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Research Note

Lingual Exercise in Older Veterans With Dysphagia: A Pilot Investigation of Patient Adherence

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Purpose: Adherence is a concern in dysphagia management. Poor adherence with recommendations can negatively affect treatment efficacy and patient outcomes. For exercise-based therapies, low adherence can alter the dose of exercise delivered to the muscle, which can diminish impact of exercise. It has been established that low adherence is a problem in dysphagia treatments; however, relationships among levels of adherence and outcomes from exercise-based interventions have not been explored.
Method: In this retrospective pilot study, data were collected from a multicenter clinical demonstration program in the Veterans Affairs hospital system to examine the relationships between patient adherence with a device-facilitated lingual exercise regimen. Outcomes were compared pre- and posttreatment using a paired *t* test or Wilcoxon matched-pairs signed-ranks test, and relationships among adherence and outcome measures were evaluated using Pearson or Spearman rank correlation coefficients, as appropriate.
Results: Patient adherence was evenly distributed across participants: Adherence at the front sensor was 59.3% (*SD* = 28.2), ranging from 5.5% to 95.8%; the back sensor adherence was 55.9% (*SD* = 29.8), ranging from 1.1% to 97.2%. Maximum isometric pressure (MIP) generation, at both the front and back sensors, was increased from pre- to posttreatment ($p < .0001$, front; $p = .008$, back). Functional Oral Intake Scale (FOIS) scores were also significantly improved at the posttreatment time point as compared to baseline ($p = .005$). However, there were no significant correlations among adherence and outcome measures (front sensor adherence vs. ΔMIP, $r = -.161$, $p = .342$; back sensor adherence vs. ΔMIP, $r = .002$, $p = .991$; front sensor adherence vs. ΔFOIS, $r = -.183$, $p = .279$; back sensor adherence vs. ΔFOIS, $r = -.160$, $p = .399$).
Conclusions: These findings suggest that patient adherence with this lingual exercise program was not related to the increases in lingual pressure generation or improvement in functional oral intake observed in this cohort. These preliminary findings suggest the need for future, prospective, controlled, and randomized clinical trials to further investigate patient adherence with a lingual exercise program and related impacts of adherence on exercise dose and swallowing-related outcomes.

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Individuals under the care of a health provider are frequently asked to adhere to medical recommendations that can include medication routines or behavioral health changes, such as modifying diet or following an exercise regimen. Defined simply, adherence is the amount to which an individual alters behavior to accommodate the medical provider's advice (McNabb, 1997). Adherence to exercise protocols specifically is essential for therapy efficacy (Belza et al., 2002; Rutten et al., 2016). Without high levels of adherence to a specific exercise regimen, the prescribed dose of exercise cannot be achieved.

Poor adherence is evident within dysphagia management. Recent evidence indicates that patient adherence with dysphagia-specific recommendations is low, with a wide range of reported adherence for exercise-based interventions specifically (Krekeler et al., 2017). In several investigations of

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exercise-based interventions, "full or high adherence" with the exercise protocol was achieved by less than 30% of participants (Cnossen et al., 2014; Hutcheson et al., 2013; Shinn et al., 2013). Given these low rates of adherence, it is more than likely that patients are not receiving exercise doses as prescribed. Without high levels of adherence to a specific exercise regimen, the prescribed dose of exercise cannot be achieved, which can reduce impact of the treatment on muscular change (Peterson et al., 2005).

Despite the implications of adherence in exercise-based therapies, very few studies in dysphagia treatment have considered level of adherence with the exercise regimen when interpreting exercise-specific outcomes (Krekeler et al., 2018). Not fully accounting for dosing administration during an exercise-based study can lead to over- or underinterpretation of findings. This misinterpretation can ultimately result in statistical error, known as "compliance bias," which is a serious concern in accurate interpretation of data (Feinstein, 1974). While there is a risk of compliance bias within exercise-based dysphagia literature, the relationships between adherence, exercise dose, and outcomes have yet to be elucidated. Given that exercise dose is greatly influenced by patient adherence (Latham et al., 2004; Ohkawara et al., 2007; Peterson et al., 2005; Radaelli et al., 2015; Rhea et al., 2003), it is important to understand how patient adherence impacts outcomes measured in a clinical dysphagia treatment program, such as lingual exercise.

Lingual exercise is frequently used clinically to address concerns of lingual weakness that may underlie swallowing dysfunction (Keskool et al., 2018; Steele & Cichero, 2014). Lingual exercise has been shown to result in increased lingual pressure generation and a decrease in pharyngeal residue across patient populations (Kim et al., 2017; Lazarus et al., 2014; Moon et al., 2018; Namiki et al., 2019; Oh, 2015; H.-S. Park et al., 2019; J.-S. Park et al., 2019, 2015; T. Park & Kim, 2016; Robbins et al., 2005, 2007; Rogus-Pulia et al., 2016; Steele et al., 2016; Van den Steen et al., 2018, 2019; Yano et al., 2019). Various paradigms with different prescribed doses of lingual exercise have been reported in the literature (Krekeler, Rowe, & Connor, 2020). For example, when looking at exercise frequency, there is a large range of reported times per day and days per week lingual exercise was performed, from as often as 5 times per day, 7 days per week to 1 time per day, 2–3 days per week (Krekeler, Rowe, & Connor, 2020). Furthermore, other dosing components, such as intensity, are not always well described (Krekeler, Rowe, & Connor, 2020). Some investigations using a low-tech approach (e.g., lingual press to roof of mouth) describe length of hold for a lingual press (J.-S. Park et al., 2019), while others give scripted instructions to "push the tongue firmly onto the palate" without defining length of hold (H.-S. Park et al., 2019). Even with device-facilitated approaches to lingual exercise, some have used a progressive strengthening approach where a percentage of maximum pressure was increased throughout the duration of the intervention (Oh, 2015; Yano et al., 2019), while others involved trained consistently at the same intensity (J.-S. Park et al., 2015; Steele et al., 2016). These variations across components of exercise dose make it difficult to interpret exercise effects across studies and pose a challenge to replication of study procedures in comparative trials.

While some studies mention recording patient adherence using various approaches (e.g., home dairies; T. Park & Kim, 2016; Robbins et al., 2005, 2007; Van den Steen et al., 2018, 2019), only two studies (Lazarus et al., 2014; Namiki et al., 2019) have included information regarding actual patient adherence to these prescribed exercises, suggesting that the actual dose of exercise delivered is largely unknown. Additionally, studies reporting adherence levels rely on patient self-report in the form of an exercise log, which is subject to over- or underreporting. The purpose of this pilot study was to examine how objective measures of patient adherence and exercise dose during a device-facilitated lingual strengthening program impact the outcome of lingual pressure generation in a cohort of Veterans with dysphagia. We hypothesized that Veterans with better adherence to the lingual strengthening program would achieve greater changes in lingual pressure generation.

Method

All procedures were approved by the University of Wisconsin–Madison Institutional Review Board and the William S. Middleton Memorial Veterans Hospital Ethics Review Committee.

Participants

Data were gathered retrospectively from an outcomes database for Veterans with dysphagia enrolled in an ongoing clinical treatment program. Patients were eligible for participation in this clinical program if they were diagnosed with dysphagia on videofluoroscopy: *Dysphagia* was defined as a Penetration–Aspiration Scale (Rosenbek et al., 1996) score of 3 or higher on at least one bolus and/or had oropharyngeal residue (ranked on a clinical visualization rating scale: 0 = *no residue*, 1 = *trace amount of residue*, 2 = *significant amount of residue*) present at any location on at least one administered bolus. Functional Oral Intake Scale (FOIS) scores (Crary et al., 2005) were assigned by the treating clinician pre- and posttreatment to assess if there were any functional gains in oral intake grade. The measures of interest in this retrospective analysis were patient adherence, dose delivery, and accuracy of lingual exercise training (defined below) related to the primary treatment outcome of change in lingual pressure generation from pre- to posttreatment (described below), with change in FOIS scores included as a secondary outcome.

Lingual Exercise Program

Patients were enrolled in a device-facilitated, 8-week isometric progressive resistance lingual exercise program from January of 2013 through June of 2017. Lingual exercise was facilitated using either the Swallow STRengthening

OropharyNGeal (SwallowSTRONG) device (Swallow Solutions) or the Madison Oral Strengthening Therapeutic (MOST) device (Swallow Solutions), depending upon availability of devices at the clinical sites. Daily adherence data were recorded in these devices throughout the duration of treatment.

Participants were selected for this retrospective analysis if:

1. Patient adherence data were available from the SwallowSTRONG or MOST device. Given the clinical nature of the ongoing intervention program, not all patients have these adherence data available across their entire treatment program. As such, to be included in this analysis, all participants were required to have recorded adherence data available for the duration of their enrollment in the treatment program for at least the front lingual sensor.
2. The patient demonstrated lingual weakness prior to exercise. Given the clinical nature of this program, individuals with high baseline lingual pressures, perhaps indicating intact lingual strength, were still allowed to participate. In an attempt to limit inclusion of individuals without tongue weakness in this retrospective analysis, we constrained our cohort further to only include individuals with lingual forces measured at $\leq$ 340 hPa at baseline (Adams et al., 2013). This cutoff was determined by converting normative values available for the Iowa Oral Performance Instrument in kilopascals to hectopascals. It was necessary to refer to these Iowa Oral Performance Instrument normative data given that there are no published normative data available for the SwallowSTRONG or MOST device. However, this calculation is imperfect due to differences in the design of the device pressure bulbs/mouthpieces, which we acknowledge as a limitation in this conversion.
3. The patient had a final follow-up visit within 75 days of their baseline visit. While the program was 8 weeks (56 days) in duration, the final follow-up visit may have occurred later due to scheduling- or travel-related issues. In these cases, patients were instructed to continue exercise until that time in order to avoid detraining effects prior to final measurements.

A visual representation of data collection procedures is provided in Figure 1. Prior to completing the device-facilitated lingual exercise program, participants were seen for a baseline clinical visit where baseline maximum isometric pressure (MIP) measurements were taken and participants were instructed on how to operate the device independently for home practice.

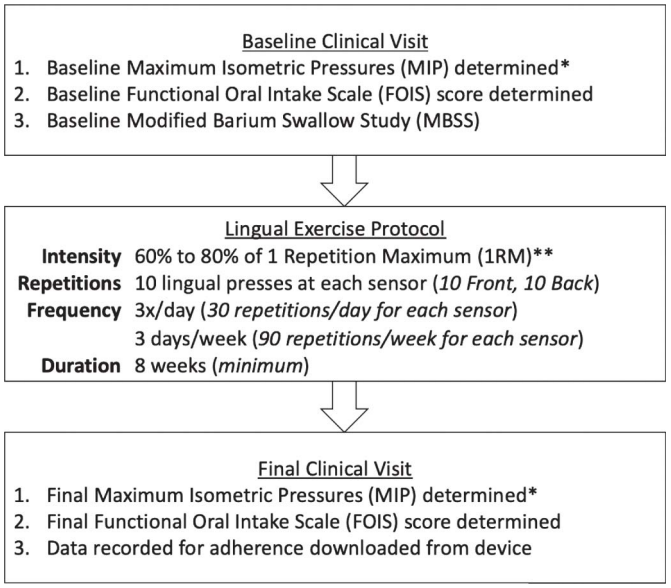
The MOST and SwallowSTRONG systems were each composed of a device (e.g., netbook or tablet) capable of recording and providing visual biofeedback regarding lingual pressure generation by way of connection to an intraoral, custom-fit mouthpiece and transducer box. The software installed on these devices recorded lingual press repetition and pressure data. These data included number of repetitions completed, accuracy with which therapeutic targets were met (based on the established maximum isometric lingual pressure, or MIP, threshold), and the date exercises were completed. These data were stored in a section of the program accessible only by clinicians, ensuring that participants were not able to view or tamper with recorded session data. Participants also received visual biofeedback during treatment sessions regarding accuracy of lingual presses performed (a green thumb indicated achievement of the therapeutic target) and overall session data (total number of repetitions during which therapeutic targets were achieved across a single session).

Dose of Lingual Exercise Prescribed (Intensity, Repetitions, Frequency, Duration)

Intensity. Baseline MIP measurements were collected with completion of one-repetition maximum pressure trials at front and back sensors. Participants were instructed to press the anterior and posterior portions of their tongue as hard as possible against the designated sensor. Up to three sets of three trials were completed to account for variability in lingual pressure generation to determine MIP for both the front and back sensors. If variability between the first and second sets was less than 5%, then fewer sets were required to calculate maximum pressure. If variability was greater than 5% across sets, the MIP measurement across the three sets was recorded. Once MIP was determined, an initial therapeutic target for the first week of the participant's home exercise program was set at 60% of MIP. Therapeutic targets were increased to 80% of the baseline MIP by the speech-language pathologist after completion of 1 week of the program. New maximum MIP values were determined every 2 weeks (Weeks 3, 5, and 7 of the 8-week program), and subsequent therapeutic targets were established as 80% of these MIPs for the remaining weeks of treatment. During the first in-person clinical session, each patient demonstrated an understanding of how to navigate to the MIP task through their MOST or SwallowSTRONG device to allow for redetermination of MIP on those weeks. The treating clinician met with the patient via telehealth or phone call every 2 weeks to determine and set the new percent MIP threshold on the device. A final set of MIPs were collected upon completion of the therapy program during an in-person clinical visit.

Repetitions and frequency. All patients were instructed to perform exercises at the front and back locations of the tongue. However, due to difficulty with achieving full contact between the back sensor and the hard palate, data for MIPs and adherence from the back sensor were not available for seven participants in this retrospective analysis. This difficulty may have been related to the positioning, shape, and size of the sensor within the mouthpiece as part of the design of this device. The home therapy program (see Figure 1) consisted of 3 days of training per week, with three sets of 10 anterior presses (front sensor) and three sets of 10 posterior lingual presses (back sensor) per day, as recommended in the sports medicine literature (American College of Sports Medicine, 2009; Tipton & American College of Sports Medicine, 2006). This results in a total of 30 repetitions total per

Figure 1. Study timeline. Outcome variables collected at baseline and final clinical visits, description of lingual exercise protocol dose.



*For both lingual sensors: front (anterior) and back (posterior) using either SwallowSTRONG or MOST device
**MIPs remeasured every 2 weeks to determine % of 1RM

day (for each sensor) and 90 repetitions total per week (for each sensor).

Duration

The prescribed duration of this home therapy program is 8 weeks. However, due to scheduling-related issues, some patients exercised for longer than 8 weeks. The total number of days each patient enrolled in the home exercise program was recorded and used to adjust calculations of adherence, dose delivery, and accuracy for statistical analysis. Patients were instructed to complete the exercises as described above, until the day of their follow-up appointment.

Recording and Measurement of Adherence, Dose Delivery, and Accuracy

During the lingual exercise program, daily participation data were recorded by the lingual exercise device. For each patient, the device recorded the number of sessions completed (per day) and whether or not the force target was met for each repetition at the front and back lingual sensors (attempts vs. presses that met target). These data were stored on the device throughout treatment and were exported from the device at the final clinical visit and stored in de-identified Excel files. From these stored data, the following measurements of patient adherence, dose delivery, and training accuracy for each sensor (front and back) were calculated using the following formulas:

$$\text{Adherence}\ (\%) = \frac{\text{Total number of lingual presses attempted}}{\text{Prescribed number of repetitions}} \times 100 \quad (1)$$

$$\text{Dose delivery}\ (\%) = \frac{\text{Number of lingual presses that met target}}{\text{Total number of lingual presses attempted}} \times 100 \quad (2)$$

$$\text{Accuracy}\ (\%) = \frac{\text{Number of lingual presses that met target}}{\text{Total number of lingual presses attempted}} \times 100 \quad (3)$$

$$\text{Prescribed number of repetitions} = \text{number of weeks enrolled in program} \times 90\ \text{reps/week} \quad (4)$$

In this study, we defined adherence as the number of lingual presses attempted (at each sensor) out of the total number that patients were prescribed to complete: Patients were instructed to press each sensor (front and back) 10 times per session, three sessions per day, and 3 days per week. As such, the prescribed number of lingual presses that should be completed in 1 week, per sensor, is 90. Thus, the denominator "prescribed number of repetitions" was calculated on an individual basis because program duration varied

(56–75 days) among included participants. One participant from the available cohort completed double the number of repetitions prescribed for the duration of treatment, resulting in adherence > 100%. This was identified as an outlier in this data set (greater than 3 *SD*s from mean, *z* score > 4) and was therefore removed. We defined dose delivery based on the number of lingual presses that met force threshold targets (*intensity*) for that assigned week to capture how many successful presses were completed out of the number that were prescribed. Finally, we defined accuracy during the home training program as the number of presses that met target out of the total number that were attempted by each patient (different from the prescribed amount, this represents the *actual* number attempted).

Responders Versus Nonresponders

To examine differences among individuals with high and low adherence who responded or did not respond to treatment, we calculated the top and bottom quartiles (see Figure 2) of individual participant adherence to form two groups: low adherence (bottom quartile) or high adherence (top quartile). We then further subdivided these groups by "response to treatment," which was defined as increasing MIP compared to baseline ("nonresponders" = no change, < 5 hPa increase, or decrease in MIP from pre- to posttreatment and "responders" = increase in MIP). Ultimately, four groups were defined and are presented below: (a) high adherence, responders; (b) high adherence, nonresponders; (c) low adherence, responders; and (d) low adherence, nonresponders.

Statistical Analyses

Statistical analyses were performed using SAS Analytics Software (SAS Institute) and SPSS (IBM). To ensure adherence and changes in lingual pressure were equivalent across devices, an independent-samples *t* test was used. Given that this was a retrospective analysis using a clinical database, a priori power calculations were not possible. Rather, a convenience sample was used to include as many participants from the database as possible who met the criteria described above.

To compare data between the SwallowSTRONG and MOST devices, patient adherence and change in MIP at the front sensor were compared between participants using each device with independent *t* tests. Changes after treatment (Δ = posttreatment − pretreatment) for outcome measures of lingual pressure (MIP) were evaluated using a paired *t* test and Wilcoxon signed-ranks test for change in FOIS. Relationships among patient adherence, dose, accuracy, and change in lingual pressure generation as well as change in FOIS were evaluated with Pearson or Spearman rank correlation coefficients, as appropriate. A critical $\alpha = .05$ was used to determine statistical significance in all analyses.

Results

Participants

This analysis included 37 participants selected from the larger cohort of 178 patients who were enrolled in the program between 2013 and 2017 (see Table 1). Of these participants, 36 were male, and the average age was 69.1 years. Adherence and MIP data from the front sensor were collected from all participants. Adherence and MIP data from the back sensor were only available from 30 participants. For the total group ($N = 37$), etiology of dysphagia was varied (see Table 2), with the largest percentage having dysphagia as a result of head and neck cancer ($n = 13$). Adherence rates for lingual exercise at the front and back sensors also varied by etiology of dysphagia (see Table 2).

Adherence rates at the front sensor were not statistically different ($p = .43$) between patients training with the

Figure 2. Distribution of adherence data. Each marker indicates an individual participant.

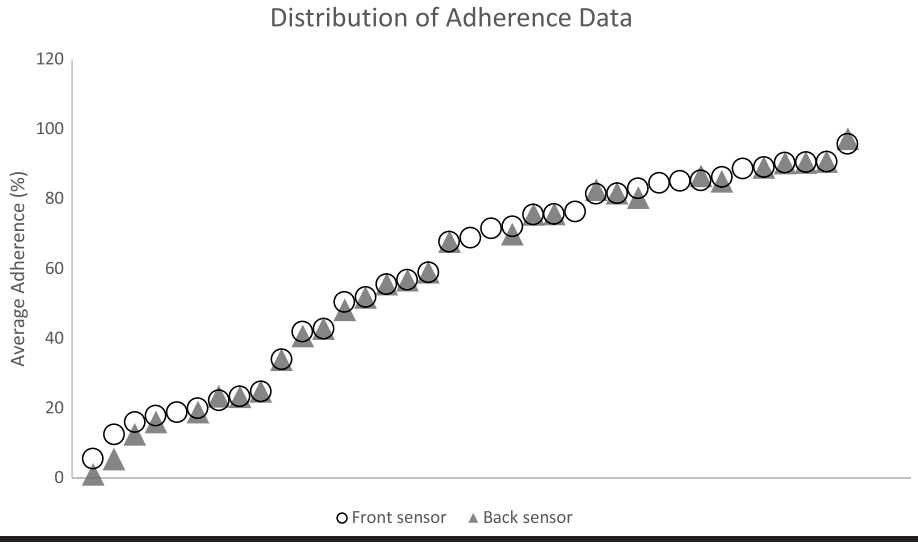


Table 1. Reasons for exclusion from larger cohort (total eligible = 178 patients).

Number excluded	Reason
n = 118	Adherence data unavailable
n = 16	Enrolled > 75 days in lingual exercise program
n = 6	Lingual pressure > 340 hPa at baseline
n = 1	Outlier

MOST device (n = 19, 55.6% adherence) compared to those training with the SwallowSTRONG device (n = 18, 63.1% adherence). Participants using the MOST device had greater gains in MIP from pre- to posttraining (p = .023); however, both groups of patients demonstrated an average increase in MIP at the front sensor (MOST = +144.4 hPa, SwallowSTRONG = +44.96 hPa).

Adherence, Dose, and Accuracy

Adherence rates were generally evenly distributed across participants at both sensors (see Figure 2). Summary data for all adherence, dose, and accuracy rates per sensor are provided in Table 3 and shown in Figure 3. Average adherence across the home therapy program at the front sensor was 59.3% (SD = 28.2), ranging from 5.5% to 95.8%; back sensor adherence was 55.9% (SD = 29.8), ranging from 1.1% to 97.2%.

Primary Outcomes From Lingual Exercise Program

Lingual pressures (MIP) at the front sensor were significantly greater ($p < .0001$) after lingual exercise, by an average increase of 96.0 hPa (SD = 134.8) from baseline (see Figure 4A). Lingual pressures (MIP) at the back sensor were also significantly increased (p = .008), by an average increase of 75.7 hPa (SD = 129.1) from baseline (see Figure 4B). The mode and mean scores for the FOIS (Crary et al., 2005) were 5 and 5.5, respectively, at baseline. Posttreatment, 11 patients had an increase in FOIS, one had a decrease, and 25 had no change in FOIS (p = .005; see Figure 4C).

Relationship Between Patient Adherence, Dose, Accuracy, and Primary Outcomes

Patient adherence with lingual exercise at the front sensor was not significantly correlated with change in MIP at the front sensor ($r = -.161$, p = .342; see Figure 5A) or change in FOIS ($r = -.183$, p = .279; see Figure 5B). Patient adherence with lingual exercise at the back sensor was not significantly correlated with change in MIP at the back sensor (r = .002, p = .991; see Figure 5C) or change in FOIS ($r = -.160$, p = .399; see Figure 5D). There were no statistical correlations between measurements of dose or patient accuracy with change in MIP or FOIS (see Figure 5).

Individual Participant Characteristics Based on Adherence and Response to Treatment

Given the relatively small and heterogenous sample size, statistical assessment of the relative impact of individual patient characteristics (i.e., dysphagia etiology, age) on study outcomes of lingual pressure generation was not possible. However, by grouping these individual participants by level of adherence and response to treatment (increase in tongue pressure generation), we were able to descriptively assess patient characteristics that could be contributing to relationships among adherence and outcomes of lingual strength. Patient characteristics included age, sex, etiology of dysphagia, and the FOIS (Crary et al., 2005) score prior to starting treatment.

Individual descriptive characteristics for each participant in the top and bottom quartiles of adherence rates at both the back and front sensors are shown in Figure 6. Relative adherence rates and MIPs at baseline and posttherapy are shown relative to each individual participant's age, baseline FOIS score, and etiology of dysphagia. As shown in the front sensor adherence figures (see Figures 6A and 6B), nonresponders in both the high- and low-adherence quartiles tended to have higher MIP measurements at baseline (blue bar). This was not the case for individuals in the back sensor low- or high-adherence quartile groups (see Figures 6C and 6D). For all four groups, there do

Table 2. Adherence rates by etiology.

Primary etiology of dysphagia	Sample size front sensor *n*	Adherence front sensor *M* (*SD*)	Sample size back sensor (*n*)	Adherence back sensor *M* (*SD*)
Head and neck cancer	13	55.9 (27.9)	12	55.9 (29.8)
Neurodegenerative	7	62.5 (30.9)	6	58.4 (31.96)
Unknown	4	78.3 (10.2)	1	67.8 (—)
Respiratory	4	52.9 (36.7)	4	51.9 (35.6)
Stroke/CVA	4	40.8 (37.0)	2	9.0 (5.0)
Thyroid	2	66.7 (21.1)	2	66.7 (21.1)
Esophageal	1	75.7 (—)	1	75.7 (—)
Cardiac	1	42.8 (—)	1	42.8 (—)
Autoimmune	1	89.1 (—)	1	89.1 (—)

Note. Em dashes indicate date not available. CVA = cerebrovascular accident.

Table 3. Comparison of percent (%) adherence, dose delivery, and accuracy.

Sensor	Variable	*M*	*SD*	Range
Front sensor	Adherence	58.3	28.2	5.5–95.8
	Dose delivery	42.7	26.6	1.1–85.5
	Accuracy	71.1	24.7	4.2–99.8
Back sensor	Adherence	55.9	29.8	1.1–97.2
	Dose delivery	36.5	22.1	0–75.9
	Accuracy	60.6	23.9	0–93.0

not appear to be any emergent patterns between adherence and other patient characteristics at baseline, including FOIS, age, or etiology of dysphagia to explain grouping in high/low adherence or response/nonresponse to treatment.

Discussion

In this foundational investigation, we sought to determine how patient adherence with a lingual exercise program related to the outcome of maximal lingual pressure generation. Rate of adherence measured in this study was defined as the number of attempted lingual presses out of the total number of lingual presses prescribed (30 per day per sensor, 3 days per week). Overall adherence to lingual exercise at both sensors was moderate (59% front, 56% back). Lingual exercise did result in increased lingual pressure generation as measured by ability to press the tip of the tongue blade to the front sensor in a voluntary, cued maximum press. Gains in MIP at the front sensor were larger than those at the back sensor (97 hPa vs. 76 hPA), which could be due to some patients having difficulty making full contact with the back sensor. However, a greater amount of adherence with the exercise protocol did not significantly correlate with increased lingual pressure generation at the front or back sensor or level of oral intake. Furthermore, when examining dose delivery and accuracy of performance with study outcomes, we still did not find any significant correlations between measures of dose or accuracy of performance and our outcome measures of change in MIP or FOIS. These findings were surprising considering that we would expect patients with the highest adherence, dose delivery, or accuracy in performance to have the greatest change in maximal lingual pressure generation.

When comparing patient adherence to other measures of patient performance, including dose (number of lingual presses that met target / prescribed number of presses) and accuracy (number of presses that met target / total number of attempted presses), we did observe some variability across measures. At both sensors, accuracy was higher than both dose delivery and adherence (see Table 3). This is not surprising given that accuracy is calculated based on the number of attempted presses for each individual patient, so there is no impact of prescribed number of presses in this measure. Dose delivery is the lowest rate, for both sensors. This indicates that, even if participants are adherent with the exercise protocol (i.e., making attempts to complete the therapy program as prescribed), they will not necessarily be successful at meeting the target force threshold for every attempted lingual press. This distinction between patient adherence and dose of exercise achieved during therapy is an important consideration for future studies designed to examine effects of exercise dose on outcomes of an intervention.

Figure 3. All accuracy, dose, and adherence data. All data from front (A) and back (B) lingual sensors for the duration of the lingual exercise intervention.

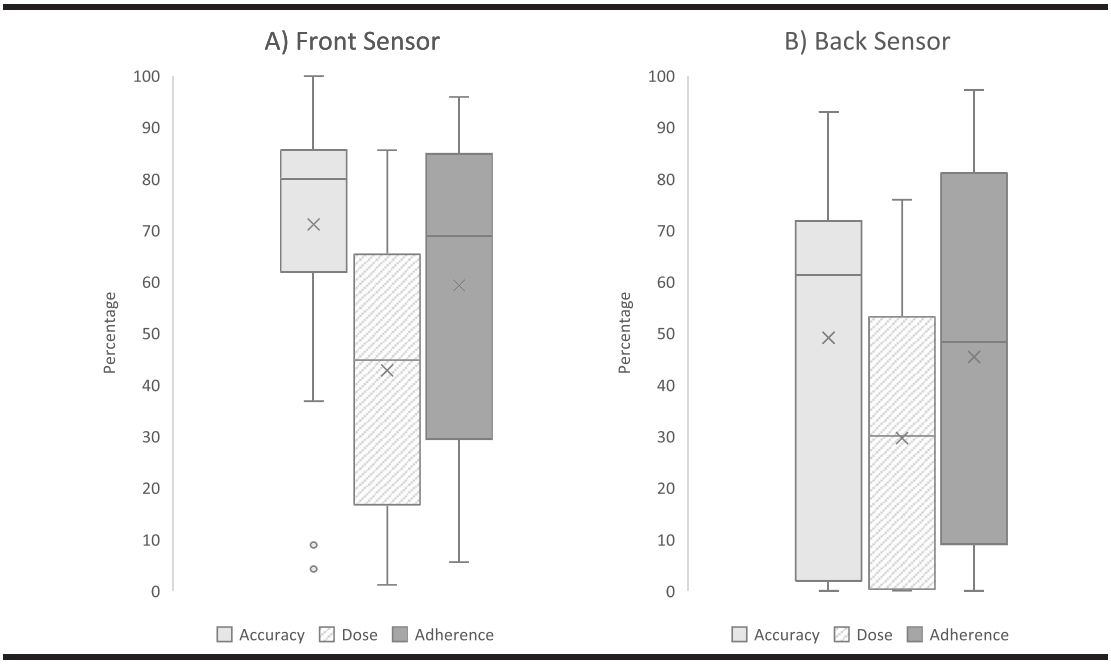
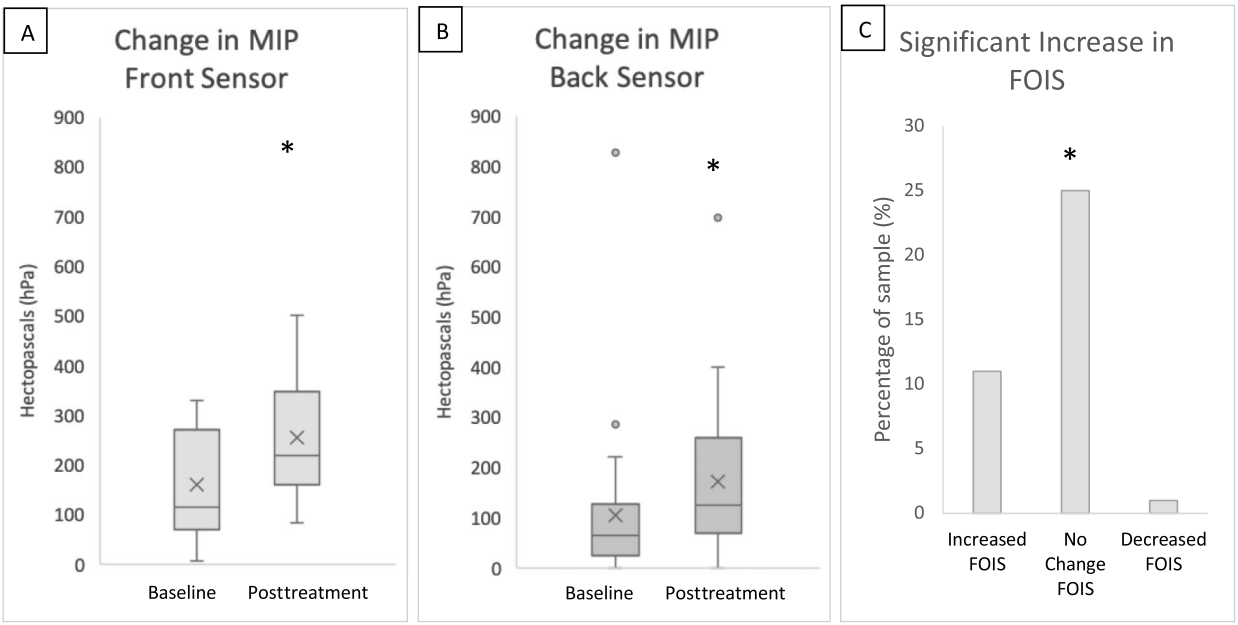


Figure 4. Changes in primary outcomes from baseline to posttreatment time points. For primary outcomes, maximum isometric pressure (MIP) from pre- to posttreatment was significantly increased in both the front (A; $p < .0001$) and back (B; $p = .008$) sensors; Functional Oral Intake Scale (FOIS) score, on average, was also increased (C; $p = .005$).



In our descriptive exploration of the highest and lowest individuals' adherence at the front and back sensors, we observed that, for both high and low adherence at the front sensor, individuals who did not respond to treatment had higher baseline lingual pressures, as compared to those who did respond to treatment. This may indicate that individuals with higher lingual pressures at baseline may not respond as strongly to the exercise intervention, regardless of adherence. To draw more meaningful conclusions, this should be investigated in a larger group of patients. However, these findings suggest that baseline lingual pressure could be an indicator of treatment success and should be considered.

Other intrinsic patient factors (age, etiology, baseline FOIS) examined in these descriptive analyses did not offer any suggestion or pattern relating to high/low adherence or responder/nonresponder. Across all four adherence groups for both sensors, etiology of dysphagia was mixed. However, the potential influence of etiology on adherence and response to lingual exercise treatment should be investigated in a larger prospective trial, as unique disease pathology has been suggested to influence adherence to dysphagia recommendations (Krekeler, Vitale, et al., 2020).

One explanation for these findings related to adherence and study outcomes could be due to varying levels of adherence throughout the exercise program. The adherence literature has suggested that individuals must be able to perceive benefit from a treatment approach to maintain adherence consistently (Sabaté, 2003). In this study, we found that lingual exercise did result in significantly improved FOIS scores, with 11 of the 37 patients having increased FOIS from baseline, with an average of 0.5 increase in total FOIS score. However, this slight improvement in FOIS may not be clinically meaningful, so we must interpret these findings with caution. Given that a majority of patients had no change or a decrease in FOIS ($n = 26$), it is possible that participants did not perceive improvement in swallowing that translated to oral intake and thus fluctuated in their motivation to exercise.

These findings could also be explained, in part, by the dose of tongue exercise used in this protocol. Although we used one commonly cited progressive, isometric lingual exercise protocol of 3 times per day, 3 days per week (T. Park & Kim, 2016; Robbins et al., 2005, 2007; Rogus-Pulia & Hind, 2015), optimal dosing for tongue exercise has not yet been definitively established (Burkhead et al., 2007; McKenna et al., 2017). The importance of dose delivery in efficacy of resistance-based exercise is well established in the rehabilitative literature, focusing on dose–response studies of muscular strength in limb (e.g., arms and legs; Latham et al., 2004; Ohkawara et al., 2007; Peterson et al., 2005; Radaelli et al., 2015; Rhea et al., 2003). However, exploration of dose–response relationships in dysphagia exercise therapies is relatively new and is not yet fully understood, as shown by a recent review (Krekeler, Rowe, & Connor, 2020). This study identified only one peer-reviewed publication available using randomized controlled methodology to explore the effects of tongue exercise frequency on measures of tongue strength and pressure generation during swallowing tasks in healthy older adults (Van den Steen et al., 2020). However, there are multiple components of dose (i.e., frequency, intensity, duration, repetitions) that still must be

Figure 5. Relationships between adherence and change in maximum isometric pressure (MIP) at front and back sensors and change in Functional Oral Intake Scale (FOIS) score. There was no significant relationship between rate of adherence, dose, or accuracy and any of the outcomes measured. For each outcome variable, the change from baseline to posttreatment (Posttreatment – Baseline) is represented on the *x*-axis and rate of adherence with front or back sensor on the *y*-axis. A positive score indicates improvement. Correlation coefficients (Pearson's *r* for change in MIP, Spearman's *r* for change in FOIS) and *p* values are displayed.

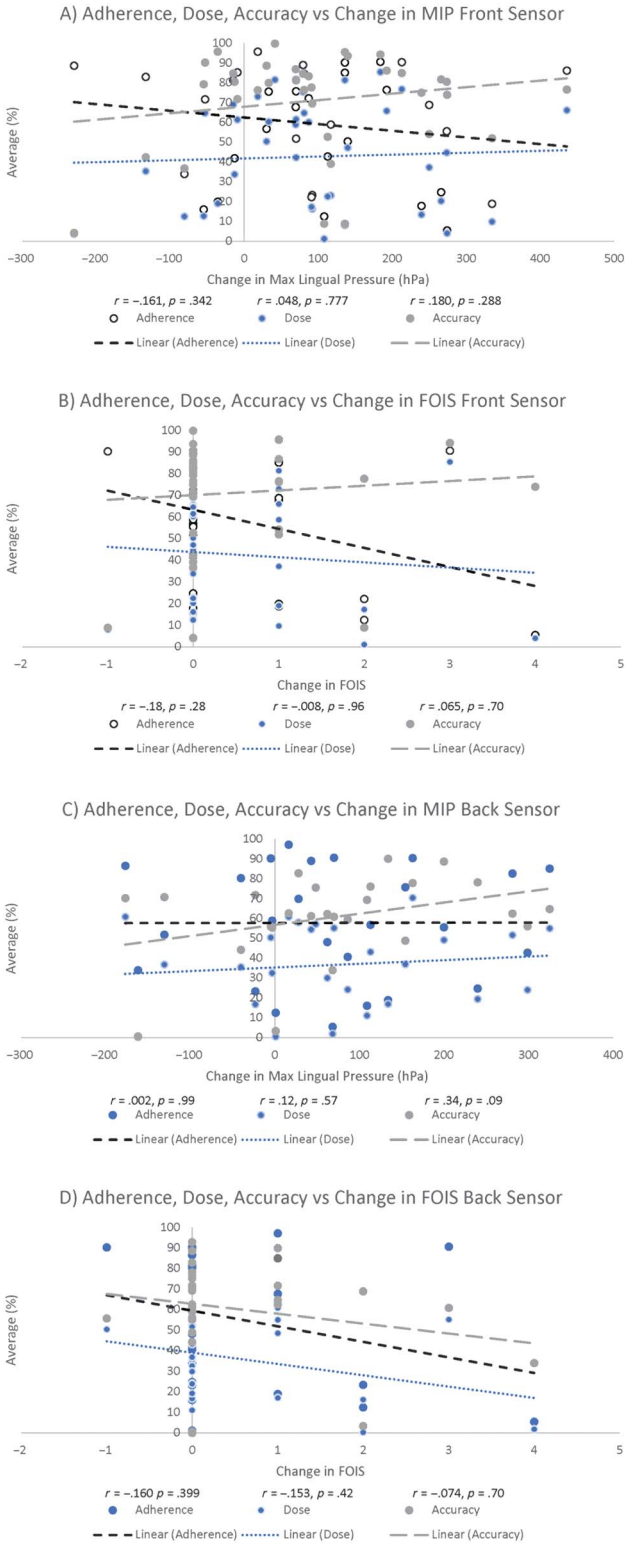
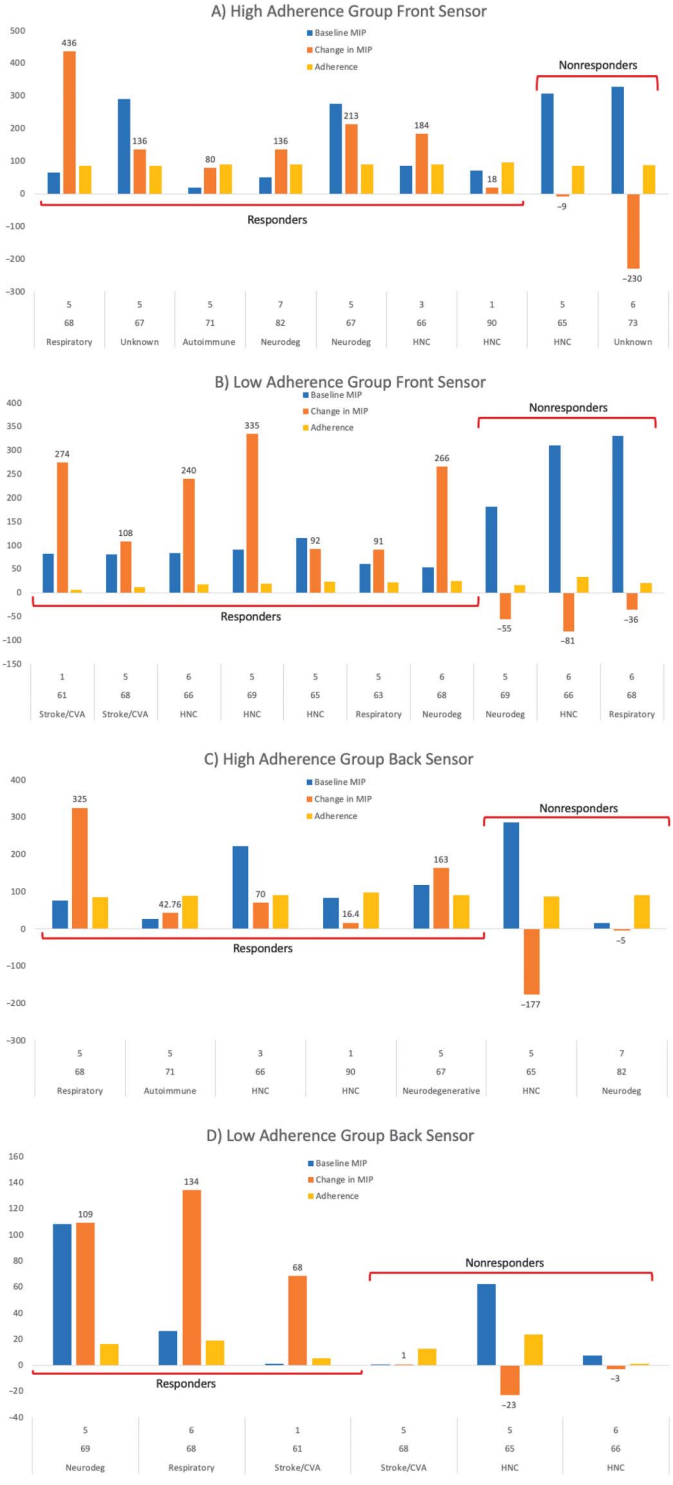


Figure 6. High-adherence versus low-adherence individual participant data. Individual participant data are represented here from the top quartile (A: high adherence front sensor, *n* = 9; C: high adherence back sensor, *n* = 7) and bottom quartile (B: low adherence front sensor, *n* = 10; D: low adherence back sensor, *n* = 6) of adherence with front sensor lingual exercise. Each group of bars (3) represents data from one individual participant for maximum isometric pressure (MIP) at baseline in blue, change in MIP from baseline in orange, and that individual's average adherence in yellow. Below each set of bars, the participant's Functional Oral Intake Scale score at baseline, age, and diagnostic category for etiology of dysphagia are listed. These participants are further grouped by whether or not they responded to treatment (responder vs. nonresponder), that is, whether or not they had an increase in MIP at the front sensor after lingual exercise: Responders increased MIP as compared to baseline; nonresponders decreased MIP as compared to baseline. CVA = cerebrovascular accident; HNC = head and neck cancer; Neurodeg = neurodegenerative.



explored within specific patient populations, not just in healthy individuals, to better understand and optimize lingual exercise as a treatment of dysphagia (Burkhead et al., 2007; Krekeler, Rowe, & Connor, 2020). Perhaps an alternative amount of exercise, with a high level of patient adherence, would show a stronger relationship between adherence with exercise and increased lingual pressure generation. Future studies should consider adherence reporting (Krekeler et al., 2017) and dose delivery (Krekeler, Rowe, & Connor, 2020) to better answer these questions.

Finally, an explanation of findings specific to the lack of relationship noted between adherence and change in FOIS could be due to lack of task specificity (Burkhead et al., 2007; Langmore & Pisegna, 2015). This concept centers around the fact that tongue exercise does not directly involve swallowing but is dependent on "transference" of skill from tongue strength to swallow physiology (Langmore & Pisegna, 2015). While tongue exercise is known to be effective in multiple patient groups to increase tongue force and improve swallowing outcomes, the evidence varies among peer-reviewed studies, and it is difficult to make summative statements spanning multiple patient populations regarding translation of increases in lingual pressure generation or tongue strength to improved swallowing function (Krekeler, Rowe, & Connor, 2020; McKenna et al., 2017).

Limitations

Although findings of this retrospective study provide important preliminary data that will inform the design of a larger prospective trial, there are still several limitations to this work. Given the retrospective design, this cohort of Veterans, as part of a larger clinical program, are assigned to treatment without a randomization component or a control arm. Furthermore, a portion of the participants in this trial used the MOST device, with the other portion using the SwallowSTRONG device. Although these platforms and device structure are very similar, controlling for device type in a prospective trial would be preferable.

While we recognize these limitations, we affirm that the findings from this preliminary study provide relevant data to establish the importance of conducting this work in a future prospective and controlled trial. One strength to this work is that these data were collected as part of an ongoing clinical program; thus, patient adherence data from this pilot work are truly reflective of patient performance in a device-facilitated lingual exercise program. However, given the retrospective nature of this work, we were limited in assessing exercise and adherence effects on physiological components of swallowing impairment. Due to the clinical nature of the videofluoroscopic swallow studies, bolus administration (type and size) was not standardized, which limits the ability to perform in-depth, validated analyses of swallowing impairments, such as using the Modified Barium Swallow Impairment Profile (Martin-Harris et al., 2008).

Finally, we were not adequately powered to assess differences among dysphagia etiologies. Given the impact of these primary conditions on underlying biomechanics of swallowing, lingual exercise may result in differential benefits across different patient groups (Barczi et al., 2000; Paik et al., 2008). It is possible that examining these relationships in more homogenous patient groups would reveal different relationships between adherence, lingual strength, and swallowing function and should be considered in the design of future prospective trials.

Future Directions and Additional Considerations

Patient adherence and exercise dose should be carefully evaluated in future, prospective, controlled, and randomized clinical trials in various patient populations to better understand the influence of these factors on outcomes related to lingual exercise. After the completion of this preliminary work, we have identified and discussed here several study design criteria that should be considered in future larger trials to better understand these complex relationships (see Table 4). The next phase of study will allow for the assessment of impact of lingual exercise adherence and dose on swallowing physiology in a larger cohort. Once we better understand how this type of intervention works, what optimal exercise prescription looks like, and what types of populations (i.e., etiologies and comorbidities) lingual exercise programs will most benefit, we predict that the relationships between adherence and outcomes will likely be more forthcoming.

Conclusions

In this study, we demonstrated weak relationships among patient adherence and outcomes of increased lingual pressure as a result of lingual exercise. Furthermore, improvements in functional oral intake as measured by FOIS scores were not related to patient adherence. We believe these pilot data indicate the need for future controlled, prospective

Table 4. Considerations for future trials examining adherence with exercise treatments.

1. Prospective, randomized clinical trial with control and/or sham treatment arm
2. Consideration of exercise dose (multiple dose groups + adherence measures)
3. Unbiased measurement of both adherence and dose delivery
   a. Direct observation or device facilitated
4. Consideration of baseline lingual pressure measurements (MIP)
   a. During study inclusion, establish a cutoff for individuals with normal–high MIP at baseline based on available normative data for the lingual exercise device in use
   b. During stratification to RCT study groups
   c. During data analysis
5. Consideration of dysphagia etiologies and comorbidities in adherence and response to treatment
6. Assessment of swallowing physiology using a gold-standard, validated protocol (MBSImP)

Note. MIP = maximum isometric pressure; RCT = randomized controlled trial; MBSImP = Modified Barium Swallow Impairment Profile.

investigation of patient adherence with lingual exercise programs to improve treatment delivery, efficacy, and outcomes from this dysphagia intervention.

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