It was measured in minutes:seconds using a digital timer/stopwatch.

Satisfaction/comfort level. Satisfaction/comfort was defined as the perceived level of satisfaction with the electrodes and was examined using the Satisfaction/Comfort Questionnaire detailed above. Once more, data were de-identified, and the researcher who completed the statistical analysis was blinded to the type of electrode used.

Statistical Analyses

The statistical analyses were carried out using SAS Version 9.4 (SAS Institute). This study was designed to have at least 80% power to detect a difference in the primary variables of interest, that is, SNR, baseline amplitude, and normalized mean amplitude of swallow trials. The sample size was determined via a power analysis based on pilot results. Alpha level was set to .025 to correct for multiple comparisons. Data were visualized using line graphs. Quantile–quantile plots and the Shapiro–Wilk test were also used to assess normality. Intra- and interrater reliability were assessed through intraclass correlation coefficients. Margins for these tests were calculated using our preliminary data acquired with the conventional electrodes, which were considered as the current gold standard. Descriptive statistics were

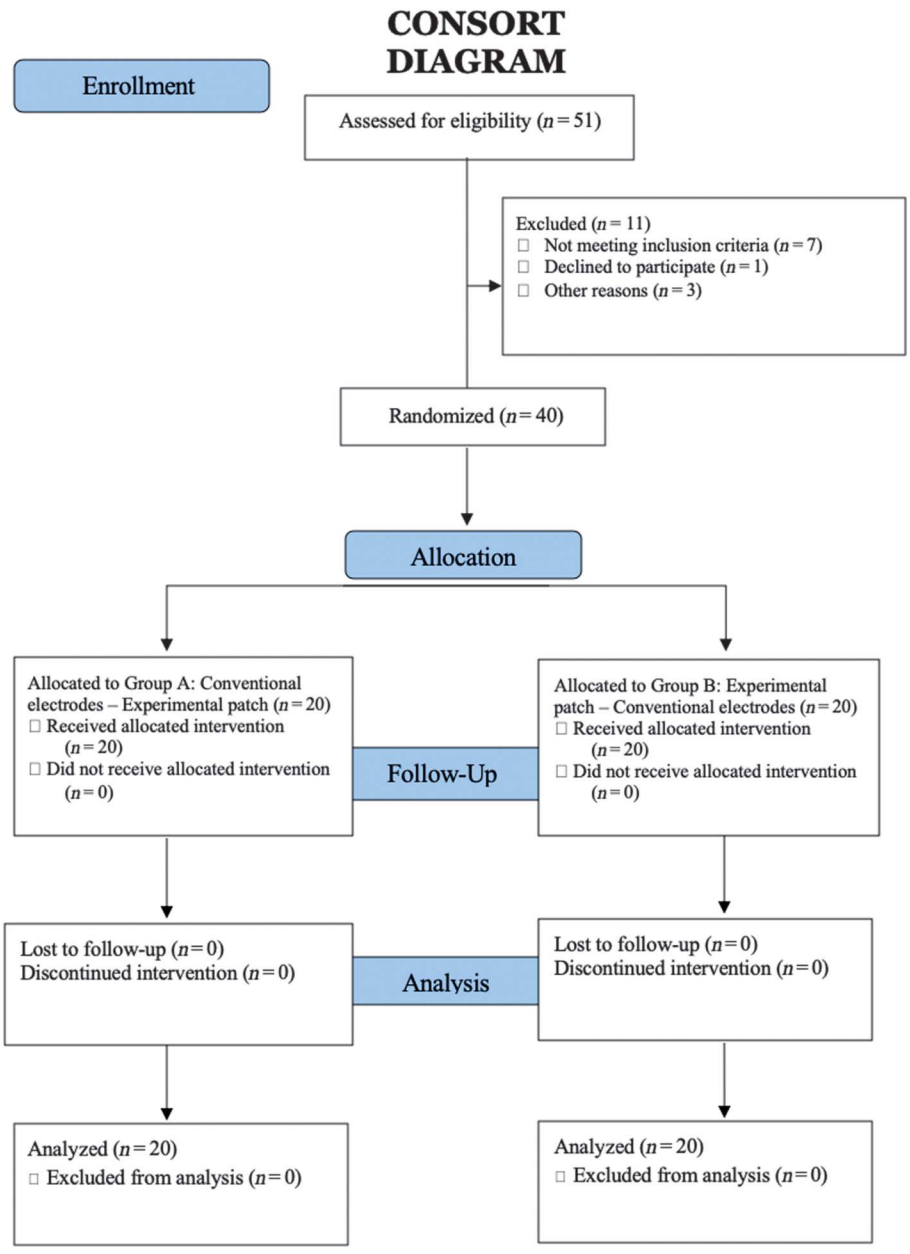
used to report safety and adverse effects. Paired *t* tests were used to test for differences in efficiency of electrode placement and satisfaction/comfort level. Effect size was computed using Cohen's *d*.

Results

Participants

The CONSORT flow diagram is shown in Figure 3. Out of the 51 individuals screened for this study, 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, 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, 40 healthy adults ($M_{age} \pm SD$, 67.5 ± 7.85) participated in this study. The study group included 24 men and 16 women. All participants presented with normal swallowing abilities and cognition. Participants' BMI were also recorded, because BMI may affect

Figure 3. Consort diagram.



signal quality. Demographics and participant characteristics are provided in Table 2.

Results of the Experiment

Reliability

Reliability analysis was completed for 10% of the sample data for the primary variables of interest (i.e., SNR, baseline amplitude, and normalized mean amplitude of the swallow trials). The intraclass correlation coefficient for inter- and intrarater agreement was excellent for all variables and ranged from .88 to .99 and from .98 to .99, respectively (see Supplemental Material S1).

Signal-Related Factors

The first aim of the study was to compare signal-quality parameters between the experimental patch and the conventional electrodes in our sample. Results of these comparisons are outlined below.

SNR. The mean SNR of the sEMG signal acquired with the experimental patch (M_{left} = 20.64 and M_{right} = 20.31) was higher than the mean SNR of the signal acquired with the conventional electrodes (M_{left} = 19.44 and M_{right} = 19.65; see Figure 4). Noninferiority tests indicated that the mean SNR of the experimental patch was not inferior to the SNR of the conventional electrodes for either the left, $t(39) = 3.95$, $p < .0002$, or the right, $t(39) = 2.66$, $p < .0056$, submental EMG activity (see Supplemental Material S2).

Furthermore, we found a small-to-moderate negative correlation between SNR and BMI for both electrode types. The SNR of the experimental patch was negatively correlated with BMI ($r = -.33$ [$p = .032$] and $r = -.37$ [$p = .016$] for the left and right electrodes, respectively). The SNR of the conventional electrodes was also negatively correlated with BMI ($r = -.51$ [$p = .001$] and $r = -.34$ [$p = .016$] for the left and right electrodes, respectively).

Signal at rest. To compare the baseline amplitude values obtained with the two types of electrodes, we calculated the mean differences. The difference was not normally distributed and was transformed using the Box–Cox transformation. Mean baseline amplitude (μV) of the sEMG signal at rest acquired with the experimental patch (M_{left} = 1.33 and M_{right} = 1.36) was slightly lower than the mean baseline amplitude acquired with the conventional electrodes (M_{left} = 1.66 and M_{right} = 1.7; see Figure 5). The noninferiority margin was also shifted using the same transformation to match the scale of the transformed data. Once more, noninferiority tests indicated that the mean baseline amplitude of the experimental patch was not inferior to the mean baseline amplitude of the conventional electrodes for either the left, $t(39) = -7.72$, $p < .0001$, or the right, $t(39) = -7.43$, $p < .0001$, channels (see Supplemental Material S2).

Signal during task performance. A total of 809 swallows were analyzed to compare the normalized mean amplitude and the sEMG burst durations between the two electrodes ($n_{experimental}$ = 406 and $n_{conventional}$ = 403). The numbers of swallows analyzed for each electrode type is slightly different because a few swallows were not analyzable due to movement artifact.

Table 2. Participant demographics and characteristics.

Variable	Participants (*N* = 40)	
	n	%
Sex		
Male	24	60
Female	16	40
Age (y)		
M ± *SD*	67.5 ± 7.85	
Range	53–85	
EAT-10		
M ± *SD*	0.35 ± 0.62	
Range	0–2	
MoCA		
M ± *SD*	28.1 ± 1.21	
Range	26–30	
BMI		
Underweight	0	0
Healthy	13	32.5
Overweight	14	35
Obese	13	32.5

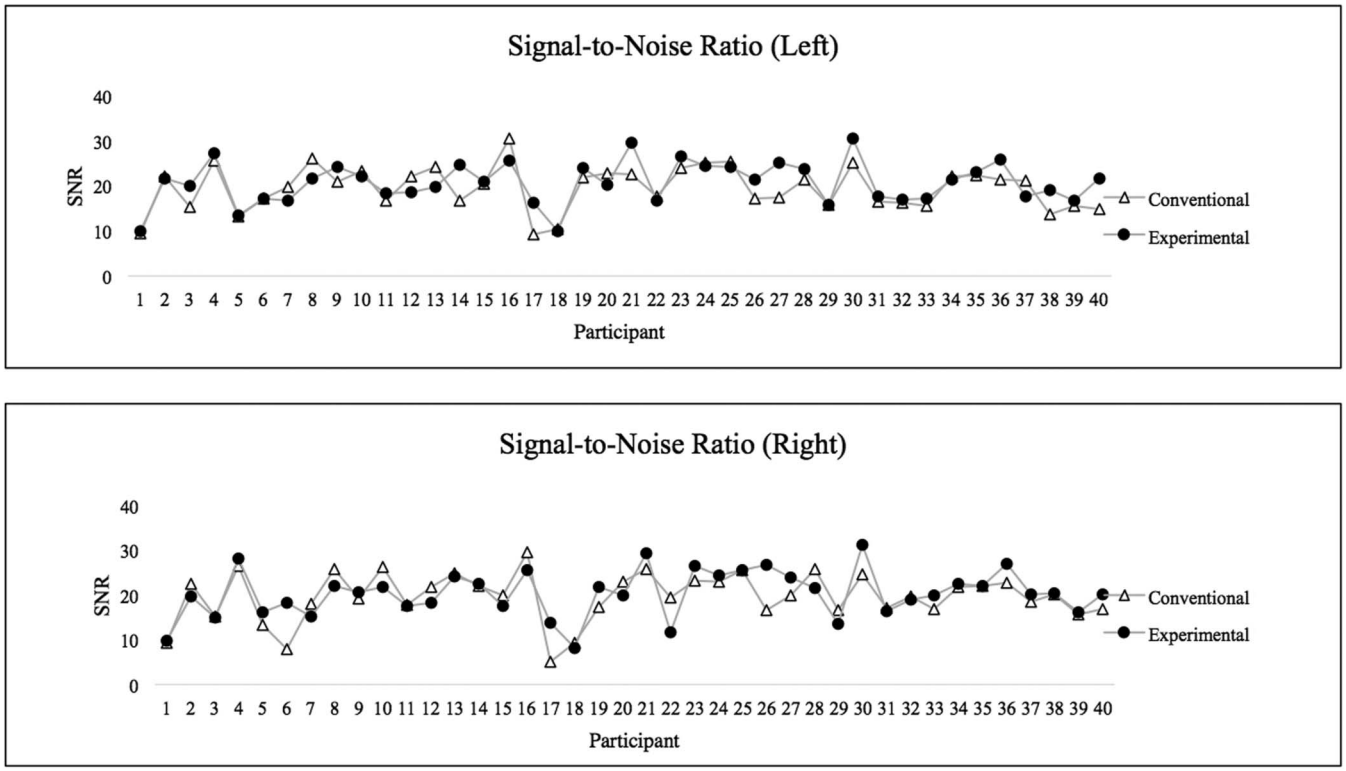
Note. y = year; EAT-10 = Eating Assessment Tool-10; MoCA = Montreal Cognitive Assessment; BMI = body mass index.

Normalized Mean Amplitude During Swallow Trials

Amplitude: 5-ml water trials. Means of individual normalized amplitude values for each participant for the 5-ml water trials are shown in Figure 6. The mean differences between the normalized amplitude values acquired with the experimental patch (M_{left} = 11.57% and M_{right} = 12.03%) and the conventional electrodes (M_{left} = 12.15% and M_{right} = 13.04%) were within the equivalence margin of ± 3.1 for the left and right channels (see Supplemental Material S3). Specifically, 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 $p < .0001$, indicating equivalent mean amplitude values for the experimental patch and conventional electrodes 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 $p = .0224$. Thus, the normalized amplitude values for the right channel on the 5-ml water trials were deemed statistically equivalent as well.

Amplitude: 10-ml water trials. Means of individual normalized amplitude values for each participant for the 10-ml trials are shown in Figure 7. The mean differences between the normalized amplitude values acquired with the experimental patch (M_{left} = 11.9% and M_{right} = 12.83%) and conventional electrodes (M_{left} = 12.54% and M_{right} = 13.94%) were within the equivalence margin of ± 4.68 for the left and right channels (see Supplemental Material S3). Once more, results indicated that the normalized mean amplitude values obtained using both types of electrodes

Figure 4. Signal-to-noise ratio (SNR) for each participant (left and right).



were equivalent/comparable for both the left (t_u = 5.49 and t_l = −7.20; overall $p < .0001$) and right channels (t_u = 3.36 and t_l = −5.28; overall $p < .0012$).

Burst Duration of sEMG Signal During Swallow Trials

Duration: 5-ml water trials. The mean durations of sEMG burst for each participant during 5-ml water trials are shown in Figure 8. The mean differences between the sEMG burst duration with the experimental patch (M_{left} = 1.31 s and M_{right} = 1.31 s) and conventional electrodes (M_{left} = 1.27 s and M_{right} = 1.25 s) were also within the equivalence margin of ± 0.35 for both channels. Specifically, the mean durations of sEMG burst acquired using both types of electrodes were equivalent/comparable to each other for both the left (t_u = 9.48 and t_l = −7.25; overall $p < .0001$) and right channels (t_u = 9.03 and t_l = −6.35; overall $p < .0001$). Supplemental Material S4 summarizes the results of the mean duration of sEMG burst values.

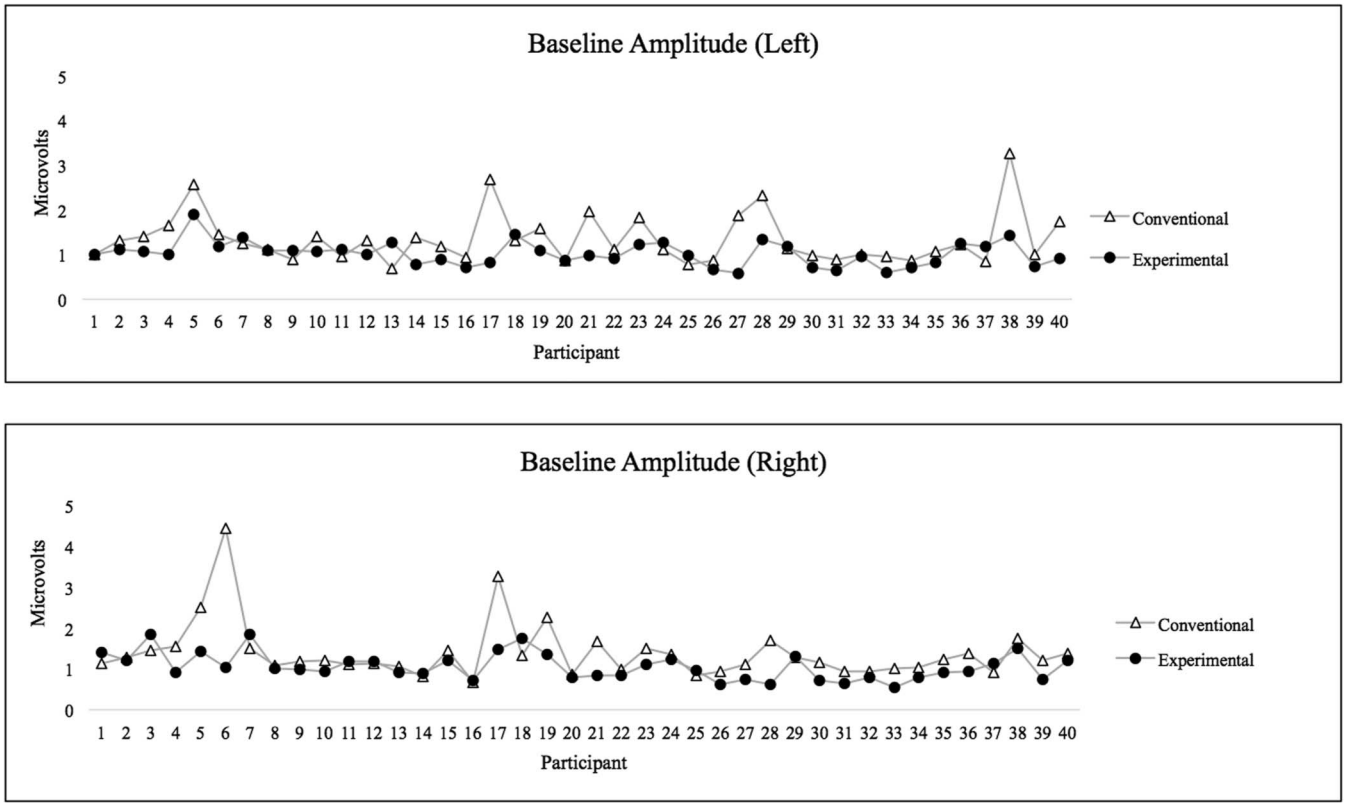
Duration: 10-ml water trials. Finally, the mean durations of sEMG burst for each participant during 10-ml water trials are shown in Figure 9. The mean differences between the duration of sEMG burst with the experimental patch (M_{left} = 1.34 s and M_{right} = 1.33 s) and conventional electrodes (M_{left} = 1.31 s and M_{right} = 1.32 s) were within the equivalence margin of ± 0.42 for the left and right channels. Once more, results indicated that the mean durations of sEMG burst for the 10-ml water trials obtained using both types of electrodes were equivalent/comparable to each other for both the left (t_u = 6.75 and t_l = −6.11; overall $p < .0001$) and right channels (t_u = 6.58 and t_l = −6.23; overall $p < .0001$). Supplemental Material S4 summarizes the results of the mean duration of sEMG burst values.

Safety and Preclinical Factors

The second aim of the study was to determine the comparative safety and efficiency of the two electrode types and the satisfaction/comfort level of participants. Results are outlined below.

Safety and adverse effects. As seen in Table 3, redness and skin irritation were not observed or reported either immediately or 5 min after the removal of the experimental patch. However, redness was observed after the immediate removal of the conventional electrodes in three participants. In two of these participants, mild redness was still present 5 min post removal. Skin irritation was reported by one of the participants after the removal of the conventional electrodes; however, no concerns were reported after 5 min. Itchiness was reported by one participant after the immediate removal of the experimental patch and by two participants 5 min post removal of the conventional electrodes. No pain was reported immediately or 5 min after the experimental patch was removed. However, two participants

Figure 5. Resting baseline amplitude values for each participant (left and right).



reported experiencing mild pain after the removal of the conventional electrodes, one right after and one 5 min later. Both participants rated their pain level as 1 (i.e., *extremely mild pain*) on a 10-point scale. Overall, the frequency of observed adverse effects was slightly higher with the conventional electrodes.

Efficiency of electrode placement. The mean duration of the experimental patch's affixation was 2 min 44 s (36.8; range: 1:23–4:27 [minutes:seconds]), whereas the mean duration of the conventional electrodes' affixation was 2 min 33 s (31.8; range: 1:43–4:22). The difference was typically below 60 s. Contrary to our hypothesis, this difference was not statistically significant, $t(39) = 1.87$, $p = .9657$.

Satisfaction/comfort level. High satisfaction/comfort was reported with both electrode types based on the Satisfaction/Comfort Survey (see Table 4). Satisfaction/comfort level was significantly higher with the experimental patch (48.62/50) compared to the conventional electrodes (48.06/50), $t(39) = 1.71$, $p = .0476$, albeit with a relatively small effect size ($d = 0.226$).

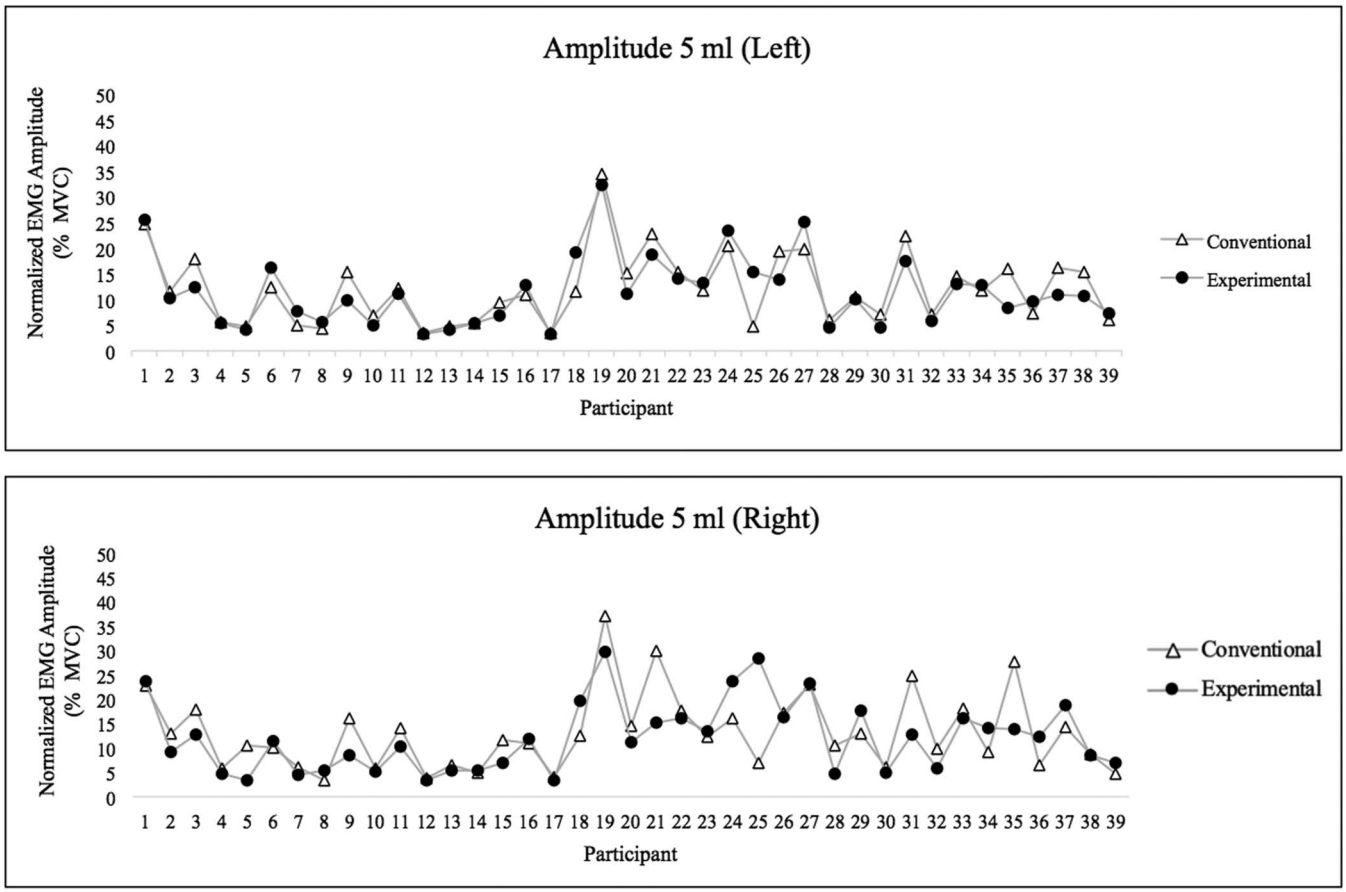
Discussion

The purpose of this study was to validate a novel flexible skin-conforming sEMG patch specifically designed to record muscle activity from the submental area, against commercially available and widely used conventional snap-on sEMG electrodes. Specifically, we completed a randomized crossover design study to compare the two EMG recording applications in signal-related parameters, and in terms of safety and preclinical variables.

Signal-Related Factors

In terms of signal quality, our results show that all signal-related factors were comparable between the two electrode types. First, SNR and baseline amplitude values, which both signify the inherent quality of EMG recordings, were comparable (Kamen & Gabriel, 2010; Konrad, 2005). These results can be explained by several factors. First, two components that contribute to high-fidelity sEMG recordings are electrode type and placement. The Surface Electromyography for the Non-Invasive Assessment of Muscles recommends using bipolar or differential pair electrodes that are proportional in size to the muscles of interest (Hermens & Freriks, 2017; Hermens et al., 2000). In this study, both electrode types were used in a bipolar configuration to selectively amplify the difference in the signal from the muscle action potentials while suppressing the common signal. This is an important recommendation that is not always followed in clinical practice. In terms of placement, consistent

Figure 6. Normalized mean amplitude values during 5-ml swallow trials for each participant (left and right). EMG = electromyography; MVC = maximum voluntary contraction.

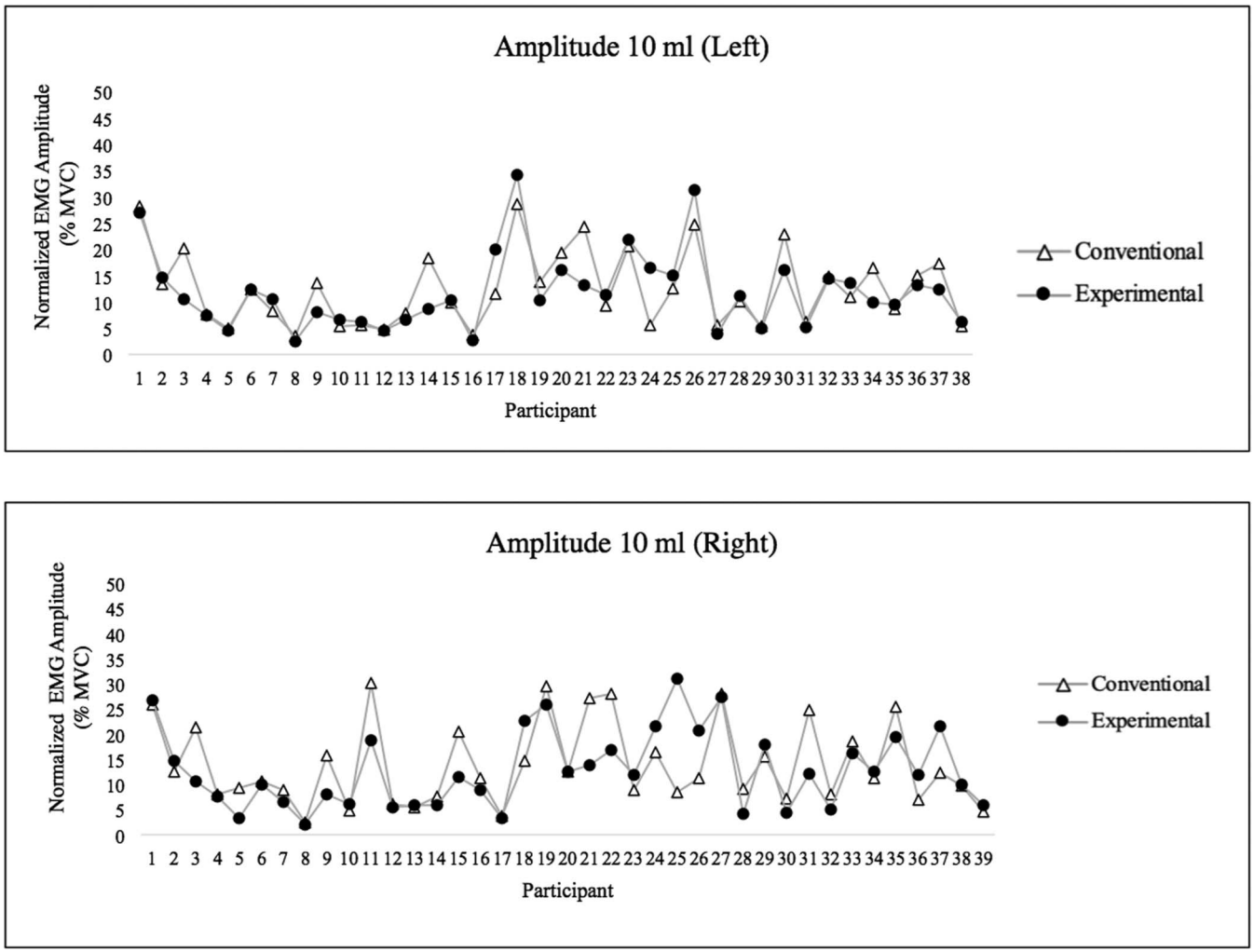


placement results in more reliable amplitude values, a smaller common-mode rejection ratio, and better SNR (Hermens & Freriks, 2017). Our ultrathin patch includes electrodes with 1.5-cm electrode distance that are specifically designed to record muscle activity of submental muscles and to conform to the curvilinear anatomy of the area under the chin. This produces excellent and conformal electrode-to-skin contact and consistent sensor placement (M. K. Kim et al., 2019). Electrodes' placement locations were also overall consistent with prior EMG studies that have investigated swallowing muscle activity. However, the majority of these studies report electrodes' placement on the submental region lateral to each side of the midline without specifying interelectrode distance, which at times varied from 1 to 2 cm (Crary et al., 2006; P. M. Palmer et al., 1999; Vaiman & Eviatar, 2009). We also ensured good skin-to-electrode contact by cleaning the skin using 70% alcohol wipes (Huckabee et al., 2012; P. M. Palmer et al., 1999; Reimers-Neils et al., 1994; Vaiman & Eviatar, 2009; Wheeler et al., 2007).

Another component that contributes to high-fidelity sEMG recordings includes data acquisition parameters of the recording equipment. We used a bandpass filter with bandwidth of 20–500 Hz as well as a 60-Hz notch filter. The spectrum of surface-recorded EMG is typically concentrated between 0 and 400 Hz (Hermens & Freriks, 2017). The cutoff frequencies allow the important sEMG energy to be captured while removing lower frequencies (i.e., movement artifacts) and higher frequencies (e.g., equipment noise; C. J. De Luca, 2002; G. De Luca, 2003; Stepp, 2012). It is difficult to completely eliminate movement artifacts during swallow trials, but we decreased their influence to the best of our ability. Specifically, we added filters and asked participants to stay as still as possible before, during, and right after the swallow trials. If a significant movement artifact was observed at any point, we disregarded that trial. Additionally, our sampling rate was set to 1000 Hz well above the Nyquist frequency for sEMG. Our data acquisition parameters clearly resulted in high-quality signals and allowed us to make valid comparisons between the two systems of interest.

Although the baseline amplitude values were comparable for the majority of the participants, in some participants, larger differences in baseline amplitude values were observed. These could be partly explained by issues related to electrode-to-skin contact, as there were a few instances where the electrodes started coming off and required the application of

Figure 7. Normalized mean amplitude values during 10-ml swallow trials for each participant (left and right). EMG = electromyography; MVC = maximum voluntary contraction.



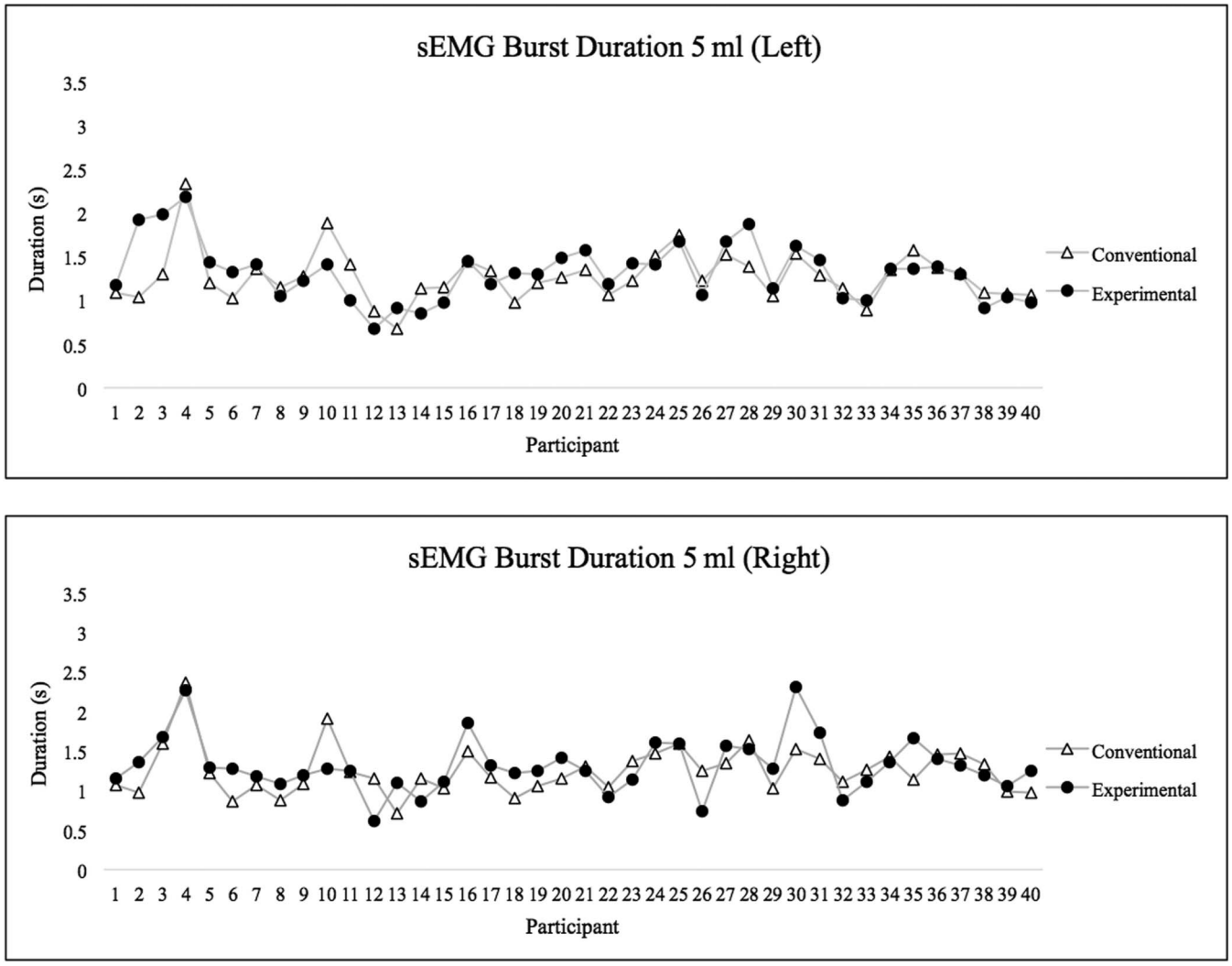
more adhesive. Impedance changes secondary to decreased skin-to-electrode contact could explain these differences.

Signal During Task Performance

Our findings revealed that normalized amplitude and burst duration values obtained using both types of EMG applications were equivalent across swallows. This is in agreement with a prior study that compared epidermal electrodes with conventional snap-on sEMG electrodes and showed that the mean amplitude values were similar for both systems (i.e., M = .433 vs. .414 mV, respectively) across different swallows (Constantinescu et al., 2016). However, several limitations of this work make any direct comparisons with the current study challenging. First, the boluses used in the Constantinescu et al. (2016) study were not standardized. Instead, participants were asked to take a small sip of water or swallow their own 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 signal quality comparisons between EMG applications. In addition, in the Constantinescu et al. (2016) study, the investigators compared raw and nonnormalized amplitude values, which do not allow for valid comparisons between subjects (Mathiassen et al., 1995). Because sEMG signal differs between individuals and within the same individual over different sessions, normalization of the amplitude values is necessary for valid intersubject comparisons to be made (Hermens & Freriks, 2017; Hermens et al., 2000).

The sEMG burst swallow duration was also comparable between the two electrode types and similar to values reported in prior literature (Crary et al., 2006; Hrycyshyn & Basmajian, 1972; Perlman et al., 1999). However, to our knowledge, there have been no studies that have compared this duration between different sEMG electrode

Figure 8. Mean duration of surface electromyography (sEMG) burst during 5-ml swallow trials for each participant (left and right).



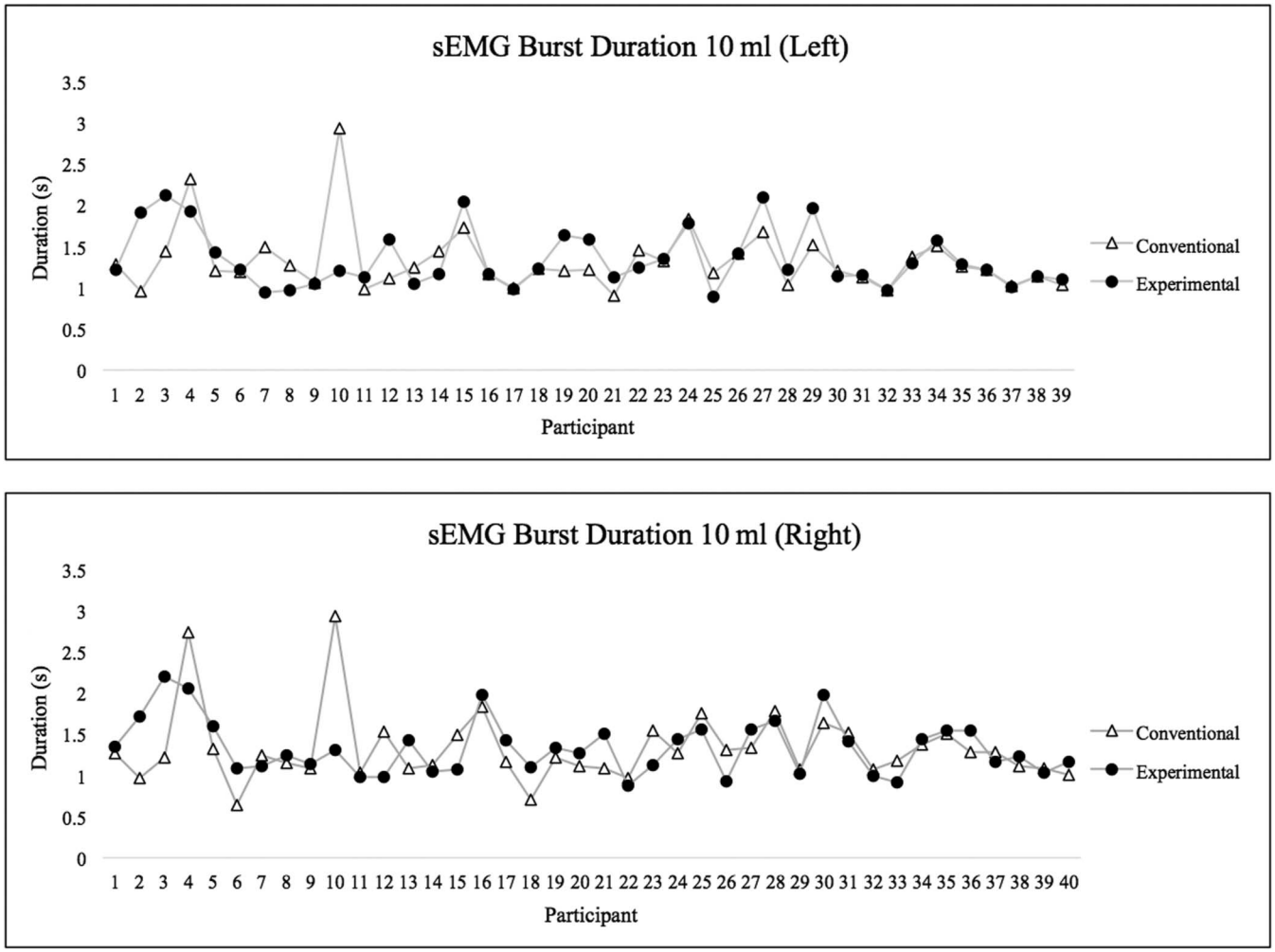
types. Previous studies that have compared duration of sEMG burst using conventional electrodes have shown a bolus volume effect, that is, the duration of sEMG burst increases with larger boluses (Hrycyshyn & Basmajian, 1972; Perlman et al., 1999). Similarly, in this study, the mean duration of sEMG burst during the 10-ml swallow trials was longer than the mean duration of sEMG burst during the 5-ml swallow trials, also supporting a bolus volume effect (Crary et al., 2006; Hrycyshyn & Basmajian, 1972; Perlman et al., 1999). In addition, the boluses were measured precisely; participants were instructed to consume the full amount in one swallow and 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.

An additional finding included that there was a moderate negative correlation between SNR and BMI for both electrodes. This indicates that, as participants' BMI increased, SNR for both electrode types decreased. Subcutaneous tissue thickness contributes to interindividual variability in sEMG signal and should be considered as a contributing factor in this finding (Day, 2002). It has to be emphasized, however, that despite this finding, BMI was not associated with any other signal-related parameters and the detectability of the signal was not affected.

Safety and Preclinical Factors

Although examining signal quality and accuracy is highly important for validation, it is also critical to examine safety and efficiency of the electrodes for clinical translation. Therefore, our second aim was to compare safety and efficiency parameters and satisfaction between the two electrode types for our sample of healthy older adults. As expected, no significant safety concerns were noted with

Figure 9. Mean duration of surface electromyography (sEMG) burst during 10-ml swallow trials for each participant (left and right).



either type of electrodes tested. Some mild adverse effects, such as mild itchiness and redness of the skin, were slightly more frequently present after the removal of the conventional electrodes. Similarly, mild pain was reported by two participants only after the removal of the conventional electrodes. No pain was reported at any time in association with the use of the experimental patch. These findings are in agreement with previous studies that have shown that using thin biocompatible wearable electrodes is typically less irritating to the skin (Kwak et al., 2011; Pang et al., 2013). This is because they allow for more air permeability and ventilation of moisture and residue from the skin than traditional electrodes (Kwak et al., 2011; Pang et al., 2013). In fact, the use of conventional electrodes required four stickers, which enabled strong adhesion. Although both electrode types were adhering to the skin well, at the end of the experiment, it was more difficult to remove the conventional electrodes compared to the experimental patch,

Table 3. Occurrence of safety and adverse effects.

		Experimental patch		Conventional electrodes	
Assessment measure	**Adverse effects**	**Immediately**	**5 min after**	**Immediately**	**5 min after**
Visual Inspection Form	Redness	0	0	3	2
	Skin irritation	0	0	1	0
	Itchiness	1	0	0	2
Pain Screening Form	Pain	0	0	1	1 (new)

Table 4. Satisfaction/comfort survey.

Satisfaction/comfort survey
1. I was *comfortable* during skin preparation (e.g., cleaning with alcohol wipes).
2. I was *comfortable* while the experimenter placed the electrodes on my skin.
3. I was *comfortable* while the electrodes were attached to my skin.
4. I was *comfortable* when the electrodes were removed from my skin.
5. I would use the electrodes again in the future.

which may also explain the increased frequency of skin irritation with these commercial electrodes.

Contrary to our hypothesis, we did not find any statistically significant differences between the two electrodes based on efficiency of placement, indicating that, at this time, both electrode types require similar time for placement on the subject/patient. Despite the fact that our experimental patch is one piece, at this time, it requires application of body adhesive to increase skin–electrode contact. This likely explains the similar timeline for placement of both electrode types. Specifically, the time difference to place both electrode types was typically less than 1 min. This difference is also likely not clinically significant. In addition, we did not observe a training effect in the efficiency of electrode placement (i.e., the placement did not become faster overall as the study progressed). The researcher who collected the data had used both the conventional and experimental electrodes with many prior subjects before the initiation of the study. As such, any training effect could have occurred before the initiation of this validation study.

The only statistically significant difference between the two electrode types (albeit with a small effect size, $d = 0.226$) was found when comparing satisfaction levels. Specifically, participants consistently rated their satisfaction level with the experimental patch higher than their satisfaction level with the conventional electrodes. This higher satisfaction rate is in agreement with prior studies reporting overall high user satisfaction with flexible, skin-conforming devices (e.g., Botella et al., 2016; Fensli et al., 2010). Furthermore, studies that have examined patient satisfaction with the use of telehealth in the treatment of dysphagia have consistently reported high satisfaction rates and preference toward telehealth versus in-person practices (Kantarcigil & Malandraki, 2017; Malandraki & Kantarcigil, 2017; Malandraki et al., 2014; Sharma et al., 2013). Several participants also offered some interesting qualitative feedback while using the experimental patch, such as "These were lighter than the other ones" and "It is hardly noticeable" as well as further expressing high satisfaction with the newly developed wearable sEMG patch.

Our study has some limitations. First, stable adhesion is one of the challenges of the experimental patch version used in this study. Specifically, there were several instances where the patch started coming off in the middle of data collection and required more adhesive to be applied. Additionally, tearing of the patch was observed in seven out of 40 trials, when the experimental patch was being removed from the subject's skin at the end of the session. Since this study was completed, a newer version of the patch has been developed that already has stronger adhesion capabilities and increased durability (M. K. Kim et al., 2019). Future studies should also include neck circumference or tissue elasticity measurements to examine how these factors influence skin adhesion and signal quality. Second, this study was conducted in healthy older adults. It will be important to continue testing further iterations of the experimental patch with older adults and other age groups until it is optimized. It would also be beneficial to receive feedback from clinicians during this process. Since clinicians will be the main individuals who will train patients on how to use the electrodes, their input on electrode placement, data visualization, and acquisition would be invaluable (Leonard-Barton & Sinha, 1993). Upon optimization, the next step would be to examine the utility of the experimental patch on patients with dysphagia through randomized controlled trials. In these future trials, we plan to examine whether patients can be trained in independent electrode placement for telehealth applications and patient adherence with different types of electrodes.

Clinical Implications

Currently, dysphagia clinicians 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. Furthermore, with lessons learned from the current COVID-19 pandemic, efforts to develop optimal swallowing telerehabilitation devices are more urgent than ever. Upon optimization, the experimental electrode patch validated in this study will be examined as a tool for remote provision of swallowing treatment. 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 and telerehabilitation.

Conclusions

We validated a newly developed flexible, skin-conforming, and ultrathin sEMG patch specifically designed to record submental muscle activity during swallowing. Our findings suggest that this configuration of electrodes embedded in a flexible patch conforms well to the submental area using an external adhesive and allows for high-quality recording of the electromyographic signal. In addition, we showed that their technical performance (i.e., signal-related parameters) is similar to the performance of widely used conventional snap-on sEMG electrodes. Results of the safety and preclinical factor comparisons further supported that the new sEMG patch is safe to use and healthy older adults are satisfied with it. This study is the first in a series of studies that

will be conducted to ensure the validity and effectiveness of this newly designed sEMG patch before its use in the management and telemanagement of swallowing disorders is examined.

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