Phonation Resistance Training (PhoRTE) With And Without
Expiratory Muscle Strength Training (EMST) For Patients With Presbyphonia

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(PhoRTE/EMST Study)

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Abstract

Respiratory and phonatory systems undergo various changes with age that can lead to changes in voice production. This condition is known as Presbyphonia. As respiratory muscles play a pivotal role in voice production. We aim to use an expiratory muscle strengthening training (EMST) device , in addition to standard therapy (Phonation resistant training exercise - PhoRTE) to improve voice outcomes in patients with Presbyphonia. The subjects with vocal atrophy will be enrolled and randomized into two groups: (a) Only Phonation resistant training exercise (PhoRTE) (b) PhoRTE with EMST. The outcomes measures will be pre and post acoustic and aerodynamic measures, Voice Handicap Index - 10 (VHI – 10), and Aging Voice Index (AVI).

Background and Introduction

The phonatory and respiratory systems undergo many age-related changes in their anatomy and physiology that can lead to undesirable effects on the voice. These changes have detrimental effects on the lives of elderly individuals. Few studies have evaluated the use of voice therapy treatment options for age-related voice disorders. The aim of this study is to compare a voice therapy program developed specifically for patients diagnosed with presbyphonia, Phonation Resistant Training Exercises (PhoRTE), with and without the addition of an expiratory muscle strength training (EMST) protocol that has been shown to strengthen the expiratory respiratory muscles. We hypothesize that the addition of EMST to PhoRTE is at least as effective as PhoRTE alone in treating vocal fold atrophy in elderly patients.

Objective

The primary objective of this study is to identify if there is additional benefit of providing EMST training to the individuals with Presbyphonia. We aim to compare the outcome measures between the two groups to conclude the results.

Outcomes

Outcomes will be collected at the start of the study, at the start of each therapy session, and during one-week post-therapy follow-up.

This study is a two arm, prospective randomized investigation to examine the impact of PhoRTE and EMST on VHI-10, AVI, acoustic, aerodynamic, and auditory-perceptual outcomes collected pre-(baseline) and post-intervention (short-term follow-up).

VHI-10

The primary outcome is the Voice Handicap Index-10 (VHI-10) score.25 The VHI-10 is a patient-centered outcome that quantifies a patient's perception of handicap caused by a voice disorder and will be measured at every session. VHI-10 will be anchored to baseline VHI-10 score (each item anchored) for the 1 week follow-up (will be administered without anchoring. Secondary outcomes include the following:

AVI

The Aging Voice Index (AVI) is a new patient-centered outcome that quantifies quality of life impact a voice disorder has on older adults. It will be compared at baseline and during the final 1-week follow up.

Aerodynamic Measures

Average airflow in speech, average number of breaths, average duration of a standard reading passage (The Rainbow Passage). Our prior work has demonstrated sensitivity to change following treatment for these acoustic and aerodynamic measures.

Acoustic Measures

Cepstral Spectral Index of Dysphonia (CSID), a multifactorial estimate of dysphonia severity that correlates with the visual analog scale for overall voice severity used in the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V), Cepstral Peak Prominence and its standard deviation, Cepstral Peak Prominence Fundamental Frequency (CPP F_0) and its standard deviation, and average vocal intensity in dB SPL.

Voice Quality by Blinded Raters

Overall voice severity determined by CAPE-V score provided by blinded raters.

Study design and Methods

This is a prospective study. University of Pittsburgh will be recruiting patients as well under their own IRB. Emory participants will be voice patients from the Emory University Voice Center. A research coordinator will review clinic schedules to identify potential participants and will alert the clinical team members by affixing a notice to the potential participant's chart. Once the clinical team has determined eligibility for the study based on evaluation/diagnosis, potential participants will be contacted and offered the opportunity to participate in the study. If the patient agree to participate they will be randomized to either of the study arms: (a) Only PhoRTE (b) PhoRTE with EMST. A randomization table will be created prior to recruit to determine the treatment assignment for each patient.

Participants

N=28 male and female participants diagnosed with vocal fold atrophy. 14 patients will be recruited for each arm of the study.

Inclusion/Exclusion

Age 65 years or older with chief complaint of a voice problem with VHI-10 >=1. Primary diagnosis of vocal fold atrophy only as determined by a multi-disciplinary team of fellowship-trained laryngologist and voice-specialized speech-language pathologist, and willingness to be randomized to treatment option. No concomitant laryngeal diagnoses or diseases known to affect voice function, including: amyloidosis, arytenoid dislocation, laryngeal cancer, cricoarytenoid fixation, vocal fold cyst(s), vocal nodules, vocal fold polyp(s), dysplasia, vocal fold fibrous mass(es), glottal web, vocal fold immobility, laryngeal stenosis, laryngocele, leukoplakia,

Parkinson's disease, Reinke's edema, respiratory recurrent pneumonia, sarcoidosis, spasmodic dysphonia; any chronic lower airway disease such as chronic obstructive pulmonary disease (COPD), asthma, chronic bronchitis, emphysema, cystic fibrosis; history of acute stroke, untreated hypertension, or untreated gastroesophageal reflux disease (GERD).

Consent
A trained study team member will be responsible for recruiting patients. On the day of their first visit, the informed consent will be obtained. The informed consent process will occur in a private room before starting any therapy. The participants will be randomized to either of the study arms, if they consent.

Intervention/Experimental Protocol

Outline Of Procedures
The experimental protocol consists of pre-treatment and post-treatment acoustic and aerodynamic data collection and four 45-minute sessions of voice therapy. All subjects will complete PhoRTE therapy, and those in the EMST+PhoRTE arm in the study will also undergo EMST training. Before each PhoRTE therapy, subjects will report to the PI so that therapists are blinded as to which treatment group each subject is in.

Baseline	Therapy 1	Therapy 2	Therapy 3	Therapy 4	Post-Tx
Pre-Tx Acoustic and Aerodynamic Measurements, VHI-10, AVI, MEP	PhoRTE +/- EMST VHI-10 MEP	PhoRTE +/- EMST VHI-10 MEP	PhoRTE +/- EMST VHI-10 MEP	PhoRTE +/- EMST VHI-10 MEP	Acoustic and Aerodynamic Measurements, VHI-10, AVI, MEP

PhoRTE Therapy (Standard of Care Treatment)
Each therapy session will last for 45 minutes.
1st PhoRTE treatment session
- Check in with your patient about current status
    - Do you have any questions since we last met? Do you have any concerns about your ability to commit to PhoRTE?
- Check in with the patient to verify implementation of voice care program
    - Dehydration, non-phonatory inflammation (reflux, illness)
    - Phonotrauma (throat clearing, cough)
    - Caffeine
- Provide patients with PhoRTE therapy information sheets, phrase list, and practice sheets
- Set up the patient for home practice
    - Verify that patient is able to download a decibel meter app successfully, and configure the app's settings with a sound pressure level meter for home practice

- o Orient the patient to the app; teach them how to open and utilize the app for home practice; demonstrate for the patient how to standardize mic-to-mouth distance
  - o Verify that 10 functional phrases for practice are written. Review phrases for length and that they are representative of typical communication
- Teaching proper breathing form
  - o Establish efficient respiratory mechanisms to effectively execute PhoRTE exercises
  - o Ex. "Place your hand on your upper abdomen just above your belly button. Now, I want you to sustain the sound "sh" for as long as is comfortable. Notice the inward movement of your hand as you exhale and sustain "sh." Let's practice this breathing a few more times until you feel comfortable with this task."
  - o Tip for clinician → monitor for hyper-functional muscle use in the abdomen and throat during these breathing tasks by visually or auditorily identifying any extraneous tension as well as by eliciting patient report
- Teaching increased pulmonary drive
  - o Clinician: "Now let's practice the same task but make the "sh" stronger. This type of breathing is what you'll need to effectively exercise your voice during PhoRTE. Notice that your hand moves in further and faster because you have to use more air to produce that "sh" with strength. Let's practice this breathing a few more times until you feel comfortable with the task."

Before therapy sessions
- Determine noise level in treatment room
- Position sound level meter 12 inches from patient's mouth
- Sustain /a/ at modal pitch and comfortable loudness; have patient use speaking voice in two takes – Rainbow Passage and monologue of 30-60 sec
- Calculate the patient's vocal intensity range (i.e. maximum dB SPL minus minimum dB SPL
- The starting PhoRTE vocal exercise target is 50-60% of dynamic range, and add dB SPL amount to average vocal intensity of monologue
- Complete EMST calibration and MEP measurement (see description below)

Exercise 1 – Phonation-Respiratory Isotonics (PhoRTE-ISO)
- Clinician: "Place your hand on your upper abdomen. Now, I want you to sustain the sound "ah" with a strong, energized voice for as long as your are able. Your starting vocal intensity is_____dB. You will need to achieve your target vocal intensity and maintain it during the entire "ah" to get maximal benefit from this PhoRTE exercise. I want you to check that your mouth is at the appropriate distance from the app. Let's practice this first PhoRTE exercise a few times until you feel comfortable with the task. Remember to record on your PhoRTE log the length of time you are able to hold each "ah.""

Exercise 2 – Eccentric-Concentric Cricothyroid Contraction (PhoRTE-EC)
- Clinician: "Just like stretching exercises are good for your arms and legs to keep you young and flexible, first we are going to produce an ascending and descending pitch glide with a strong, energized voice without strain. Place your hand back on your upper abdomen. Again, your starting target vocal intensity is_____dB. You will need to achieve your target intensity and maintain it during the entire pitch glide. If you have difficulties achieving a strong, energized voice at the low wend of your range, don't worry. That's typical. After completing five ascending-descending glides, then reverse and produce five descending-ascending glides with a strong, energized voice without strain."

Exercise 3 – Phonation-Respiratory Power Endurance (PhoRTE-PE)
- Exercise A → functional phrases in a higher, energized calling voice
  - Clinician: "Place your hand back on your upper abdomen. Again, your starting target vocal intensity is_____dB. You will need to achieve your target intensity and maintain it during the production of functional phrases. The first time we are going to say the phrases in a higher pitch with an energized voice as if we are calling to our neighbor by throwing your voice." (Clinician demonstrates megaphone gesture with hands around mouth). Breathe as you feel necessary but avoid overtly large breaths before each subsequent
- Exercise B → functional phrases in a lower, energized voice of authority
  - Clinician: "Place your hand back on your upper abdomen. Again, your starting target vocal intensity is_____dB. You will need to achieve your target intensity and maintain it during the production of functional phrases. This time we are going to say them in a lower pitch with an energized voice of authority. Breathe as you feel necessary but avoid overly large breaths before each subsequent sentence."
- Tips to the clinician
  - Start at resting expiratory level (the point in the breathing cycle at the end of quiet expiration). Beware they are not breath holding or using a strained/pressed production. The goal is for the patient to increase muscle activity of the abdominal musculature rather than over-utilizing/straining laryngeal musculature. Encourage the patient to, at most, take a small replenishing breath between each phrase.
  - Natural variability in vocal intensity around the target dB will exist due to differences in speech sound sonority and linguistic stress patterns.
  - Some patients have more difficulty with the voice of authority (vs. the calling voice). This difficulty may be due to a number of sources: (1) the positive nature of the phrase does not lend itself to a voice of authority, for example, "I love you; (2) structurally, the nature of presbyphonia results in patients using laryngeal compensation to achieve better vocal fold closure, which leads to a higher pitch; (3) some people's personality or past experiences makes it uncomfortable for the patient to produce a voice of authority. The key for patients is to remember that this manner of production promotes the natural

pitch variability in conversation, and is not meant to conjure up negative feelings or emotions.

- o Have the patient observe an appropriate recovery period in which they sit silenty for a duration of 10-20 seconds between completion of exercises 3a and 3b. The purpose of the rest period is to, theoretically, clear lactic acid and other short-term metabolic effects of exercise.
- o Start at resting expiratory level (the point in the breathing cycle at the end of quiet expiration). Beware they are not breath holding or using a strained/pressed production. The goal is for the patient to increase muscle activity of the abdominal musculature rather than over-utilizing/straining laryngeal musculature. Encourage the patient to, at most, take a small replenishing breath between each phrase.

Exercise 4 – Phonation-Respiratory Muscular Endurance-Short (PhoRTE-ME)
- Clinician: "Place your hand back on your upper abdomen. Again, your starting vocal intensity is____dB. You will need to achieve your target intensity and maintain it while you are speaking. We are going to speak in a strong, energized voice for a minimum of 30 seconds but no more than 2 minutes. Breathe as you feel necessary but avoid overly large breaths before each subsequent sentence.

EMST Training (Study procedure)
The EMST device will be used to incrementally strengthen the respiratory muscles each week. The device will be calibrated each week using a manometer. Maximum expiratory pressure (MEP) will be measured before beginning each therapy session, and this will be used to calibrate the device for the weekly exercises. The device will be set to 75% of MEP for the week's exercises.

Recording Baseline and Post-Treatment Acoustic and Aerodynamic Measures
Participants will read the following sentences/exercises for measurement of acoustic and aerodynamic values:
Acoustic…
1) "The blue spot is on the key again."
2) "How hard did he hit him?"
3) "We were away a year ago."
4) "We eat eggs every Easter."
5) "My mama makes lemon muffins."
6) "Peter will keep at the park."
Aerodynamic…
    The Rainbow Passage: "When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end."

Home Practice Forms

☐ PhoRTE target vocal intensity: _____ dB
☐ PhoRTE target vocal effort: _____ /10

PhoRTE Voice Tasks	Reps	1	2	3	4	5	6	7	8	9	10	Comments
Ex 1 Strong and long PhoRTE ah												
Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												
Ex 1 Strong and long PhoRTE ah												
Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												
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Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												
Ex 1 Strong and long PhoRTE ah												
Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												
Ex 1 Strong and long PhoRTE ah												
Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												
Ex 1 Strong and long PhoRTE ah												
Ex 2 Pitch glides in PhoRTE voice												
Ex 3 Phrases in PhoRTE "calling" voice												
Ex 4 Phrases in PhoRTE "authority" voice												
Ex 5 Speak w PhoRTE voice for a noisy place												

Date (repeated for each block)

Write 10 phrases to speak us ng your strong PhoRTE voice. Sec the table below for gu dance on writing 10 functional phrases for PhoRTE Exercises 3 and 4.

Good Examples	Poor Examples
Hello, how are you? (5 syllables)	Hello. (too short)
I need my medication. [7 syllables)	I need my blood pressure medcation that I take every morning. (too bng)
Let's go for a walk this morning. (8 syllables)	Let's watch the solar ecipse. (not representative of daily demands)

1. _____

2. _____

3. _____

4.

_____

6. _____

7. _____

8. _____

9. _____

10. _____

## PhoRTE™ Home Practice Information Sheet

Complete 1 set of the PhoRTE voice tasks a total of 6 days per week. Track your progress by recording the results of your practice on the PhoRTE patient charting form.

Ex 1	Say AH in your strong PhoRTE voice for as long as possible without strain.
Ex 2	Glide on AH in your strong PhoRTE voice. 5x as low-high-low, 5x as high-low-high.
Ex 3	Speak your functional phrases in a strong and higher PhoRTE "calling voice".
Ex 4	Speak your functional phrases in a strong and lower PhoRTE "voice of authority".
Ex 5	Speak in a strong PhoRTE voice so you can be heard in a noisy restaurant.

OMNI Vocal Effort Scale

Some people do not have an app or meter to measure vocal intensity during their PhoRTE practice. In that case, use the following OMNI Effort Scale to complete the PhoRTE tasks at your target vocal effort. Always remember to stay at vocal effort level 6 (i.e., *somewhat hard*) when you complete your practice.

Based on the scale below, use the numbers from 0-10 to indicate how much effort you perceive when using your voice TODAY?
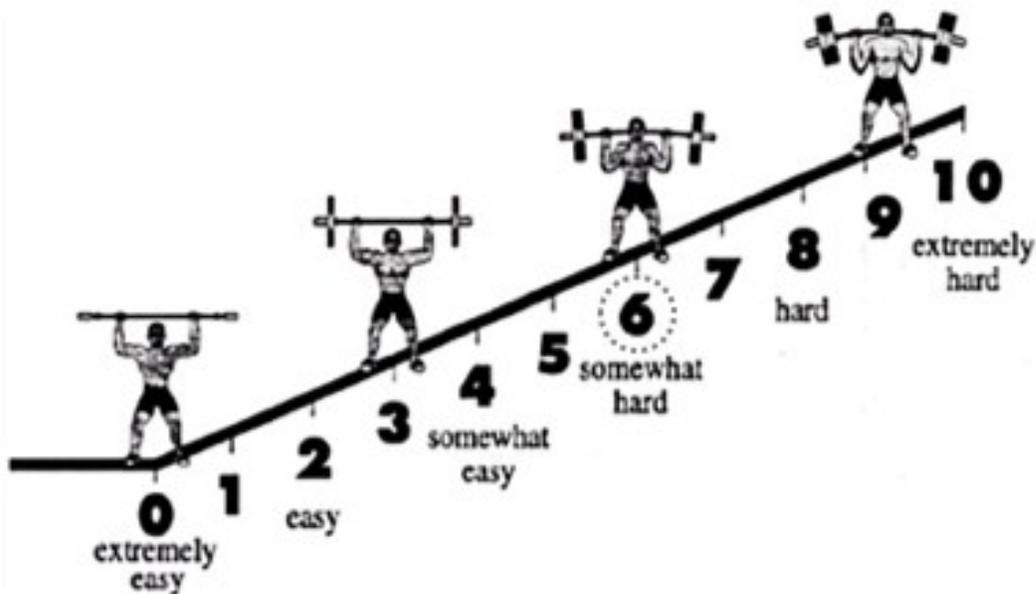
Data collection and Management

Research Electronic Data Capture (REDCap), will be used to manage all participant data from initial screening through study completion. Each subject will be given a subject number and patient's identifying information will be stored in the database. Once the data collection is completed, the data will be downloaded from the REDcap application in a way that all personal health identifiers are removed. The deidentifed data will be stored in a secure Emory server and shared with University of Pittsburgh for the purpose of analysis. All the personal identifiers will be kept only in REDcap database until the completion of study.

Database Design
Data will be collected and managed through REDcap database. It is a secure web application designed to support data capture for research studies, providing user friendly web-based case reports, data validation and a DE identified data export mechanism to statistical packages such as SAS, SPSS, STATA.

Data Entry
At the <u>start of each therapy session</u>, the study coordinator (PI or Co-I if study coordinator is not available) will have the participant sit in the Voice Research Lab and complete the following outcomes:
- MEP measurement through the manometer
- Complete VHI-10 in REDCap

The study coordinator will enter the following data into REDCap:
- Weekly practice logs for PhoRTE and/or EMST

Data Reduction
The PI will reduce the data according to the following protocol.

Acoustic
The sentence, "we were away a year ago" will be spliced and saved. File name: **SubjectID_acoustic_timepoint. Ex: 06_acoustic_week1.**
Next, the ADSV software will be used to compute: CSID, CPP, CPP F0, CPP F0 sd, avg vocal intensity in dB SPL.
Data entered in REDCap.

Aerodynamic
The passage will be reviewed and any errors or pauses deleted. The file will be saved. File name: **SubjID_aero_timepoint. Ex: 06_aero_week3.**
The User Protocol One software in PAS will be used to calculate Average airflow in speech, average number of breaths, average duration of reading passage.
Data entered in REDCap.

Auditory Perceptual Analysis
3 blinded raters (tbd) will listen to the sentence "we were away a year ago" and rate on 100mm VAS in REDCap. The initial and final evaluations will be rated, for a total of 2 samples per participant x 28 participants = 56 samples.
Raters will be paid $20/hour for ratings. Ratings should take in total 2 hour-long sessions.

Participant Payment
Participants will be compensated $100 in total, $10 for the initial intake measurements, $10 for each therapy session attended, and $50 for the 1-week follow-up after therapy is completed.

Safety

Adverse Events

An interim analysis will be conducted at the midpoint of the study to ensure that PhoRTE+EMST is safe. During the study, each participant will be asked if they perceive their treatment to be harmful to them. If participants evince a VHI-10 increase of greater than 5 points[34] *in addition to* reporting that voice therapy is harmful, then the study will be paused, re-evaluated, and possibly terminated. The study statistician (Dr. Rothenberger) will perform this interim analysis: clinical investigators will remain blinded to the results in order to avoid bias. Clinical investigators will only be informed of results if there is a substantial safety concern by the midpoint of the study.

Fidelity Checks

Each therapy session will be video-taped for future fidelity checks by the PI. These checks will ensure SLP accuracy in delivering CTT skill instructions, homework instructions, and maintaining conversation as the sole therapeutic stimulus. The review will occur after session 2 and 4 so that the PI can provide feedback to the SLP.

Data Analysis Plan

The purpose of the study is to measure any differences in the two study arms. Thus, t-test will be performed. Descriptive statistics will be utilized to identify the normality of the data.

Summary

The results from this study will allow the clinicians to improve patient outcomes. Hopefully, this study will be a precursor to future studies, aimed at treating Presbyphonia.

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