

# Flexibility for Intensity Dosing in Lingual Resistance Exercises: A Large Randomized Clinical Trial in Typically Aging Adults as Proof of Principle

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#### ABSTRACT

**Objective:** The objective of this study was to determine the effect of intensity dosing during tongue exercise on tongue pressure generation, adherence, and perceived effort.

**Design:** This was a five-site, prospective, randomized clinical trial. Outcome measures were obtained across multiple baselines, biweekly during exercise, and 4-weeks post-intervention.

Setting: The general community at each study site.

**Participants:** Typically aging adults between 55–82 years of age with no history of neurological or swallowing disorders. Eighty-four volunteers completed the study.

**Interventions:** Participants were randomly assigned to one of four exercise groups: (a) maximum intensity/no biofeedback, (b) progressive intensity/no biofeedback, (c) maximum intensity/biofeedback, and (d) progressive intensity/ biofeedback. Half of the participants completed a maintenance exercise program. **Outcome Measures:** Maximum isometric pressure (MIP), regular effort saliva swallow pressure, adherence, and the Borg Rating of Perceived Exertion Scale. **Results:** All exercise protocols were efficacious for gains in MIP (large effect sizes; Cohen's *d*). Group 3 made gains in regular effort saliva swallow pressure (medium effect size). There was a significant change in perceived exertion for regular effort saliva swallow pressure at 8 weeks. Tongue pressure gains were maintained at 1 month, regardless of maintenance group status. Mean adherence across groups was high. **Conclusions:** All groups improved pressure generation. Intensity dosing differ-

**Conclusions:** All groups improved pressure generation. Intensity dosing differences did not affect strength gains, adherence, or detraining. Regular effort saliva swallow pressure may be most responsive to maximum intensity with biofeedback. The findings suggest flexibility in approach to tongue exercise protocols. Tongue muscles may differ from limb muscles in terms of dose response and neuroplasticity principles.

Parameters of muscular fitness include muscle strength (force of pressure generation), hypertrophy (muscle size increase), endurance (repeated or sustained pressure generation of muscle groups participating in a movement), and power (timely force generation), with resistance exercises

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specifically targeting muscle strength (Burkhead et al., 2007; Clark, 2003; Deschenes & Kraemer, 2002; Liguori & American College of Sports Medicine [ACSM], 2021). Tongue resistance exercise has been used in dysphagia (swallowing difficulty) rehabilitation for decades to strengthen lingual musculature with the rationale that the tongue plays a critical role in safety and efficiency of oropharyngeal swallowing (Butler et al., 2011; Robbins et al., 1995; Steele & Cichero, 2014). Both typically aging adults and persons with dysphagia show reduced lingual maximum isometric pressure

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(MIP) generation and reduced pressure for regular effort saliva swallows (McKenna et al., 2017; Robbins et al., 2016; Smaoui et al., 2020). Based on screening tool data, sarcopenia and dysphagia are associated in typically aging adults (Firat Ozer et al., 2021). In addition to promoting gains in tongue pressure generation, tongue resistance exercise has the potential to improve swallowing function, though evidence is mixed (McKenna et al., 2017; Smaoui et al., 2020). The rate of deconditioning following completion of a tongue resistance exercise protocol is also unclear (Clark et al., 2009; Fukuoka et al., 2022; Oh, 2015; Van den Steen et al., 2019, 2021).

Many approaches in dysphagia rehabilitation use the ACSM guidelines as a starting point for exercise design. Intensity is one of the principles of exercise prescription for resistance training under these guidelines and refers to the amount of resistance (loading) applied during an exercise repetition (Liguori & ACSM, 2021). The ACSM's guidelines recommend starting with a lighter intensity (40%-50% of an individual's 100% maximum force) for older adults who are considered beginners to the exercise, with incremental overload increases of no more than 10% (Micheli, 1988) to avoid injury. The latter concept is referred to as progressive overload, meaning a gradual increase in the magnitude of resistance across the exercise protocol. Progressive overload is considered necessary and ideal in the limb strength training literature (ACSM, 2009; Rhea et al., 2003). The most recent study to investigate differences in intensity prescription for tongue resistance exercise found no difference in efficacy between three different intensity levels, 60%, 80%, and 100%, of an individual's 100% maximum force. Progressive overload was not included in this study; rather, participants were assigned an intensity level at the start of the study and continued to exercise at the same assigned intensity level for the duration of the exercise protocol. While two intensities were submaximal (60% and 80% of an individual's 100% maximum force), both are still considered moderate-to-vigorous and progression was not examined (Van den Steen et al., 2019).

Optimal dosing to inform the prescription of dysphagia treatment, and tongue exercise specifically, remains unestablished and variable in practice (Krekeler, Rowe, & Connor, 2021). A starting point for tongue exercise dosage is needed with a future goal of individualization according to individual and population factors. Recent work by Krekeler, Rowe, and Connor (2021) encourages dysphagia research to focus on the exercise dosing parameters of frequency, repetitions, intensity, and duration. Within the fields of exercise science and physical rehabilitation, the substantial evidence on strength resistance training of limb musculature highlights the importance of determining dose– response relationships for specific exercises to optimize outcomes (Rhea et al., 2003); evidence-based recommendations on dosage have been outlined in the ACSM Guidelines for Exercise Testing and Prescriptions (11th ed; Liguori & ACSM, 2021). In addition to optimizing performance outcomes with treatment, clearly defined dose-response relationships provide evidence-based prescriptions to insurance payors and set representative expectations for clinicians, patients, and caregivers (Krekeler, Rowe, & Connor, 2021; Rhea et al., 2003). Lingual muscles, as a composite muscular hydrostat, and other bulbar musculature may respond differently to the exercise principles established using skeletal muscles (Kent, 2004; Stål et al., 2003). There is growing attention to the critical need for the development of dosing specific to the tongue and a shift away from reliance on prescriptions based on limb musculature (Krekeler, Rowe, & Connor, 2021; Van den Steen et al., 2019).

Dysphagia rehabilitation practices have been significantly influenced by experience-dependent neural plasticity principles derived from the limb literature (Kleim & Jones, 2008; Robbins et al., 2008). Training specificity has been reported in the lingual musculature, such that participants demonstrate greater changes between baseline and posttreatment outcomes (e.g., MIP) that are directly related to the trained task (strength training) than outcomes that are not (endurance; Clark, 2012). Transference from a trained skill to a similar action has been demonstrated by a program of lingual exercise increasing swallowing pressures (Robbins et al., 2005, 2007) and reducing airway invasion (Robbins et al., 2007). According to the use-it-or-lose it principle, deconditioning occurs with disuse or end of exercise, though results are mixed in the tongue exercise literature (Clark et al., 2009; Fukuoka et al., 2022; Oh, 2015; Van den Steen et al., 2019, 2021). However, despite evidence in support of shared principles between swallowing and limb neuroplasticity, the two functions differ in several aspects of their neurophysiology, and, thus, swallowing may have unique principles of neuroplasticity (Martin, 2009). Closer examination of dosing parameters and other factors (e.g., delivery, biofeedback, detraining effects) specific to tongue resistance exercise has been conducted in young adults, typically aging adults, and in animal models (Benfield et al., 2019; Clark et al., 2009; Krekeler, Rowe, & Connor, 2021; Krekeler, Weycker, & Connor, 2020; Schaser et al., 2016; Steele et al., 2016; Van den Steen et al., 2019, 2021), though additional evidence is needed to substantiate a starting point for tongue exercise paradigms as well as the application to specific populations and individuals.

The application of tongue resistance exercise in dysphagia rehabilitation faces two significant challenges: (a) dysphagia rehabilitation is often based on principles of strength training and experience-dependent neural plasticity derived from limb musculature investigations and (b) there is limited evidence regarding dose-response prescriptions for tongue exercise targeting swallowing-related outcomes and, thus, disagreement and a wide variability in approach to exercise design. Therefore, the rationale for the main part of the study was to contribute to evidence-based practice in tongue resistance exercise dosing and prescription, with a focus on intensity of exercise due to its predictive capacity for training effectiveness (Borde et al., 2015). Other areas of investigation for this study include mode of exercise delivery and participant adherence, both of which will be introduced in the following paragraphs.

Targeting a specific intensity accurately and reliably across trials of tongue exercise can be challenging, particularly for submaximal intensity exercise and during home exercise protocols outside of the clinic. Biofeedback has the potential to assist with exercise accuracy and adherence by "tak[ing] intrinsic physiological signals and makes them extrinsic, giving the person immediate and accurate feedback of information about these body functions" (Stanton et al., 2017, p. 11). Visual, auditory, or tactile biofeedback during lower limb exercise is more effective than exercise without biofeedback after stroke (Stanton et al., 2017). Examples of visual biofeedback devices frequently used in the United States for tongue resistance training include the Iowa Oral Performance Instrument (IOPI Medical LLC) and the Tongueometer Tongue Strength Biofeedback Device (CranioMandibular Rehab, Inc.). A recent systematic review and meta-analysis concluded that there is not enough evidence to provide clinical guidance on the use of biofeedback in dysphagia rehabilitation, including for tongue pressure manometry (Benfield et al., 2019). Additionally, the efficacy of using biofeedback for specific submaximal intensity targets (e.g., using a device to measure and visually depict 50% of an individual's 100% maximum lingual force) versus low-tech options (e.g., using a maximum lingual push before exercise to gauge a submaximal push without device-assisted measurement or biofeedback) has not yet been thoroughly explored.

Patient adherence to exercise protocols is critical to the development of appropriate prescription recommendations and to the synthesis of results between studies (Krekeler, Vitale, et al., 2020). Adherence to dysphagia recommendations is reportedly low, which may impact treatment outcomes and interpretation of clinical and experimental results (Krekeler et al., 2018). Adherence is multifaceted and may be impacted by difficulty of task and fatigue (Krekeler et al., 2018). Typically aging adults and patients with dysphagia have reported fatigue during swallowing and/or meals (Brates et al., 2021, 2022) with a physiologic correlate of reduced tongue pressure generation following a meal in older community-dwelling adults (Brates & Molfenter, 2021). However, very little is known about fatigue/perceived effort in dysphagia rehabilitation prescriptions.

To address the identified gaps in knowledge discussed above, the purposes of this study were to determine (a) the effect of modulating intensity (progressive vs. maximal) as a component of exercise dose and its impact on deconditioning, (b) the effect of mode of delivery (with visual biofeedback vs. without visual biofeedback) as a component of exercise prescription and its impact on deconditioning, and (c) the impact of modulating intensity and mode of delivery on adherence and related factors of fatigue/perceived effort, all in the context of typically aging people completing a tongue resistance exercise program. Ultimately, this study aims to contribute rigorous findings on the lingual response to various resistance exercise designs. Research questions and associated hypotheses included:

(1) Is tongue pressure generation impacted by resistance intensity when comparing submaximal progressive to maximum resistance? We hypothesized that the groups using a progressive resistance form of exercise would demonstrate the greatest gains in pressure generation following 8 weeks of exercise compared to baseline.

(2) Is tongue pressure generation 1-month postintervention impacted by completion of a maintenance exercise program? We hypothesized that the participants completing a 4-week maintenance exercise program would demonstrate less detraining at 1-month post-intervention compared to the participants instructed to stop all tongue exercises for 1 month.

(3) Is tongue pressure generation impacted by mode of delivery when comparing the visual biofeedback to no visual biofeedback during tongue resistance exercise? We hypothesized that the groups using a visual biofeedback device during exercise would demonstrate the greatest gains in pressure generation following 8 weeks of exercise compared to baseline.

(4) Is participant adherence to the exercise program impacted by resistance intensity and mode of delivery? We held no specific hypothesis regarding adherence. This was an exploratory research question, given the very limited data that are available on this topic in dysphagia rehabilitation.

(5) Is perceived effort during tongue pressure generation tasks impacted by tongue resistance exercise over the course of 8 weeks of exercise? We hypothesized that all tongue resistance exercise groups would demonstrate lower levels of perceived effort during tongue pressure generation tasks following 8 weeks of exercise compared to baseline.

# Method

# Participants

Participants were recruited from five states for a parallel-arm randomized clinical trial. Study sites included

Table 1. Inclusion and exclusion criteria for participation in study.

Inclusion criteria:	Exclusion criteria:
<ul> <li>Aged 55 years or older</li> <li>&lt; 3 on the Eating Assessment Tool (Belafsky et al., 2008)</li> <li>&gt; 24 on the Mini Mental State Examination (Rovner &amp; Folstein, 1987)</li> <li>Normal oral structure observed using a brief, standardized intra-oral screener (e.g., symmetrical facial structures, range of motion/tone of lips, jaw, tongue)</li> <li>Controlled hypertension, diabetes mellitus, corrected vision/hearing allowed</li> </ul>	<ul> <li>History of any of the following:</li> <li>Neurogenic disorder</li> <li>Seizures</li> <li>Pain disorder involving jaw</li> <li>Oral surgery other than routine dental surgery</li> <li>Swallowing difficulty</li> </ul>

Case Western Reserve University (Cleveland, OH), Emerson College (Boston, MA), James Madison University (Harrisonburg, VA), Samford University (Birmingham, AL), and Texas Christian University (Fort Worth, TX). The Samford University Institutional Review Board (IRB) served as the oversight IRB and each contributing university signed an IRB Authorization Agreement with Samford University's IRB. The IRB approval of the study protocol was secured prior to study recruitment. Typically aging, community-dwelling adults (aged 55+ years) without swallowing or neurological disorders were recruited from the local community at each study site. See Table 1 for inclusion and exclusion criteria. Medical history was collected via self-report. Before enrollment in the study, participants voluntarily signed a written informed consent document.

## Groups

Research sessions were completed in each study site investigator's university or hospital laboratory. A master randomization list for de-identified participant IDs, exercise group assignment, and counterbalanced order of outcome measurements for each study session was created for each study site using a random number generator. Participants were randomly assigned to one of four tongue strengthening exercise groups: (a) a maximum (100% of an individual's 100% maximum force) resistance intensity exercise group that did not use biofeedback during home exercise (Max/–BF), (b) a submaximal resistance intensity exercise group that did not use biofeedback during home exercise and increased intensity by 10% biweekly (Progressive/–BF), (c) a maximum (100% of an individual's 100% maximum force) resistance intensity exercise group that used visual biofeedback during home exercise (Max/+BF), and (d) a submaximal resistance intensity exercise group that used biofeedback during home exercise and increased intensity exercise and increased intensity exercise group that used visual biofeedback during home exercise and increased intensity exercise group that used biofeedback during home exercise and increased intensity by 10% biweekly (Progressive/+BF).

## Exercise Regimen

Baseline measures were taken on two separate visits to allow the participants to become accustomed to the tasks and equipment. Training to the exercise regimen occurred at the end of the second baseline visit. See Table 2 for specific exercise instructions. All exercise groups were instructed to complete three sets of 10 repetitions each day, 3 days a week, for 8 weeks. These dosing parameters are aligned with the ACSM's resistance exercise guidelines for

 Table 2. Outline of intensity, visual biofeedback, and pushing instructions by group.

Group	Intensity of resistance	Tongueometer biofeedback during home exercise	Instructions for pushing on bulb
1	Maximum (100% MIP)	No	Push your tongue up against the front part of the roof of the mouth using the bulb with max effort (as hard as you can push) and hold for 2 s for each repetition.
2	Progressive (50%–80% of MIP)	No	Push your tongue up against the front part of the roof of the mouth using the bulb with% of your max effort (max effort means as hard as you can push) and hold for 2 s for each repetition. Before you start your sets, complete 1 max effort push (as hard as you can push) to feel what your max effort feels like. Then complete the exercise sets pushing at% of your max effort.
3	Maximum (100% MIP)	Yes	While watching the application on the tablet screen, push your tongue up against the front part of the roof of the mouth using the bulb with max effort (as hard as you can push) until you reach the target pressure and hold for 2 s for each repetition.
4	Progressive (50%–80% of MIP)	Yes	While watching the application on the tablet screen, push your tongue up against the front part of the roof of your mouth using the bulb with% (kPa) of your max effort (max effort means as hard as you can push) until you reach within your set target range (±25% of target pressure) and hold for 2 s for each repetition.

*Note.* MIP = maximum isometric pressure; s = seconds; kPa = kilopascals.

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older healthy adults and prior research on tongue resistance exercise (Krekeler, Rowe, & Connor, 2021; Liguori & ACSM, 2021). A 4-s rest between each repetition and a 2to 3-min rest between each set were instructed, following recommendations made by Borde et al. (2015). The progressive resistance exercise groups started the first 2 weeks of exercise at 50% of an individual's 100% maximum force, progressed by 10% every 2 weeks, and finished the exercise program at 80% of their 100% maximum force. The participants in the submaximal resistance intensity exercise group that used biofeedback during home exercise set their Tongueometer range to  $\pm 25\%$  of their target intensity (updated every 2 weeks). An exercise push was considered "successful" if the push fell within the range. Participants were instructed to hit the target pressure as precisely as possible and aim for the middle of the range (i.e., their specific pressure target). Each participant's 100% of maximum, regardless of group, was remeasured every 2 weeks and a new target intensity was calculated from this value for the following 2 weeks. See Table 3 for a description of the study visits.

Regardless of group assignment, visual biofeedback during training of the exercise intensity was provided for all participants using the Tongueometer and bulb, connected via Bluetooth to an Android tablet. The Tongueometer device provides visual biofeedback of the pressure with which a person pushes on an air-filled bulb with their tongue via a digital radial dial within the Tongueometer application. Participants in the visual biofeedback groups (Groups 3 and 4) received a Tongueometer device and bulb and an Android tablet to take home for the duration of

Table 3. Study visit descriptions.

	1
Visit	Description
Baseline 1	Screening, consent, and outcome measures taken
Baseline 2 (within 1 week of Baseline 1)	Outcome measures taken, target intensity calculated, and participant trained to assigned exercise target
Week 2	Outcome measures taken, target intensity recalculated, and participant trained to new exercise target
Week 4	Outcome measures taken, target intensity recalculated, and participant trained to new exercise target
Week 6	Outcome measures taken, target intensity recalculated, and participant trained to new exercise target
Week 8	Outcome measures taken and participant trained to the maintenance program as randomized
1-month follow-up	Outcome measures taken

the 8-week study to use when completing their home exercise program. To control for differences between the four groups, the participants without a biofeedback device completed their home exercises using a Tongueometer bulb that was not attached to a Tongueometer device and did not give the participants feedback on exercise performance. Bulbs were assessed for punctures and deflation at each visit. Each participant used the same Tongueometer bulb for the duration of the study protocol. During the first visit, each participant's Tongueometer bulb was marked using a small piece of tape to standardize bulb placement across 8 weeks. The tape was placed so that when the bulb was on the tongue just behind the upper central incisors, the participant could feel the tape at border of their lips. All participants were provided with written exercise instructions to refer to in the home setting. The groups using the Tongueometer device/tablet for exercise were also sent home with written and pictorial instructions for using the device and tablet that housed the Tongueometer application.

At the end of 8 weeks, participants randomized to the maintenance program (half of the participants from each exercise group) were instructed to continue with their assigned exercise regimen but at 1 day a week for 4 weeks. Participants in the progressive intensity groups continued to target 80% of their 100% maximum force during the maintenance period. Participants not randomized to the maintenance program were instructed to stop with their assigned exercise regimen.

## Training

All participants completed limited sets of calibration training to their target intensity using the Tongueometer device at the beginning of their participation and every 2 weeks when their target intensity was adjusted according to the remeasured 100% maximum force. Participants were considered "trained" when they were able to perform the exercise at  $\pm 25\%$  of their target intensity for eight consecutive trials. During training, participants assigned to exercise groups without the use of a visual biofeedback device were blind to pressure readings but were given verbal feedback if they missed the target. Participants assigned to exercise groups using the visual biofeedback device, watched the Tongueometer application tablet screen during the practice, and received verbal feedback regarding their performance.

## **Outcome Measures**

Tongue pressure outcome measurements included MIP and regular effort saliva swallow pressure. The MIP and regular effort saliva swallow pressure measurements were collected at every study visit (two baselines, Week 2, Week 4, Week 6, Week 8, and a 1-month postvisit) prior to any training and practice using both the Tongueometer and the IOPI (IOPI Medical LLC) tongue manometry devices. For MIP, the participants were instructed to push their tongue against the bulb as hard as possible for 2 s. For regular effort saliva swallow pressure, they were instructed to swallow their saliva in a normal manner. The presentation of each measure was counterbalanced.

The MIP measures were taken with a Tongueometer device across five trials to recalculate the participants' MIP and set/reset the target intensity since the participants assigned to visual biofeedback were using the Tongueometer device during home practice; however, the Tongueometer measures were not used as outcome data for this study because the device's measures had not been validated against published tongue pressure normative values at the time the study was conducted. The MIP and regular effort saliva swallow pressure measures were also taken using the IOPI across five trials each, averaged for each task, and presented here as the study outcome measures. Prior to the set of regular effort saliva swallow pressure measurements, participants were allowed to drink 10 ml of water to help moisten the mouth and facilitate the presence of saliva for multiple swallowing trials. Participants were instructed not to talk during tongue pressure measurements; 30 s of rest were timed between each trial and 2-3 min of rest were timed between task sets to avoid fatigue. An anteromedian placement was used during all measurements, and the IOPI bulbs were also marked with tape in an identical manner as described for the Tongueometer bulbs above to facilitate consistent bulb placement for each participant across visits. The order in which the devices were used was counterbalanced. Participants were blinded to all tongue pressure values during outcome measurement (the devices were not within view) and investigators did not provide any verbal cues regarding participants' performance on outcome measures.

Adherence was tracked as an outcome measure and defined as the proportion of the total number of exercise repetitions completed by number of total exercise repetitions prescribed across 8 weeks. Each participant was instructed to provide self-report of fidelity to protocol by completing an exercise log for each day of exercise. Participants randomly assigned to a maintenance exercise program (three sets of exercise, 1 day per week for 4 weeks following the 8-week main protocol) were also instructed to complete a maintenance exercise log.

The Borg Rating of Perceived Exertion Scale (Borg scale; see Appendix) was used during every follow-up

visit to track self-reported perceived level of effort (Williams, 2017). After each set of MIP and regular effort saliva swallow pressure measurements, respectively, participants viewed a printed Borg scale to rate their perceived effort. Thus, each follow-up visit yielded two separate Borg scale scores, one for the MIP task and one for the regular effort saliva swallow pressure task. Scale scores range from 6 (indicating no perceived effort) to 20 (indicating a maximal perceived effort). Standardized instructions based on the scale's language regarding physical exertion were used to guide each participant's decision about their perceived level of effort for a task.

# Statistical Analysis

A G\*Power 3.1 (Faul et al., 2007) a priori power analysis indicated a sample size of 25 per exercise group was required for a power of .99. The between-group factor was exercise group, which comprised both visual biofeedback and exercise intensity. A secondary between-group factor was participation in a maintenance program, which was considered in the comparison of measures at Week 8 and 1-month postvisit. The within-group factor was time (baselines, Week 2, Week 4, Week 6, Week 8, and a 1month postvisit).

Outcome measures included changes in lingual pressure during MIP and regular effort saliva swallow pressure, adherence to the exercise protocol, and Borg scale scores of participants' perceived effort during tongue pressure tasks. Tongue pressure data collected using the IOPI were used for reporting and statistical analyses because the IOPI is a reliable research device with documented norms (Adams et al., 2013, 2015).

One-way analysis of variance (ANOVA) determined differences between the groups at baseline for demographic information and screening measures. Two-way mixed ANOVAs with both time and group as withinsubject and between-subject factors, respectively, were used to analyze the primary dependent variables. Adherence was compared between exercise groups using one-way ANOVA. Pearson's correlations determined associations between adherence level and mean amount of change from baseline to post-intervention Week 8 for both MIP and regular effort saliva swallow pressure. Wilcoxon signed-ranks test was used to compare ordinal Borg scale scores across visits. Kruskal-Wallis H tests were used to compare ordinal Borg scale scores across groups at specific time points. The effect of maintenance exercise was examined using three-way mixed ANOVAs. An  $\alpha$  level of .05 was used for the analyses but adjusted for relevant post hoc testing using Bonferroni correction if indicated. SPSS (Version

Table 4. Demographics, screenings, and adherence by group (M [SD]).

Group	N	Age (years)	EAT-10	MMSE	Adherence (%)
Max/-BF	21	64.3 (6.9)	0.3 (0.48)	29.4 (0.60)	97.8 (10.1)
Prog/–BF	22	66.4 (7.9)	0.5 (0.80)	29.2 (1.2)	100.1 (5.8)
Max/+BF	21	63.4 (5.6)	0.2 (0.54)	29.6 (0.75)	92.7 (12.8)
Prog/+BF	20	61.6 (5.2)	0.3 (0.55)	29.2 (1.2)	95.2 (9.2)

*Note.* EAT-10 = Eating Assessment Tool; MMSE = Mini-Mental State Examination; Max = maximum intensity resistance; BF = visual biofeedback during exercise; Prog = progressive resistance intensity.

28.0; IBM Corp.) was used to conduct all statistical analyses.

## **Results**

## **Participant Demographics**

Recruitment was open from June 2021 to August 2022. Eighty-seven participants were enrolled (61 women) in the study and were randomly assigned to one of the four exercise groups. Three participants did not complete the protocol and were not included in the final data analyses. Reasons for withdrawal included two participants not returning for scheduled study visits and one participant having schedule conflicts for continued participation. Data from 84 participants (60 women, 24 men) were included in data analyses. The combined mean age was 64.0 years (SD 6.6, range: 55-82 years). Table 4 outlines the average demographic and screening information for each study group. There was no significant difference between exercise groups for age, F(3, 83) = 2.02, p = .12, or for any of the screening measures, Eating Assessment Tool, F(3,(83) = 0.84, p = .47, and MMSE, F(3, 83) = 0.69, p = .56.Given no baseline group differences for average demographic and screening information, we can presume that the randomization procedures of the study design were successful.

#### MIP

There was no significant difference between the IOPI baseline data collected on two separate visits for MIP, t(83) = -0.49, p > .05, d = -0.053. Therefore, the mean baseline MIP was calculated as the average of the two baselines. The mean baseline for the MIP task was 47.7  $\pm$  10.1 kPa (range: 20.6–78.4 kPa).

A mixed ANOVA examined the differences between groups and within each group across time. The two-way interaction between time (study visit week) and group was not statistically significant, indicating that there were no differences in MIP changes across time between the groups, F(3, 80) = 1.06, p > .05, partial  $\eta^2 = .04$ . There was a main effect for time, F(1, 80) = 101.07, p < .001, partial  $\eta^2 = .56$ . Post hoc testing demonstrated a treatment effect from baseline to Week 8 with large effect sizes for all exercise groups (see Table 5), indicating all groups significantly increased their MIP with treatment. Cohen's U<sub>3</sub> ranged from 80.5–94.9 (Max/–BF and Max/+BF, respectively), representing the percentage of participants who improved above their baseline MIP values.

#### Regular Effort Saliva Swallow Pressure

There was no significant difference between the IOPI baseline data collected on two separate visits for regular

	Group											
Visit	Max/-BF	p**	d	Prog/-BF	p**	d	Max/+BF	p**	d	Prog/+BF	p**	d
Baseline	46.6 (8.7)			45.1 (11.5)			45.9 (8.7)			53.5 (9.7)		
Week 2	50.9 (12.3)			46.7 (10.1)			51.6 (9.3)			57.9 (11.5)		
Week 4	53.8 (11.5)			49.1 (13.0)			55.3 (9.2)			61.6 (14.0)		
Week 6	52.3 (9.5)			50.6 (13.1)			57.2 (10.8)			60.2 (12.3)		
Week 8	55.1 (13.1)	< .001*	86	53.3 (13.0)	< .001*	-1.14	58.2 (9.5)	< .001*	-1.64	65.0 (14.8)	< .001*	98

Table 5. Mean (standard deviation) maximum isometric lingual pressures (kPa) by visit and group.

Note. kPa = kilopascals; Max = maximum intensity resistance; BF = visual biofeedback during exercise; Prog = progressive resistance intensity.

\*Significant at < .0125 with Bonferroni adjustment. \*\*One-sided p value and effect size d from paired-samples t tests comparing maximum isometric pressure at baseline and Week 8.

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effort saliva swallow pressure, t(83) = -1.46, p > .05, d = -0.16. Therefore, the mean baseline regular effort saliva swallow pressure was calculated as the average of the two baselines. The mean baseline for this task was  $16.9 \pm 8.89$  kPa (range: 1.4–44.6 kPa).

The two-way interaction between time (study visit week) and group was not statistically significant, indicating that there were no differences in saliva swallow pressure across time between the groups, F(3, 80) = 0.53, p > .05, partial  $\eta^2 = .02$ . There was a main effect for time, F(1, 80) = 16.64, p < .001, partial  $\eta^2 = .17$ . Post hoc testing demonstrated a significant change in swallowing pressure by Week 8 for the Max/+BF group only (see Table 6). At Week 8, there was no significant difference in regular effort saliva swallow pressure gains between visual biofeedback groups (+BF vs. -BF), F(1, 82) = 1.34, p = .25, partial  $\eta^2 = .02$ .

## Maintenance

For enrollment randomization at each study site, half of the expected sample within each exercise group was randomly assigned to complete the maintenance exercise program. Out of the 84 complete data sets for the study, two participants assigned to the maintenance program did not complete the 1-month follow-up visit. Two participants assigned to the maintenance program completed only 25% of their maintenance exercises (1 day) and, therefore, were recorded as having nonmaintenance status. Thus, 45 participants were coded as having nonmaintenance status and 37 participants were coded as having maintenance status. For MIP, a comparison of Week 8 and 1-month postvisit demonstrated a nonsignificant three-way interaction between time, group, and maintenance status (yes/no), F(3, 72) = 2.3, p = .08, partial  $\eta^2 =$ .09. There was no interaction between time and maintenance status, F(1, 72) = 0.05, p = .82, partial  $\eta^2 = .001$ . Regardless of the maintenance status, there was no difference between MIP values at Week 8 and 1-month postvisit, F(1, 72) = 0.09, p = .77, partial  $\eta^2 = .001$ .

For regular effort saliva swallow pressure, the threeway interaction between time (Week 8, 1-month postvisit), group, and maintenance status (yes/no) was not statistically significant, F(3, 72) = 0.17, p > .05, partial  $\eta^2 = .007$ . There was no interaction between time and maintenance status, F(1, 72) = 1.3, p = .25, partial  $\eta^2 = .02$ . Across maintenance status, there was no difference in regular effort saliva swallow pressure values at Week 8 and 1-month postvisit, F(1, 72) = 0.32, p = .58, partial  $\eta^2 = .004$ .

## Mode of Delivery

A main effect for biofeedback comparing maximum resistance intensity to submaximal resistance intensity groups was not found. Therefore, groups with biofeedback were compared to those without, regardless of assigned intensity. At Week 8, there was no significant difference in MIP gains between participants using a visual biofeedback device during exercises and participants not using a visual biofeedback device for exercises, F(1, 82) = 3.15, p = .08, partial  $\eta^2 = .04$ .

### Adherence

Three participants did not provide their exercise logs at the final study visit (one each from the Max/–BF, Progressive/–BF, and Max/+BF groups). Mean patient-reported adherence was 97% (range: 49%–117%). Average adherence for each group is reported in Table 4. There were no differences in adherence levels between groups, F(3, 80) = 2.45, p > .05, partial  $\eta^2 = .08$ . Adherence did not change over the course of 8 weeks of exercise (p > .05), and adherence level was not correlated with gains in tongue strength for either of the outcome measures (p > .05).

## Borg Scale Scores of Perceived Effort

There was no significant median difference between the two baseline Borg measures for the MIP task, z = -0.24, p > .05. Therefore, mean baseline Borg was

Table 6. Mean (standard deviation) regular effort saliva swallow pressures (kPa) by visit and group.

		Group										
Visit	Max/-BF	p**	d	Prog/-BF	p**	d	Max/+BF	p**	d	Prog/+BF	p**	d
Baseline	16.8 (10.2)			14.1 (7.6)			16.8 (6.8)			20.3 (10.1)		
Week 2	17.6 (9.8)			17.2 (13.0)			21.1 (8.8)			22.1 (17.0)		
Week 4	21.4 (12.8)			20.4 (17.2)			22.1 (12.9)			25.2 (19.4)		
Week 6	21.9 (14.8)			16.6 (11.8)			21.3 (13.0)			23.5 (14.7)		
Week 8	21.8 (15.5)	.034	42	17.6 (15.7)	.11	27	23.7 (14.0)	.008*	58	28.6 (22.1)	.02	51

*Note.* kPa = kilopascals; Max = maximum intensity resistance; BF = visual biofeedback during exercise; Prog = progressive resistance intensity. \*Significant at < .0125 with Bonferroni adjustment. \*\*One-sided*p*value and effect size*d*from paired-samples*t*tests comparing regular effort saliva swallow pressure at baseline and Week 8.

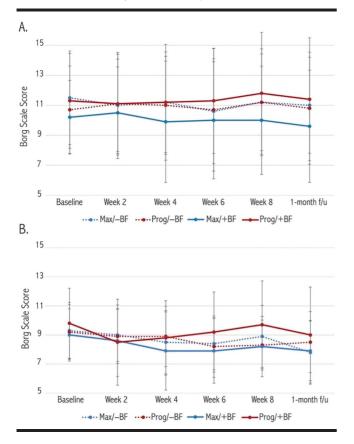
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calculated as the average of the two MIP Borg baselines. The mean MIP Borg scores at baseline, Week 8, and 1-month postvisit were  $10.9 \pm 2.9$ ,  $11.2 \pm 3.6$ , and  $11.2 \pm 3.7$ , respectively. There was no significant median difference between the MIP Borg scores at baseline and Week 8, z = -1.17, p > .05, or Week 8 and 1-month postvisit, z = -0.55, p > .05. Median Borg scores for the MIP task were not significantly different between exercise groups at baseline,  $\chi^2(3) = 1.25$ , p > .05, at Week 8,  $\chi^2(3) = 1.62$ , p > .05, or at 1-month postvisit,  $\chi^2(3) = 5.62$ , p > .05; see Figure 1.

There was no significant median difference between the two baseline Borg measures for the regular effort saliva swallow pressure task, z = -1.91, p > .05. Therefore, mean baseline Borg was calculated as the average of the two regular effort saliva swallow pressure Borg baselines. The mean Borg scores at baseline, Week 8, and 1month postvisit for regular effort saliva swallow pressure were  $9.3 \pm 2.0$ ,  $8.8 \pm 2.3$ , and  $8.8 \pm 2.5$ , respectively. There was a significant median difference between the

**Figure 1.** Descriptive data showing trend for participants' Borg scale scores of perceived effort (A) remaining stable over time for maximum isometric pressure and (B) decreasing over time for regular effort saliva swallow pressure. Max = maximum intensity resistance; BF = visual biofeedback during exercise; Prog = progressive resistance intensity; f/u = follow-up.



regular effort saliva swallow pressure Borg scores at baseline and Week 8, z = -2.89, p < .05, but no significant median difference between Week 8 and 1-month postvisit, z = -0.38, p > .05. Median Borg scores for the regular effort saliva swallow pressure task were not significantly different between exercise groups at baseline,  $\chi^2(3) = 1.28$ , p > .05, at Week 8,  $\chi^2(3) = 3.68$ , p > .05, or at 1-month postvisit,  $\chi^2(3) = 2.80$ , p > .05; see Figure 1.

## Discussion

Our research questions involved the impact of resistance intensity dosing parameter of exercise prescription, a 4-week maintenance exercise program, and the mode of delivery (visual biofeedback use or not) on tongue pressure generation, the impact of resistance intensity and mode of delivery on participant adherence to exercise protocol, and the impact of the related factor of fatigue/ perceived effort on tongue pressure generation tasks. Main findings include significantly increased tongue pressure generation for all exercise groups, no deconditioning effect observed after 4 weeks, and no significant main effect of visual biofeedback. A general high level of adherence to exercise protocol was demonstrated by all exercise groups and was not associated with gains in tongue pressure generation. Finally, participants' perceived level of effort for the regular saliva swallow task did appear to decrease over time.

Within a standard framework of resistance exercise design for typically aging adults (i.e., initial light intensity that progresses, frequency  $\geq 2$  days a week, three sets of 10 repetitions for beginners; Borde et al., 2015; Liguori & ACSM, 2021), intensity/progression, and visual biofeedback were manipulated to better understand potential, differential tongue response to the varied approaches. Intensity was chosen as the dosing parameter of focus for this work for two reasons: (a) It was included in recommendations for examining the dose-relationship in dysphagia rehabilitation moving forward (Krekeler, Rowe, & Connor, 2021), and (b) Intensity has been found to be the best predictor of the effect of resistance training on muscle strength in work focused on dose-relationship of exercise in typically aging adults (Borde et al., 2015).

## **Tongue Pressure Generation**

Contrary to our hypothesis that the groups using progressive resistance would show the greatest gains in tongue pressure generation, this study found that all exercise groups showed similar significant gains and large effect sizes in MIP following 8 weeks of tongue resistance exercise. Manipulation of the intensity parameter has been studied previously (Van den Steen et al., 2019), but not within the context of progressive resistance versus pushing at a consistent proportion of one repetition max. Van den Steen et al.,'s (2019) study suggests that tongue pressure generation improves regardless of intensity targeted during exercise (specifically 60%, 80%, and 100% of an individual's 100% maximum force). Our MIP findings confirm that the intensity parameter of dosing for tongue resistance exercise may not represent the most important dosing factor. Furthermore, our findings suggest that tongue muscles do not appear to respond differently to progressive resistance versus consistent maximal effort.

All exercise groups increased regular effort saliva swallow pressure following the exercise regimen, but only the Max/+BF exercise group showed significant change from baseline (with a medium effect size) following 8 weeks of exercise. This suggests that if increasing oral swallowing pressures is the target of tongue resistance exercise, the approach of maximum intensity using visual biofeedback is most effective. The findings lend some weight to the transference principle of neural plasticity (Kleim & Jones, 2008) given that tongue resistance exercise led to functional improvement in swallowing pressure generation, a task that was not practiced over the 8-week exercise regimen. In other words, tongue resistance exercise does tap into the transference principle to induce functional swallowing outcomes, though instrumental findings are needed to fully support the transference of increased strength to functional and physiological swallowing outcomes. This study did not include instrumental assessment of functional swallowing, but previous studies present preliminary instrumental findings to suggest transference as a potential and important aspect of tongue resistance exercises (Robbins et al., 2005, 2007). Our findings suggest that, to tap into transference of tongue resistance exercise-to-swallow function, maximum intensity exercise may be required.

This study also affirms saliva swallowing as a submaximal task (Fei et al., 2013; Peladeau-Pigeon & Steele, 2017; Robbins et al., 1995) and confirms the variability of pressures generated for regular effort saliva swallow pressure in typically aging adults (Peladeau-Pigeon & Steele, 2017). Peladeau-Pigeon and Steele (2017) reported baseline regular effort saliva swallow pressure measurements using the IOPI in typically aging persons as much higher values (M of 39.5 across upper three age groups for women and men) than reported in this study (16.9 kPa). However, the participants in the 2017 study did receive continuous visual biofeedback during data collection. Our regular effort saliva swallow pressure measures appear to be more aligned with findings from seminal work on swallowing pressure (Robbins et al., 1995). At baseline, our participants had a regular effort saliva swallow pressure M of 36% (range: 4%–78%) of 100% maximum force with no change following 8 weeks of exercise (M of 37% of 100% maximum force). This is also a lower proportion than previously reported for both saliva (Peladeau-Pigeon & Steele, 2017) and bolus swallows (thin to puree; Youmans et al., 2009). Methodological and/or measurement differences likely contribute to some of the discrepancies discussed above.

These findings suggest some room for flexibility in the design of a tongue resistance exercise program in terms of intensity level and progression, as all approaches were effective for increasing tongue pressure generation. Our findings provide a launching point when considering prescription of dosing intensity and delivery mode, with the goal of a patient-centered approach in future prescription research. For example, instruction to push with maximum effort for each repetition may be more appropriate for a patient who needs to improve oral tongue pressure for bolus clearance (e.g., sarcopenia, head/neck cancer) or a patient with cognitive impairment in need of a simple instruction. On the other hand, for a higher level patient with traumatic brain injury or stroke for whom the clinician wants to enhance the cognitive demand of the exercise, a progressive resistance approach to tongue resistance exercise may represent the best approach. Motor planning and organization for a motor task can be internally simulated or overtly executed, and both forms require motor and cognitive processes (Mulder, 2007; Schaefer et al., 2022). Hypothetically, motor imagery, a motor-cognitive network that is involved in both overt and covert action (Jeannerod, 2001), may be engaged by a demanding task such as submaximal progressive resistance. This work contributes to the foundation for tongue exercise protocols, although, as Krekeler, Rowe, and Connor (2021) highlight, optimal dosing for each exercise pertinent to swallowing will need to be explored according to individual and population factors (e.g., etiology of dysphagia, age, sex, medical status).

## Maintenance

Both MIP and regular effort saliva swallow pressure performance were maintained over a 1-month period for all participants. That is, the data do not suggest a detraining effect after 4 weeks, even for the participants who did not complete a maintenance program. This finding is comparable to more recent studies that also suggest resistance of tongue muscles to deconditioning following tongue resistance exercise (Oh, 2015; Van den Steen et al., 2018, 2019). However, the trend is hard to generalize across study findings, given the various types of exercise protocols and instrumentation used, as well as the use of different timeframes to assess deconditioning. This finding contrasts with the reported detraining of skeletal limb musculature after 4 weeks (Burkhead et al., 2007; Mujika & Padilla, 2001). Although aging may increase the vulnerability to deconditioning (Ivey et al., 2000; Toraman, 2005; Van den Steen et al., 2018), this effect was not noted in our sample. Future research is needed to examine detraining at different time points posttreatment, in various clinical populations, and in relation to functional swallowing outcomes.

## Biofeedback

Contrary to our hypothesis that the groups using a visual biofeedback during exercise would show the greatest gains in tongue pressure generation, this study found no effect of biofeedback by Week 8 (post-intervention) for either MIP or regular effort saliva swallow pressure. That is, the participants who did not use the Tongueometer device during exercise made the same gains in tongue pressure generation as the participants who used the Tongueometer during exercise. However, a post hoc power analysis (G\*Power 3.1) indicates this study may be underpowered to show the effect of biofeedback (38 participants needed in each group compared to the 20-22 currently included). We did see a nonsignificant trend toward biofeedback effect with our current MIP data (p = .08) with a small to medium effect size and anticipate that future research will likely elucidate the utility of visual biofeedback during exercise using tongue manometry devices. This trend aligns with review work, showing that the use of biofeedback in dysphagia rehabilitation appears promising (Benfield et al., 2019). Both short- and long-term effects of augmenting physical rehabilitation with biofeedback warrant investigation (Benfield et al., 2019; Stanton et al., 2017). However, it is notable that there was no biofeedback trend for the saliva swallow pressure outcome.

# Adherence

There was overall high self-reported adherence to the exercise protocol and a high completion rate of exercise logs, in contrast to review work highlighting low adherence in dysphagia rehabilitation (Krekeler et al., 2018). Our finding of high adherence could be different than low adherence reported for patients with dysphagia because our study included typically aging healthy adults. However, adherence data in dysphagia rehabilitation research have historically not been tracked and/or reported and researchers are urged to continue documenting adherence when developing management approaches (Krekeler, Vitale, et al., 2020). The different approaches to intensity dosing, progression, and delivery using biofeedback in this study did not influence adherence level in this study's investigation. Stated another way, no component of the exercise protocols in this study seemed to deter participants from completing their exercises; however, this could prove different for a sample of participants with dysphagia.

# **Perceived Effort**

A final consideration is perceived effort as an indication of perceived fatigue level during swallowing-related tasks. Due to the morphological structure of tongue muscle fiber type composition, the tongue may be fairly resistant to fatigue in healthy individuals (Kent, 2004; Stål et al., 2003), even with maximum effort pushing during exercise (Van den Steen et al., 2019). However, there are some indications that lingual fatigue can be induced and impact nonspeech and speech tasks (Solomon, 2000, 2006) and swallowing-related measures (Brates & Molfenter, 2021). Participants in this study provided their Borg scale ratings of perceived effort for MIP and regular effort saliva swallow pressure tasks at each study visit. Participant perceived effort of tongue pressure generation tasks decreased over time for regular effort saliva swallow pressure. For MIP, average participants' scale scores of perceived effort remained in the "very light-to-fairly light" range. For regular effort saliva swallow pressure, average participants' scale scores of perceived effort started "very light," and lowered to an average "very, very light-to-very light" range following 8 weeks of tongue resistance exercise.

Viewed as an index of perceived fatigue level, even though perceived effort for MIP remains stable during exercise, swallowing pressure may start to be perceived as less effortful over time. This finding suggests that the tongue resistance exercise program facilitated a lower level of perceived effort during swallowing for typically aging adults. This warrants further investigation, given evidenced perception and behavioral signs of fatigue across a meal in typically aging persons (Brates et al., 2022; Brates & Molfenter, 2021).

However, it is important to note that fatigue involves multiple factors, including consideration of central versus peripheral contributions, and is challenging to quantify in dysphagia (Solomon, 2006; Tornero-Aguilera et al., 2022). It is possible that the Borg scale (Williams, 2017) is not sensitive enough to tongue pressure generation tasks. The scale's application to perceive vocal effort before and after intervention has preliminarily been investigated (van Leer & van Mersbergen, 2017), but has not been studied extensively in dysphagia. Anecdotally, participants at different study sites reported difficulty in matching their perceived effort level for MIP and regular effort saliva swallow pressure tasks using Borg description examples that are written for general exercise using whole body terms. Additional research on perceived effort/ fatigue and its relationship to clinical measurements is needed in dysphagia rehabilitation.

# Limitations

This study represents a proof-of-concept investigation in typically aging adults-generalizations cannot be conclusively made to clinical populations with dysphagia. Additional evidence is needed for dosing optimization of tongue resistance exercise in both typically aging adults and various dysphagic populations. This study did not include instrumental outcome measurements to determine functional swallowing outcomes that may result from gains in tongue pressure generation; however, significant changes in swallowing function may not be observable in typically aging adults who do not demonstrate notable baseline dysfunction. The inclusion of a control group would have strengthened the study design. It is possible that the progressive intensity with biofeedback exercise group experienced some intensity range overlap during exercises, given that their Tongueometer range was set to  $\pm 25\%$  of target intensity. It would not have been feasible to require these participants to hit an exact pressure target for each repetition, and pilot work before enrollment showed that  $\pm 25\%$  was the most feasible range for this exercise group. However, even with some potential intensity range overlap in this exercise group, the ACSM's guideline for exercise prescription with older healthy adults classifies 40%-50% of an individual's 100% maximum force as "light intensity" and 60%-80% as "moderate-to-vigorous intensity" (Liguori & ACSM, 2021). Therefore, even if there was some overlap of intensity ranges during exercise for this group, it is likely that most participants were exercising at a light intensity for the first 2 weeks and a moderate-tovigorous intensity for the remainder of the protocol. Intensity modulation and accuracy remain an outstanding challenge in dosing for lingual exercise. Adherence data were collected via participant self-report, which is subject to over- or underreporting (Krekeler, Yee, et al., 2021), and, thus, may include some inaccurate reporting. Finally, the detraining period likely represented a short-term investigation of deconditioning; longer and repeated follow-up investigations are needed to determine maintenance interval requirements.

## Conclusions

The tongue may be unique from other skeletal muscles in its response to dosing and delivery parameters of tongue resistance exercise. This may lend to some flexibility in design when considering prescriptive intensity of tongue resistance exercise to meet different patient characteristics and facility resource availability. Typically, aging adults appear to show high levels of adherence (buy-in) to tongue resistance exercise and a 4-week maintenance program was not necessary to preserve gains in tongue pressure generation performance in this population. Additional research is needed for dose optimization and functional swallowing outcomes with tongue resistance exercise, though our preliminary work suggests that swallowing pressure improves with gains in tongue pressure generation, and improvement in regular effort saliva swallow pressure may be most efficacious using a maximum intensity with biofeedback approach.

# **Data Availability Statement**

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

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## Appendix

Rating of Perceived Exertion Borg Rating of Perceived Exertion Scale

6		How you feel when lying in bed or sitting in a chair relaxed?
7	Very, very light	Little to no effort.
8		
9	Very light	
10		
11	Fairly light	
12		Target range: How you should feel with exercise or activity?
13	Somewhat hard	
14		
15	Hard	
16		
17	Very hard	How you felt with the hardest work you have ever done?
18		
19	Very, very hard	
20	Maximal exertion	

Note. Information from https://www.cdc.gov/physicalactivity/basics/measuring/exertion.htm.