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Vocal Function Exercises for Normal Voice: The Effects of Varying Dosage

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VOCAL FUNCTION EXERCISES FOR NORMAL VOICE: THE EFFECTS OF VARYING DOSAGE

THESIS

A thesis submitted in partial fulfillment of the requirements for the
degree of Master of Science in Communication Sciences and Disorders
in the College of Health Sciences
at the University of Kentucky

By

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ABSTRACT OF THESIS

VOCAL FUNCTION EXERCISES FOR NORMAL VOICE:
THE EFFECTS OF VARYING DOSAGE

The primary purpose of this investigation was to explore the effects of variable doses of home practice Vocal Function Exercises (VFEs) on attainment of pre-established maximum phonation time (MPT) goals in individuals between the ages of 18 and 25 with normal voice. A secondary purpose was to monitor for potentially toxic effects of high doses of VFEs. Three experimental groups completed a six-week VFE protocol and practiced twice daily. The low dose group performed each exercise once, the traditional group twice, and the high dose group four times. Results indicated significant change in VFE MPT for all three groups and higher goal attainment in the high dose group. Low doses appear insufficient to produce substantial change in voice production. Acoustic MPT improved most in the traditional dosage group, which also exhibited best maintenance and best overall outcomes. No toxic effects in vocal fold condition or phonation were observed or measured secondary to high VFE exposure.

KEYWORDS: Vocal Function Exercises, dose, intensity, maximum phonation time, compliancy, voice disorders

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VOCAL FUNCTION EXERCISES FOR NORMAL VOICE: THE EFFECTS OF VARYING DOSAGE

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Chapter One: Introduction

While many Phase 1 trials demonstrate positive treatment effects for various interventions in speech-language pathology, most treatments currently employed have little to no information from Phase 2 trials providing guidance on dose-response relationships (Roy, 2012). This issue is especially salient in the area of voice therapy, where dosing can mean the difference between no effect, the ideal effect, and toxic or adverse effects. In fact, Titze (1994) suggested that vocal fold injury can occur as a result of exceeding a certain "vibration dose," and many clinicians believe that vibration overdose is toxic. Due to this belief, a common approach is to limit acceleration and shearing forces on the vocal fold mucosa. Traditionally, vocal load has been reduced using intervention approaches such as vocal hygiene, which seeks to eliminate phonotraumatic behaviors and educate clients about vocal health. However, vocal load can also be reduced by exercises that train the vocal mechanism in ways that increase the efficiency (and decrease the phonotrauma) of vibration (Titze, 2006). One such strategy is Vocal Function Exercises (VFEs), a direct training approach that seeks to strengthen and rebalance the laryngeal musculature and enhance the relationship among the three subsystems of voice: respiration, phonation, and resonance (Stemple, Lee, D'Amico, & Pickup, 1994).

While a variety of studies have demonstrated VFEs to be effective in enhancing both normal and pathological voices, little is known about the ideal dose, or the dose that yields the greatest benefit without causing damage (Roy, 2012). Because practicing these exercises increases vocal load by increasing vibration, and because VFEs require vocalizing at the extreme ends of the pitch range, it is conceivable that excessive amounts

of practice could result in damage to the vocal mechanism. Although these exercises must be carefully monitored in order to prevent potential harm, the VFE regimen also requires a substantial amount of home practice, meaning that the exercises are frequently performed independently and without clinical supervision (Roy, 2012). While according to Stemple et al. (1994) the standard protocol for home practice involves performing a set of four exercises two times each both morning and evening, clinicians actually know very little about the ideal dose for VFEs (Roy, 2012). Without more information regarding the dose-response relationship for VFEs, it is possible that the over-zealous patient, or even clinician, could misguidedly assume that more is better.

The Difficulty of Determining Dose for Behavioral Interventions

Despite the potentially harmful effects of vibration overdose, the concept of toxicity is rarely considered in voice therapy (Roy, 2012). There exist a variety of obstacles to determining the ideal dose in interventions like VFEs. One issue is difficulty identifying the active ingredient within the intervention. Most behavioral interventions consist of a variety of potentially active ingredients that include both clinician and client acts and ultimately function to affect change in client behavior (Baker, 2012). Although it is postulated that the benefits of VFEs stem from strengthening, rebalancing, and coordinating the laryngeal musculature, this remains unclear. The controversy lies in the fact that the principles of exercise physiology and motor learning are primarily borrowed from knowledge on limb musculature, and only a superficial link exists between the musculature of the limbs and that of the larynx (Roy, 2012). If principles of motor learning do indeed apply to the laryngeal musculature, one must also consider the concept that when intervention involves learning a motor skill, it is thought to be accomplished

both online (through practice) as well as offline (through memory consolidation) (Yan, Abernethy, & Li, 2010). It is difficult to identify the precise neural substrates that underlie offline learning and to quantify those in order to account for them while determining optimal dose. Complicating this matter is that it may take several days for underlying neural changes to catch up to behavioral changes being made by the individual (Kleim & Jones, 2008).

A second obstacle to identifying the ideal dose is that interventions in voice therapy often operate non-linearly. For example, incremental adjustments may result in substantial changes (either positive or negative) in overall voice production and quality (Roy, 2012). Without knowing the threshold between the ideal dose and the toxic dose, it is difficult to pinpoint either one.

A third issue in determining dosage is that of individual variability. Some individuals will be intrinsically pre-disposed to vibration overdose while others will be hypo-responsive to a given dose or intervention (Roy, 2012). In other words, a dose that provides no measureable effect for one individual may prove to be toxic for another. While these variables exist within the client, there are also external variables such as motivation, financial resources, and family support that may contribute to deciding which dose is even feasible (Baker, 2012).

Fourth, even if an ideal dose were established in the research setting, there are challenges to implementation in the clinical setting. VFEs constitute a fairly prescriptive regimen and, in the clinical setting, are often used in combination with other interventions and modified for the individual client. It is unknown whether combinations of treatments result in additive effects that yield increased benefits or whether they reach

the point of toxicity. There is also the potential that combined treatments operating from opposing conceptual standpoints will result in no measureable effect (Roy, 2012).

Fifth, Baker (2012) raises yet another complication in quantifying dose: the idea that dosage can be influenced by target selection. For example, an intervention for Parkinson's Disease, the Lee Silverman Voice Treatment (LSVT®), is typically done on an intense schedule of four times a week for four weeks with additional daily home practice. Fox, Ramig, Ciucci, Sapir, McFarland, and Farley (2006) argue that selecting the single target of increased SPL (loudness) encourages cross-system improvements and leads to significant change in areas such as facial expression, articulation, swallowing, respiratory support, and limb movements. Thus, target selection may ultimately influence the required dose and the overall length of intervention (Baker, 2012).

Finally, these issues are further compounded by disagreement on what constitutes "intense" treatment and how one goes about quantifying dosage. High dose and intense treatment are not mutually inclusive, since a given dose may be delivered with or without intensity, and an intense treatment may ultimately be delivered in a lower dose, or even require a lower dose because of its intensity. In a lead article to a scientific forum on optimal intensity, Baker (2012) illustrates the many facets of the concept of dosage and proposes a model for its measurement. She argues that in the field of speech-language pathology, not only the *quantity* but also the *quality* of intervention must be considered. While dose can be defined in various ways that consider number and duration of sessions, overall length of intervention, density of teaching episodes, and number of client responses, the common denominator is the concept of "repeated, spaced episodes of intervention over a period of time" (Baker, 2012, p. 402). To account for the many

variables that contribute to a given dose, Baker borrows from the work of Warren, Fey, and Yoder (2007) and discusses the concept of cumulative intervention intensity, or the product of dose, dose frequency, and total intervention duration. Dose denotes the quantity of teaching episodes occurring per session. Dose frequency refers to the number of intervention sessions per unit of time, and total intervention duration refers to the total period of time over which an intervention takes place (Warren et al., 2007). Taken together, these aspects of intervention help account for both quantity and quality of a given treatment. Baker then proposed her own modifications to this model for quantifying intervention. The model accounts not only for the dose (therapy session) and teaching episodes within the session, but also for the active ingredients, which are categorized as either clinician inputs (expansions, models, recasts, questions) or client acts (production practice of a skill). She further recommended that at-home work be accounted for when calculating dose. Cumulative intervention intensity, then, would "comprise the total from each ingredient provided using SLP time, and the total from each ingredient involving non-SLP time" (Baker, 2012, p. 405). Thus, dose is the number of correct responses in a practice session in therapy or at home. In this way, both clinician-guided and independent learning are accounted for. It is with Baker's framework in mind that this discussion on dosage for VFEs begins.

Statement of the Problem

Ultimately, inaccurate doses can be more harmful than they are beneficial. As Baker (2012) explains, this is evident in pharmacology, where not only does the dose make the poison, but under-dosing can be equally perilous. For example, an under-dose of penicillin was thought to be worse than an over-dose because it resulted in the survival

of penicillin-resistant microbes (Fleming, 1945). Nonetheless, overdose has been more closely affiliated with detrimental effects, as in the case of excessive vitamin B6 supplementation resulting in sensory neuropathy (Schaumburg, Kaplan, Windebank, Vick, Rasmus, Pleasure, et al., 1983). While pharmacological models of toxicity may not be applicable to all fields of speech-language pathology, the model is appropriate for some voice interventions, especially given the aforementioned potential for toxic levels of vocal exercises (Roy, 2012).

Beyond the potential danger of toxicity, the amount of necessary intervention is a salient aspect of effective treatment for the voice pathologist. While intense treatment may elicit better outcomes, more is not always better because intensity and outcomes do not necessarily enjoy a linear relationship (Baker, 2012; Roy, 2012). Too little of an intervention may lead to poorer outcomes, frustrate the client, and fail to resolve vocal issues which may ultimately result in social withdrawal, occupational difficulty, and reduced quality of life. Under-dosing may also make treatment as (in)effective as no intervention at all. Conversely, too high of a dose may produce diminishing returns, have no additional effect, or, as previously discussed, become harmful (Baker, 2012; Roy, 2012). Over-dosing may also prompt heavier caseloads and ultimately poorer quality of care by increasing the burden on professionals. In both cases, inaccurate doses do not result in optimal outcomes and are therefore wasteful. The cost is multi-faceted in terms of time, money, and resources. It is vital that treatment be not only effective but efficient as well (Baker, 2012). Additionally, efficiency of treatment may be affected by factors outside the clinician's control, such as compliance and attendance.

Thus, information on dosage increases the efficacy and efficiency of voice interventions such as VFEs, avoids causing potential harm, improves cost-efficiency and productivity, and has important implications for clinicians, clients, and third party payers. Currently, the dearth of literature on appropriate dosing squanders resources and leaves clinicians, especially new clinicians lacking experience, to guess at appropriate intervention intensity. The problem is that the ideal dose of VFEs is simply unknown because it has not been thoroughly investigated.

Purpose of the Study

This study addressed dosage of a specific physiologic voice therapy delivered by voice pathologists, Vocal Function Exercises, as applied to a population with normal voice. Individuals with normal voice were selected because the absence of phase II dose-response studies made it prudent to begin investigation in the normal voice. Because vocal wellness exists on a continuum that includes the disordered, normal, and trained voice, individuals are always capable of improving their voice production. The intervention of focus here, VFEs, while aimed primarily at improving the disordered voice, may be equally effective for enhancing normal voice (Stemple et al., 1994). The approach is holistic in that it attends to all three subsystems of voice, which are interconnected and interdependent. Thus, any disturbance in one of the subsystems affects the other two, resulting in some form of compensation and physiologic imbalance. This imbalance may come to be perceived as a voice disorder, or it may simply result in less efficient functioning of the entire system (Stemple, 2005). The ultimate goal of the exercise regimen is to strengthen, rebalance, and coordinate the laryngeal musculature through a series of four exercises: a warm up exercise, stretching exercise, contracting

exercise, and low impact adductory power exercise (Stemple et al., 1994). In essence, these vocal exercises improve the efficiency of vibration and voice production, but the ideal dose for doing so remains unknown.

Three experimental groups with low, traditional, and high exposure to VFEs were monitored to facilitate comparison in time to goal attainment and voice quality improvement along perceptual, acoustic, and aerodynamic parameters. Potential toxicity was monitored using visual observation (stroboscopic examination) and participant self-report. The primary purpose of the study was to investigate whether increased intensity of at-home practice results in faster goal attainment in terms of maximum phonation time (MPT). This study also sought to observe diminishing returns and monitor for adverse effects of high VFE dosage, and to compare maintenance one moth post-treatment across different dosage intensity groups.

Chapter Summary

Chapter one was meant as an introduction to the concept of dose as it applies to behavioral interventions, specifically in the area of voice. Chapter two will serve to review the relevant literature.

Chapter Two: Literature Review

Previous research has demonstrated VFEs to be effective in improving both the normal and the pathological voice. There are 24 studies that explore using VFEs in a variety of populations. In the disordered voice, VFEs may improve hyperfunctional as well as hypofunctional disorders, and may be used in combination with other treatment approaches to maximize outcomes. Most recently, VFEs have been used as an established therapeutic technique for comparison to newer interventions.

VFEs for Normal Voice

Regarding VFE application to normal voice, Stemple et al. (1994) performed a double-blind, placebo-controlled study which demonstrated maximized use of phonation flow volume, decreased airflow rate, increased MPT, increased frequency range, and improved symmetry of vibration in adult women. VFEs have also been shown to significantly improve airflow volume, airflow rate, MPT, and dynamic range in opera students with normal voice as compared to a control group (Sabol, Lee, & Stemple 1995). Additionally, VFEs resulted in improved vocal efficiency in children with normal voice who sing (Sayles, 2003). Finally, Guzman, Angulo, Muñoz, and Mayerhoff (2013) found that VFEs positively affect voice quality when used in conjunction with vocal warms ups for pop singers with perceptually normal voices when compared to a control group. In conclusion, there is evidence to suggest that VFEs improve normal voice in non-singers, opera singers, children, and pop singers.

VFEs for Disordered Voice

VFEs are also efficacious in improving disordered voice, and evidence demonstrates improvements in hyperfunctional as well as hypofunctional disorders. A

study by Roy, Gray, Simon, Dove, Corbin-Lewis, and Stemple (2001) found improved Voice Handicap Index (VHI) scores, self-reported overall voice improvement, greater vocal clarity, and greater ease of speaking in elementary and secondary teachers with self-reported voice problems who followed a VFE regimen when compared to a control group and a vocal hygiene (VH) group. Similarly, Gillivan-Murphy, Drinnan, O'Dwyer, Ridha, and Carding (2006) found significant improvements on a voice symptom severity scale and on questionnaires of voice care knowledge in a group of teachers with self-reported vocal problems receiving VFEs as treatment when compared to a VH group. VFEs have also been shown to improve perturbation, harmonics-to-noise ratio (HNR), perceived voice quality, and size and speed of pitch change in primary teachers with muscle tension dysphonia (MTD) (Nguyen & Kenny 2009). The Nguyen (2009) study was a single-blinded randomized controlled trial that compared a "full exercise" (FE) group to a "partial exercise" (PE) control group. The FE group completed VFEs with a modification of the vowel /o/ to the Vietnamese vowel /ô/, which is slightly higher than the English vowel /o/. The exercise regimen and practice schedule were otherwise equivalent to VFEs as described by Stemple et al. (1994). The PE group completed only the initial warm up exercise /i/ two times twice daily. While both the PE and the FE groups improved somewhat, more subjects in the FE group experienced positive change and this group also enjoyed a higher magnitude of change. Additionally, the FE group participants demonstrated positive change on a greater variety of outcome measures. This indicates that a reduced dose of VFEs, as achieved by performing only one of the four exercises, was insufficient in comparison to the full VFE protocol. Teixeira and Behlau (2015) compared the effectiveness of VFEs and voice amplification (VA) in a

six-week therapy regimen for teachers with behavioral dysphonia. They found that both the VFE and the VA groups demonstrated positive outcomes on measures of self-rated dysphonia in comparison to the control group. However, the VFE group also showed improvement in auditory-perceptual evaluation, laryngeal status, and acoustic analysis outcome measures. The authors concluded that VFEs effectively treat behavioral dysphonia in teachers, but that VA is really only effective as a preventative measure, while lack of intervention leads to worsening the disorder.

Ziegler, Gillespie, and Abbott (2010) sum up the literature on the use of VFEs as a tool for intervention in teachers with disordered voice by pointing out that VFEs in isolation have treatment value for this population. The benefits are greatest when the program is delivered within the context of individual therapy sessions where both the clinician and client are well-trained. This conclusion was based on comparing efficacy studies of VFEs in disordered voice to a study by Pasa, Oates, and Dacakis (2007) which, contrary to the majority of research, found that a VH group of teachers with self-reported vocal abuse and voice symptoms improved more on outcome measures of voice characteristics and voice knowledge than a VFE group. These findings have been largely attributed to the study's methodology, which taught VFEs in a group setting and greatly reduced exposure to clinician input by limiting the number of sessions and eliminating one-on-one therapy (Ziegler et al., 2010). This may indicate that reduced exposure to VFEs is less effective than the traditional dose. The combined evidence elucidated by Ziegler et al. (2010) also suggested that VFEs are most effective when delivered in combination with other treatment approaches (for example VH counseling), although it is difficult in these cases to determine what portion of the outcome should be credited to

VFEs and what portion should be attributed to other therapy techniques. It seems reasonable to suspect that the benefits of VFEs are augmented by combined treatments since healthier vocal fold mucosa likely makes for a more efficient physiologic system.

VFEs have also proven successful in treating hyperfunctional disorders such as contact granulomas. Patel, Pickering, Stemple, and Donohue (2012) evaluated changes in vocal fold vibration and voice production in a single-subject before-after prospective study. A six-week VFE protocol was conducted in a 51-year-old male with a unilateral contact granuloma. While stroboscopic, acoustic, aerodynamic, and audioperceptual measures were minimally informative, high-speed digital imaging demonstrated improved efficiency of vocal function, vibratory motion, glottis closure, and impact stress. The authors concluded that there is evidence to suggest that therapy techniques using semi-occluded vocal tract techniques (such as VFEs) are useful in treating contact granulomas.

In individuals with presbylaryngeus (or aging larynx), statistically significant improvements on physiologic measures have been reported in a variety of research studies. Gorman, Weinrich, Lee, and Stemple (2008) observed increased MPT and improved aerodynamic measures indicating reduced translaryngeal flow, better glottal closure, and increased subglottic pressure following completion of a VFE regimen in participants diagnosed with presbylaryngeus. In 2008, Berg, Hapner, Klein, and Johns found improvement in Voice-Related Quality of Life (VRQoL) scores in individuals with age-related dysphonia after four sessions (five months) of voice intervention including vocal hygiene, resonant voice, and VFEs in comparison to a control group. Average improvement on the VRQoL was 19 points for the experimental group and only one point

for the control group. Furthermore, subjects in the experimental group who were described as "adherent" demonstrated better improvement (24 points on the VRQoL) in comparison to those who were "partially adherent" (improvement of 15 points). This indicates that lower doses of VFEs completed by partially adherent participants attenuated positive outcomes. Tanner, Sauder, Thibeault, Dromey, and Smith (2010) examined treatment responses in 79-year-old male monozygotic twins with vocal fold bowing to identify genetic and environmental factors associated with age related change and treatment response in a longitudinal, descriptive case study. After surgical intervention, VFEs resulted in improved VHI scores and glottal closure, although dysphonia remained severe in both cases. Intervention outcomes for each twin differed, possibly as a result of confounding factors such as differences in voice use and overall health. VFEs have also yielded improved VHI scores, reduced self-rated vocal effort and severity, and reduced overall severity, breathiness, and strain in a pre-to-post test quasi-experimental study of elderly patients with presbylaryngues (Sauder, Roy, Tanner, Houtz, & Smith, 2010). Tay, Phyland, and Oates (2012) found that a group of singers over 65 years of age who used VFEs improved on acoustic measures, MPT, and reduced their overall vocal roughness in comparison to a non-treatment group. Ziegler, Abbot, Johns, Klein, and Hapner (2014) found improved scores on the VRQoL in a VFE group as compared to a non-treatment control group. A retrospective study by Kaneko, Hirano, Tateya, Kishimoto, Hiwatashi, Fujiu-Kurachi, and Ito (2015) examined 16 participants with vocal fold atrophy who completed a six-week VFE protocol and compared them to a historical control group of similar age range. While the historical control group made no improvements, the VFE group demonstrated significant improvement on the Grade,

Roughness, Breathiness, Asthenia, Strain (GRBAS) scale, MPT, jitter, VHI, normalized mucosal wave amplitude, and normalized glottal gap. Bowing index did not change significantly, and the study concluded that despite the lack of change on this outcome measure, VFEs may improve muscular function during voicing, thereby yielding improvements in subjective, objective, and self-assessment measures. There is evidence to suggest that VFEs successfully treat presbylaryngeus or age-related vocal fold atrophy.

VFEs have also been attempted with transgender populations. In 2013, Gelfer and Van Dong explored the voice outcomes for male-to-female (MTF) transgender clients seeking voice feminization when treated with symptomatic voice therapy in combination with VFEs for six weeks. Three MTF transgender participants provided voice samples that were compared to male and female control samples. While VFEs did not appear to improve acoustic or perceptual outcome measures, the participants themselves reported satisfaction with the addition of VFEs into their treatment.

Finally, VFEs may be used in cases of laryngeal injury, as demonstrated by Sharma, Martin, and Pracy (2009). This case study examined an individual with a laryngeal fracture secondary to penetrating shrapnel injury, which was surgically repaired. Voice improvement was rapid using a three-month VFE protocol with practice twice daily, and MPT more than doubled in length. Thus, in this case study, VFEs improved voice after laryngeal injury.

VFEs As a Standard of Care

More recently, VFEs have served as a therapeutic benchmark against which to compare alternative voice interventions. One such example is a study completed by Pedrosa, Pontes, Pontes, Behlau, and Peccin (2015) which compared VFEs to a new

voice treatment program entitled the Comprehensive Voice Rehabilitation Program (CVRP). In this randomized blinded clinical trial, 80 professional voice users with functional dysphonia were randomized into a CVRP or VFE group and completed six treatment sessions. Both groups improved on all outcome measures, which included self-assessment, perceptual evaluation of voice quality, and laryngeal examination. The authors concluded that both programs were effective in treating functional dysphonia in professional voice users. A second example is a randomized controlled trial completed by Kapsner-Smith, Hunter, Kirkham, Cox, and Titze in 2015, which compared phonation through flow-resistant tubes (FRT) to VFEs as an established therapeutic technique. Twenty participants with dysphonia were assigned to one of four groups: immediate FRT, immediate VFE, delayed FRT, or delayed VFE. Both groups improved relative to the control groups and the authors concluded that both treatment techniques may improve voice quality of life in people with dysphonia.

In sum, the literature on VFEs as described by Stemple et al. (1994) demonstrates that VFEs are effective in the normal voice and in the highly trained voice (e.g. opera singers). This technique also improves disordered voice in individuals with functional dysphonia, contact granulomas, presbylaryngeus (i.e., vocal fold atrophy), and muscle tension dysphonia. Gains on subjective, objective, and self-assessment measures have been systematically observed. Therefore, VFE effectiveness can be demonstrated in a variety of populations and for many vocal parameters.

VFE Dose

The literature with respect to optimal VFE dosing is sparse, but a few speculations can be extrapolated from the preexisting research. The study by Stemple et al. (1994)

looked at VFEs in adult women with normal voice. Part of the study's findings indicated that for the experimental group, the greatest gain in weekly phonation times occurred between weeks one and two. After that point in time, the majority of the participants' times plateaued, since they had met their MPT goal based on individual physiologic capacity. Since the participants in the experimental group achieved their goals so quickly, yet completed a six-week protocol, this may indicate that only a low dose of VFEs is necessary to produce positive results in the normal voice. However, it would be difficult to draw conclusions regarding maintenance of those improvements without further research of low dose-response relationships.

As with any intervention, adherence to treatment is paramount. In a comparison study examining the effects of monitored versus unmonitored VFEs in adult women with normal voice, Ellis & Beltyukova (2011) found that both groups performing VFEs significantly increased their MPT and maximum phonational frequency range (MPFR). However, the group monitored for compliance via audio recordings improved significantly more than the unmonitored group. Since poor compliance most likely meant alterations in dosage, it seems that adhering more strictly to the prescribed dosage led to greater improvement in normal voice. Thus, reduction of VFE exposure may diminish outcomes in normal voice. This conclusion partially contradicts the idea that low exposures of VFEs may be sufficient in individuals with normal voice. However, given the complex relationship among dose, dosage, and compliance, a direct contradiction cannot be assumed.

The Pasa et al. (2007) study reduced the administered VFE dose by using a two hour group session with four group sessions over a period of ten weeks, thereby reducing

individual exposure to the clinician and resulting in suboptimal outcomes. This study found that a VH group of teachers with self-reported vocal abuse and voice symptoms improved more on outcome measures of voice characteristics and voice knowledge than a VFE group. This may indicate that reduced exposure to VFEs is less effective than the traditional dose in individuals with self-reported voice problems.

A case study by Radhakrishnan and Scheidt (2012) found that modifying the VFE regimen resulted in post-treatment improvement on perceptual, objective, and self-perceptual outcome measures in a participant with presbylaryngeus. In that retrospective, single case report, the patient was unable to achieve the posture required for VFEs and was unable to match pitch for the final adductory power exercise. The VFE posture was therefore modified: the pitch glides and final low-impact power adductory exercises were performed on /o/. Secondary to the participant's difficulty with pitch matching, she was simply instructed to complete the final exercise by ascending in pitch slightly each time. While this may have modified the intensity of the VFE protocol by decreasing the complexity or accuracy required for each task, the frequency and amount of practice was kept constant at two times each twice daily. Thus, it is important to consider the converging and diverging aspects of dose and intensity. It is arguable that the Radhakrishnan and Sheidt (2012) study preserved VFE dose while modifying intensity and specificity in that they reduced the strenuousness of the intervention but not the amount. However, changing aspects of any protocol may innately modify dose since, as Baker (2012) mentions, we cannot pinpoint the precise active ingredient(s) that make intervention effective. For VFEs, the active ingredient is thought to be the semi-occluded vocal tract posture, which heightens source-filter interaction allowing for greater

economy of voice in terms of collision stress or vibration dose (Titze, 2006). Thus, it would be important to question whether modifying VFE technique to use the vowel /o/ for the series of exercises significantly compromises an active therapeutic ingredient. If so, perhaps lower doses of VFEs are effective in individuals with vocal fold atrophy.

In summary, there are no direct studies on dosage as it applies to VFEs. The weak conclusions that can be drawn are as follows:

1. Low doses of VFEs may be sufficient to improve the normal voice
2. Low doses of VFEs may not improve the normal voice to the same extent that higher doses would.
3. Low doses of VFEs may be insufficient to improve the disordered voice.
4. Traditional doses of VFEs with modified intensity may be sufficient to improve the disordered voice.

Other Voice Interventions and Dose

While the literature on VFE dosage is sparse, information about dosing can also be gleaned from research exploring dose in other types of voice interventions. These have primarily examined the effects of the Lee Silverman Voice Treatment (LSVT). A comparison between VFEs and LSVT can be drawn because both interventions target the three subsystems of voice: respiration, phonation, and resonance. LSVT is delivered in a high intensity format of four weekly sessions for four weeks plus additional daily homework. LSVT delivery is referred to as intense dosage in terms of frequency of treatment, repetitions within sessions, and effort required for each task. Intensive training is thought to recalibrate the patient's internal feedback system and allow the person to internally cue appropriate loudness during speech (i.e., result in long-term functional

changes in behavior). Furthermore, intense training of a single target is thought to result in cross-system improvements (Fox & Ramig, 2006).

Various alterations have been made to the LSVT protocol. Spielman, Ramig, Mahler, Halpern, and Gavin (2007) examined the effects of an extended LSVT program (LSVT-X) in 12 participants with idiopathic Parkinson's disease. Treatment was delivered in one-hour sessions twice weekly for eight weeks and outcomes were compared to a historical group who had completed the traditional dose of one-hour sessions four times weekly for four weeks. While both groups enjoyed the same amount of direct time with the clinician, the LSVT-X group completed far more homework with a different distribution of treatment sessions and greater expanses of time between treatment sessions. Thus, intensity was reduced in the LSVT-X group in some ways, but dosage may have actually been greater in that there were more home practice sessions. Results indicated that both groups had comparable increases in vocal SPL and both groups maintained these improvements at six months. Both groups had improved VHI scores and listener ratings. Interestingly, interviews with the clinicians who delivered LSVT-X indicated that treatment seemed less efficient in terms of learning the target. The authors speculated that more time was spent in the pre-learning stage for individuals in the extended treatment group. However, data in the LSVT-X group trended toward increasing vocal SPL from post treatment measures to one-month follow up, indicating that the extended treatment may have established better motor patterns that continued to improve even after treatment ended.

Another study by Wohlert (2004) examined the efficacy of LSVT in various formats. Participants with Parkinson's disease were divided into three groups. One

group received the traditional treatment (four times a week for four weeks), another received treatment twice a week for eight weeks, and the last group received treatment twice a week for four weeks. They found that vocal SPL, MPT, and pitch range improved but that at the three-month follow up most of these gains were substantially reduced for all groups. The authors concluded that the schedule of treatment did not appear to have a predictable impact on outcomes, although statistical analyses were not completed. These results would indicate that halving the dosage of LSVT led to comparable improvement, since one of the groups received only two weekly sessions for four weeks. However, these results have not carried a great deal of weight due to methodological errors such as incomplete randomization and differences in data collection from other LSVT studies (Spielman et al., 2007).

A study by Searl, Wilson, Haring, Dietsch, Lyons, and Pahwa (2011) attempted to demonstrate the feasibility of LSVT LOUD in a group format for 15 individuals with Parkinson's Disease. Participants received 90-minute sessions led by three clinicians weekly for eight weeks. Daily homework was completed in larger amounts than in traditional LSVT delivery. Statistically significant improvements for vocal intensity, maximum fundamental frequency, fundamental frequency range, and VHI scores were observed. The increase in SPL for group LSVT was slightly reduced compared to traditional delivery, though compliance with homework was strongly correlated to changes in loudness. Extended treatment may have reduced motivation or compliance with homework. Still, 80% of participants were judged as louder after completing treatment. The authors concluded that it is feasible to complete LSVT in a group format with some modifications.

It is important to note that while LSVT has been shown to be effective in improving vocal SPL in patients with Parkinson's disease, intensity of treatment alone was insufficient to produce positive outcomes. Several studies have compared LSVT to other interventions such as respiratory effort treatment delivered in the same format (intensity) and have found that the latter does not result in similar benefits (Baumgartner, Sapir, & Ramig, 2001; Ramig & Countryman, 1995; Ramig, Countryman, O'Brien, Hoehn, & Thompson, 1996). Thus, intensity alone is insufficient and, as Baker (2012) states, active treatment ingredients must be identified. She further argues that "…the target itself could influence just how many sessions are required, and, ultimately, the total intervention duration" (Baker, 2012, p. 404).

Nonetheless, intense intervention may play an important role in optimizing outcomes. Some voice clinicians have even suggested a type of voice boot camp as an intensive, short-term program for people with chronic dysphonia (Patel, Bless, & Thibeault, 2011). The program involves multiple sessions a day and incorporates a variety of therapeutic approaches to achieve maximum gain in a matter of days. Thus far, outcome studies for these types of programs have not been completed. Verdolini-Marston, Lessac, Glaze, and Caldwell (1995) described the effects of an intensive model of treatment for confidential voice and resonant voice therapy programs in individuals with vocal nodules. Treatment was delivered in a total of eight individual sessions over a two-week period. All participants in both experimental groups improved on one or more outcome measures post-treatment, while none of the participants in the control group demonstrated improvement. The authors indicated that compliance with homework was a predictor of success in both experimental groups, but noted that it was "not definitive

whether the success of treatment was related to the type of treatment technique participants received (i.e., ingredient of treatment) or the dosage (i.e., intensive vs. standard)" (Verdolini-Marston et al., 1995, pg. 652.e41). The authors then called for a standardization of treatment received between individuals.

In an evaluation of the impact of intensive treatment on functional, service, and well-being outcome measures in clients with functional dysphonia, Wenke, Stabler, Walton, Coman, Lawrie, O'Neill, Theodoros, and Cardell (2014) compared intense treatment to standard treatment. In this study, an intense treatment group (n = 7) received four, one-hour sessions weekly for two weeks, while a standard treatment group (n = 9) received weekly one-hour sessions for eight weeks. Both groups received vocal hygiene education and a total of eight hours of therapy, which was individualized and consisted of evidence-based behavioral techniques. Results indicated higher satisfaction and greater VHI improvement after intense treatment, as well as improved attendance. Furthermore, the intense treatment group demonstrated continued improvement at follow-up, indicating that motor learning continued in the absence of rehabilitation. This is consistent with the Spielman et al. (2007) finding that an experimental group receiving LSVT-X improved from post-treatment to follow-up. Wenke et al. noted that intense treatment may have "enhanced motor learning and provided greater opportunity for the individual to consolidate the learnt vocal techniques and vocal hygiene behaviors" (Wenke et al, 2014 p. 652.e40). Conversely, the standard treatment group reported wanting additional practice or more therapy, indicating that they did not feel that they had mastered the voice techniques. In corroboration with this sentiment, the treating clinician indicated that standard group participants spent more time revising acquisition of learned vocal

strategies, indicative of a "pre-practice" phase where the patient aquires basic knowledge of the task through conscious attention. This is also consistent with the LSVT-X experimental group from the Spielman et al. (2007) study. Because treatment was distributed over more time, the extended treatment group may have spent more time in the pre-practice stage. This is important to therapeutic outcomes because the principles of motor learning dictate that practice closely approximates the desired target. If vocal techniques take longer to consolidate, then practice may not closely resemble the desired behavior. Ultimately, the authors of the Wenke et al. (2014) study concluded that intensive treatment had potential to improve healthcare cost efficiency and satisfaction for both client and clinician by improving attendance and treatment completion, ultimately leading to better outcomes. However, as with the Verdolini-Marston et al. (1995) study, no standardization of treatment was implemented. Thus, there is evidence to suggest that intense treatment can lead to better outcomes with greater efficiency, but this is not explicitly linked to dose. Treatment delivery, compliance, motivation, and a host of other factors also play important roles in patient outcomes.

Principles of Sensory Motor Learning and Dose

Increasing the frequency and amount of therapy may facilitate learning at the neuronal level, as postulated by Pulvermuller and Berthier (2008). This study found that longer therapy sessions in a short time period were more efficient than therapy distributed over longer times. Support for this idea can also be found in the principles of motor learning, which dictate that repetition is necessary to induce lasting change and that it may take several days of training to establish underlying neural changes. Higher intensity stimulation can induce long-term potentiation that makes the behavior resistant

to decay in the absence of training (Kleim & Jones, 2008). This result may have been demonstrated by the LSVT-X group (Spielman et al., 2007) and the intense treatment group (Wenke et al., 2014). Motor skills are learned both online (i.e., during training) and offline (i.e., after training ends). The latter is important for skill stabilization and consolidation, whereby offline behavioral skill improvements occur after end of practice. Consolidation, in turn, is vital for long-term retention of motor skills (Dayan & Cohen, 2011). Long-term retention has important implications for maintenance of therapeutic effects and follow-up data collected for research. It is important to note that rehearsal of procedural information in short-term memory promotes formation and consolidation of information for the long-term, highlighting the importance of practice methods and dosage. For example, principles of motor learning state that frequently repeated motor patterns reinforce neural patterns, and that blocked practice is important during initial skill acquisition (Classen, Liepert, Wise, Hallett, & Cohen, 1998). So long-term maintenance is partly dependent on how motor skills are acquired to begin with, and acquisition has everything to do with practice, compliance, dose, intensity, and service-delivery of treatment.

In summary, there are few studies on treatment intensity and dose in intervention for voice. The weak conclusions that can be drawn are as follows:

1. There is literature to support intense treatment in terms of efficiency, improved outcomes, compliance, patient satisfaction, neuroplasticity, and maintenance.
2. Efficacy of treatment is dependent both on dose and intensity as well as on active therapeutic ingredients.
3. Dose and intensity have not been systematically differentiated or studied.

4. Toxic effects of intense voice treatment have not yet been defined in the literature.

Research Hypotheses

1. Higher dosage of home practice VFEs will lead to faster goal attainment in normal voice.
2. All dosage groups will improve in comparison to baseline and attain physiologic VFE MPT goals. This hypothesis is based on the fact that in the Stemple et al (1994) study on VFEs in young adult females with normal voice, nearly all subjects plateaued in terms of MPT after two weeks of practice. In a six-week regimen like the one used in this study, it is reasonable to expect that even lower doses of VFEs will result in goal attainment.
3. The high dosage group will demonstrate better maintenance once month post-treatment. This hypothesis is based on research completed in another intervention that targets the three subsystems of voice, LSVT. In the Spielman et al. (2007) study, an extended protocol with increased home practice resulted in data at one-month follow-up that trended toward increasing vocal SPL in comparison to post treatment measures. The authors speculated that better motor patterns may have been established that continued to improve even in the absence of treatment.

Chapter Summary

Chapter two served to review pertinent literature regarding VFEs and dosage for voice interventions. In essence, the ideal dose of VFEs is simply unknown because, like many interventions for voice, it has not been thoroughly investigated. Chapter three will introduce the methods used to help address this problem.

Chapter Three: Methodology

All recruitment, intervention, and data collection procedures were approved by the Institutional Review Board (IRB) at the University of Kentucky (UK).

Participants

A total of 30 female participants with normal voice were recruited from the University of Kentucky College of Health Sciences (see Appendix A). Participants met the following inclusion criteria: female, between 18 and 25 years (>18 and <26), non-smokers, and hearing within normal limits. A year or more of classical vocal training, history of uncontrolled asthma, and presence of vocal fold pathology identified by laryngeal examination constituted exclusion from the study (see Appendix C). Twenty-eight participants were enrolled and completed baseline assessment protocol. In the first week, eight participants withdrew from the study but were replaced with new recruits. A total of 28 participants completed the study.

During the first session, consent was obtained using forms approved by the UK IRB (see Appendix B). All participants were briefly educated on abusive vocal behaviors and agreed to abstain from these behaviors for the duration of the study.

Exercise Procedure

Participants were placed randomly into one of three groups: low exposure, typical, or high exposure. All groups completed VFEs twice daily, once in the morning and once in the evening, seven days per week for six weeks (see Appendix G). The low exposure group did all exercises one time through. The typical exposure group performed all exercises twice each. The high exposure group completed all exercises

four times each. Based on the participant's vital capacity, each individual in all three experimental groups was given a goal for MPT (VC/ 80mL/s = MPT goal).

Training. After baseline measures were obtained, each participant met with a research assistant, who taught them VFEs as described by Stemple et al. (1994). Training of all research assistants was done prior to beginning the study. Training was formal and conducted by a specialist in voice disorders with extensive experience training and performing VFEs. The first training session established technique using a group format with breaks for individual coaching. The next training session allowed for individual practice with an experienced clinician. The third training session consisted of review and practice with a second year graduate student with experience performing and teaching VFEs. Twenty percent of all research assistant-conducted sessions with study participants were monitored by an expert in voice. An additional 20% of all sessions were monitored by a second year graduate student with experience with VFEs.

Once each participant had learned VFEs from the trained research assistant, an expert in voice joined the session to solidify technique and obtain MPT baselines. Participants were then provided with a Dropbox link containing a face video specific to their dosage group that provided them with instructions, pitches, and walked them through home practice. Additionally, each participant received home practice MPT score sheets specific to her dosage assignment.

Compliance and home practice. Exercises were completed at home with frequency dictated by group placement using the provided face videos. Compliance was monitored using practice record sheets, which participants brought to weekly check-ins. Participants received reminders to practice via email twice a day.

Weekly check-ins. Participants returned weekly for check-ins with a research assistant, who recorded MPTs and adjusted technique as necessary with the help of supervising clinicians. A total of seven sessions were attended, for a total of six weeks of VFEs.

Outcome Measures/ Assessment Parameters

Based on the Committee on Phoniatrics of the European Laryngological Society recommendation that self-assessment, auditory-perceptual, stroboscopic, acoustic, and aerodynamic parameters be included in a functional assessment of voice, all of these parameters were included (Speyer, 2008). These assessments provided a variety of outcome measures, however the primary outcome measure was MPT.

Baseline measures were obtained prior to intervention and included patient self-assessment (VRQoL, see Appendix F), audio-perceptual assessment (CAPE-V, see Appendix E) completed by a clinician specialized in voice, stroboscopic examination, acoustic measures (MPT, jitter percent, shimmer dB, noise to harmonics ratio, frequency range), and aerodynamic measures (vital capacity, subglottic pressure/ mean peak air pressure, laryngeal airflow rate, laryngeal airway resistance/ aerodynamic resistance, see Appendix D). Participants also provided VFE MPTs using the appropriate mouth postures consistent with a semi-occluded vocal tract.

Participants attended weekly check-ins for six weeks subsequent to learning VFEs. At each check-in, they completed the VRQoL to assist in monitoring for toxic effects. VFE MPTs (using semi-occluded mouth postures) were recorded at weekly check-ins. After three weeks of exercises, stroboscopic examination was performed to verify presence/absence of observable toxic effects.

Post-experimental measures were obtained after six weeks of exercises and included all parameters obtained at baseline including VFE MPTs. Participants discontinued exercise practice and weekly check-ins at this time.

Four weeks after protocol completion, participants returned for their one-month follow-ups and all assessment parameters obtained at baseline were collected again, including VFE MPTs.

Chapter Summary

Chapter three outlined the methods used to contribute to the literature on dosage as it applies to use of VFEs in normal voice. Following in chapter four are the results.

Chapter Four: Results

Demographics

A total of 28 female subjects between the ages of 18 and 25 were recruited from the University of Kentucky College of Health Sciences and enrolled in this study. Eight participants discontinued their participation but were replaced with new recruits. A total of 28 subjects completed the study. Subjects were non-smokers with normal voice. Each underwent a full voice assessment before and after a six-week VFE intervention protocol. Subjects returned one month post-intervention for an additional voice assessment. During the six-week intervention period, each participant completed home practice twice daily (morning and evening) using a practice log to record the VFE MPT results. The number of repetitions during home practice was determined by the participant's random group assignment. The low dose group did each exercise once, the traditional dose group completed each exercise twice, and the high dose group performed each exercise four times. Each subject attended a weekly check-in to monitor compliance, provide VFE MPTs, and turn in practice logs. Weekly average phonation times were calculated for each participant (see Appendix I). Table 4.1 presents the characteristics of the low, traditional, and high dose groups for the variable of age. In the low dose group, ages ranged from 18 to 25; average age was 21.10 and median age was 20. In the traditional dose group, ages ranged from 18 to 24; average age was 21.56 and median age was 21. In the high dose group, ages ranged from 18 to 25; mean age was 20.60 and median age was 20.5.

Table 4.1: Demographics

Group	Age	Mean Age	Median Age	Standard Deviation
Low Dose	18, 19, 19, 20, 20, 21, 23, 25, 25	21.10	20.00	2.619
Traditional Dose	18, 10, 21, 21, 21, 22, 23, 24, 24	21.56	21.00	1.944
High Dose	18, 18, 19, 19, 20, 21, 21, 22, 23, 25	20.60	20.5	2.271

Groups. The low dose group consisted of nine participants, two of whom discontinued their participation. The traditional dose group contained nine participants, one of whom discontinued her participation. The high dose group contained ten participants, five of whom discontinued their participation. This resulted in a withdrawal rate of 22%, 11%, and 50% for the low, traditional, and high dosage groups, respectively. Subjects who withdrew from the study were replaced by new recruits the subsequent week. Because intervention had already begun and subjects could not be completely re-randomized, replacement was completed by filling vacancies in each group as needed to maintain equal numbers across groups. This information is represented in Table 4.2, which provides dosage group descriptions, number of participants, and the number of participants who discontinued their participation.

Table 4.2: Dosage Assignments

Group	No. of Participants	Discontinuing Participants
Low Dose VFEs one time each, twice daily	n = 9	2/ 9 = 22%
Traditional Dose VFEs two times each, twice daily	n = 9	1/9 = 11%
High Dose VFEs four times each, twice daily	n = 10	5/10 = 50%

Withdrawal questionnaires. Upon discontinuation of this study, participants were asked to complete a questionnaire regarding rationale for withdrawal (see Appendix H). Of the eight participants who withdrew from the study, six completed and returned the questionnaire. One of the questions probed the former participants' experience with laryngeal examination by asking what degree of discomfort they experienced when being scoped. Four participants reported no discomfort, one reported mild discomfort, and one reported extreme discomfort. The remainder of the questionnaire addressed the reason for withdrawal. Five former subjects reported that the time commitment involved in the study was too great. Two reported difficulty with mastering the required technique for VFEs. One reported that a personal matter demanded her withdrawal. One participant in the high dose group reported pain, soreness, and/or fatigue following exercises. She was further interviewed by the researcher but refused laryngeal examination. The results of the withdrawal questionnaire are detailed below in Table 4.3.

Table 4.3: Withdrawal Questionnaire Results

	Subject Report	**Subject Group**
Strobe tolerance	4 reported no discomfort	2 Low, 2 High
	1 reported mild discomfort	1 Traditional
	1 reported extreme discomfort	1 High
Reason for discontinuation	5 reported excessive time commitment	1 Low, 1 Traditional, 3 High
	2 reported difficulty with VFE technique	1 Traditional, 1 High
	1 reported a personal matter	1 Low
	1 reported pain/ soreness/ fatigue	1 High

Baseline Measures

A series of between subjects one-way ANOVAs demonstrates equivalence between groups at baseline for a number of acoustic, aerodynamic, auditory-perceptual, and self-assessment variables. These variables include age, airflow, subglottic pressure, laryngeal airway resistance, range, jitter, shimmer, noise-to-harmonics ratio, acoustic maximum phonation time, VFE maximum phonation time, CAPE-V scores (overall, roughness, breathiness, strain, pitch, loudness), and VRQoL self-ratings.

A significance value of .05 (Alpha = 0.05, Power = 80%) was used based on a power analysis completed a priori. The resulting p-values for each of these variables are listed in Table 4.4, and indicate that groups differed at baseline only in terms of laryngeal airway resistance (LAR), $p = .050$. However, the homogeneity of variance (Levene's test) was also statistically significant ($p = .002$). Therefore, to further examine this variable, two separate, more robust tests were completed: the Welch and the Brown-Forsythe tests. These tests found that groups were not significantly different in terms of LAR. Additionally, a Games-Howell post-hoc test was performed to account for unequal variance and also resulted in non-significance ($p = .996$, $p = .201$, $p = .208$).

Table 4.4: One-Way ANOVAs for Baseline Measures

	One way ANOVA p-value	Welch Test	Brown-Forsythe Test
Age	.666	.634	.667
Airflow	.533	.639	.532
Psub	.826	.813	.828
LAR	.050*	.209	.085
Range	.866	.878	.867
Jitter	.271	.245	.264
Shimmer	.537	.527	.545
NHR	.872	.839	.869
Acoustic MPT	.263	.222	.286
VFE MPT	.636	.602	.640
CAPE-V Overall	.177	.276	.202
CAPE-V Roughness	.511	.601	.529
CAPE-V Breathiness	.290	.269	.313
CAPE-V Strain	.497	.571	.515
CAPE-V Pitch	.604	--	--
CAPE-V Loudness	.953	.952	.953
VRQoL	.791	.713	.786

* denotes statistically significant value ($p \leq .05$)

Outcome Measures

Primary outcome measures. The primary purpose of this investigation was to examine the effect of varying doses of VFE home practice on attainment of pre-established MPT goals in individuals with normal voice production. VFE MPT was collected at baseline, weekly during the VFE protocol, after six-week intervention, and at one-month follow-up. Individual physiologic goals for VFE MPT were determined by dividing each participant's forced expiratory volume by 80mL/s. After data collection, average weekly VFE MPTs were calculated. Percentage of goal attainment was calculated at baseline, after intervention, and at one-month follow-up. Percentage point change was calculated for each subject using these three time points. Change was calculated comparing baseline to post-intervention, post-intervention to follow-up, and baseline to follow-up.

In the low dose group, one of nine participants reached 80% of her physiologic goal, and this occurred at her one-month follow-up. Average percentage point change between baseline and post-intervention for the low dose group was 16.44; median percentage point change was 10.00. Average percentage point change post-intervention to one-month follow-up was -1.78; median was -3.00. This indicates a decrease in VFE MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 9.22; median change was 6.00.

In the traditional dose group, three of nine participants achieved 80% of their respective physiologic goals. Goal attainment for each of the three subjects occurred at check-in four, five, and seven, respectively. Average percentage point change between baseline and post-intervention for the traditional dose group was 25.56; median percentage point change was 24.00. Average percentage point change post-intervention to one-month follow-up was -10.89; median was -9.00. This indicates a decrease in VFE MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 14.67; median change was 15.00.

In the high dose group, four of ten participants achieved 80% of their respective physiologic goals. Goal attainment for each of the four subjects occurred at check-in two, five, five, and seven, respectively. Average percentage point change between baseline and post-intervention for the high dose group was 33.30; median percentage point change was 30.00. Average percentage point change post-intervention to one-month follow-up was -16.00; median change was -15.00. This indicates a decrease in VFE MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 17.50; median change was 14.00.

The hypothesis that higher dosages of home practice of VFEs would lead to faster goal attainment in normal voice was proved. The hypothesis that all dosage groups would improve in comparison to baseline and attain physiologic VFE MPT goal was not proved. Although all subjects improved their MPT from baseline, many did not reach physiologic goal. The hypothesis that the high dose group would demonstrate better maintenance at follow-up was not proved.

Acoustic MPT was also collected at baseline, after intervention, and at one-month follow up. Percentage point change was calculated in the same manner as for VFE MPT. Average percentage point change between baseline and post-intervention for the low dose group was 5.56; median percentage point change was 5.00. Average percentage point change post-intervention to one-month follow-up was -2.78; median change was -2.00. This indicates a decrease in acoustic MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 2.78; median change was 2.00.

Average percentage point change between baseline and post-intervention for the traditional dose group was 5.78; median percentage point change was 6.00. Average percentage point change post-intervention to one-month follow-up was -0.4; median change was -1.00. This indicates a decrease in acoustic MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 5.33; median change was 5.00.

Average percentage point change between baseline and post-intervention for the high dose group was 5.43; median percentage point change was 7.00. Average percentage point change post-intervention to one-month follow-up was -3.00; median

was -1.00. This indicates a decrease in acoustic MPT during that time period. Average percentage point change from baseline compared to one-month follow-up was 0.57; median change was 2.00. The percentage point changes for acoustic and VFE MPT are provided in Table 4.5 for each dosage group.

Table 4.5: Primary Outcome Measures: VFE MPT & Acoustic MPT

VFE MPT			
	Low Dose	**Traditional Dose**	**High Dose**
Number of participants reaching 80% of goal	1 of 9	3 of 9	4 of 10
Week goal achieved	At 1-mo. follow-up	4, 5, 7	2, 5, 5, 7
Percentage point change pre-post			
Average	16.44	25.56	33.30
Median	10.00	24.00	30.00
Percentage point change post-1 mo. follow-up			
Average	-1.78	-10.89	-16.00
Median	-3.00	-9.00	-15.00
Percentage point change pre-1 mo. follow-up			
Average	9.22	14.67	17.50
Median	6.00	15.00	14.00
Acoustic VFE			
Percentage point change pre-post			
Average	5.56	5.78	5.43
Median	5.00	6.00	7.00
Percentage point change post-1 mo. follow-up			
Average	-2.78	-0.44	-3.00
Median	-2.00	-1.00	-1.00
Percentage point change pre-1 mo. follow-up			
Average	2.78	5.33	0.57
Median	2.00	5.00	2.00

Paired sample t-tests were used to examine change in primary outcome measures between each of the data collection time points using a significance value of .05. In the low dose group, acoustic MPT was significantly different baseline to post-intervention. VFE MPT was significantly different between baseline and post-intervention and also between baseline and one-month follow-up. In the traditional dose group, acoustic MPT was significantly different between baseline and post-intervention. VFE MPT was significantly different across all three data collection time points. For the high dose group, acoustic MPT was not significantly different at any time point, but VFE MPT was significantly different across all data collection time points. Resulting p-values from the data analysis can be viewed in Table 4.6.

Table 4.6: Paired Sample T-Tests for Primary Outcome Measures

Low Dose	**Pre-post p-value**	**Post-month p-value**	**Pre-month p-value**
Acoustic MPT	.035*	.138	.356
VFE MPT	.004*	.347	.039*
Traditional Dose	**Pre-post p-value**	**Post-month p-value**	**Pre-month p-value**
Acoustic MPT	.029*	.803	.096
VFE MPT	.001*	.001*	.014*
High Dose	**Pre-post p-value**	**Post-month p-value**	**Pre-month p-value**
Acoustic MPT	.148	.330	.811
VFE MPT	.001*	.003*	.001*

* denotes statistically significant value ($p \leq .05$)

Toxicity. A secondary purpose of this investigation was to observe the presence or absence of toxic effects on the vocal folds as a potential result of increased VFE home practice. Each subject underwent laryngeal examination and stroboscopy at baseline, after three weeks of VFEs, after intervention at six weeks, and at one-month follow-up. Toxicity was defined as visualization of any vocal fold pathology, erythema, or edema. No signs of toxicity were identified at any data collection point. Additionally, each participant completed the VRQoL weekly to monitor for substantial changes in self-

ratings of voice. One subject in the high dose group withdrew from the study in the first week, complaining of vocal fatigue and throat soreness. That subject completed an interview and a withdrawal questionnaire but refused laryngeal examination.

Secondary outcome measures. Finally, this study evaluated a variety of secondary outcome measures including self-assessment, auditory-perceptual, aerodynamic, and acoustic measures before and after VFE intervention. Secondary outcome measures included airflow, subglottic pressure, laryngeal airway resistance, range, jitter, shimmer, noise-to-harmonics ratio (NHR), CAPE-V scores (overall, roughness, breathiness, strain, loudness, pitch), and VRQoL self-ratings. A series of paired sample t-tests was performed for the variety of variables representing secondary outcome measures for comparisons between each of the data collection time points.

For the low dose group, CAPE-V loudness was significantly different between baseline and post-intervention. Subglottic pressure was significantly different between post-intervention and one-month follow-up. VRQoL self-ratings were significantly different between baseline and one-month follow-up.

In the traditional dose group, range and VRQoL self-ratings were significantly different between baseline and post-intervention. NHR and CAPE-V breathiness scores were significantly different between post-intervention and one-month follow-up. Range, jitter, and CAPE-V overall scores were significantly different between baseline and one-month follow-up.

The high dose group demonstrated significantly different NHR and CAPE-V overall, strain, and breathiness scores between post-intervention and one-month follow-up. Changes in secondary outcome measures are provided in Table 4.7.

Table 4.7: Paired Sample T-Tests for Secondary Outcome Measures

Low Dose	Pre-post p-value	Post-month p-value	Pre-month p-value
Airflow	.453	.430	.766
Psub	.492	.047*	.678
LAR	.259	.671	.746
Range	.619	.220	.191
Jitter	.119	.163	.661
Shimmer	.616	.146	.071
NHR	.510	.321	.285
CAPE-V Overall	.133	.225	.392
CAPE-V Roughness	.314	.251	.879
CAPE-V Breathiness	.062	.347	.110
CAPE-V Strain	.304	.243	.122
CAPE-V Pitch	.347	.345	--
CAPE-V Loudness	.000*	.347	.347
VRQoL	.111	.169	.021*
Traditional Dose	**Pre-post p-value**	**Post-month p-value**	**Pre-month p-value**
Airflow	.760	.696	1.00
Psub	.506	.212	.634
LAR	.346	.727	.363
Range	.020*	.825	.018*
Jitter	.298	.234	.014*
Shimmer	.642	.182	.196
NHR	.811	.044*	.061
CAPE-V Overall	.323	.119	.034*
CAPE-V Roughness	.263	.218	.595
CAPE-V Breathiness	.671	.020*	.074
CAPE-V Strain	.203	.929	.054
CAPE-V Pitch	.347	.347	.347
CAPE-V Loudness	.347	.347	.347
VRQoL	.043*	1.00	.133
High Dose	**Pre-post p-value**	**Post-month p-value**	**Pre-month p-value**
Airflow	.639	.297	.368
Psub	.980	.426	.406
LAR	.796	.079	.109
Range	.469	.325	.080
Jitter	.308	.110	.970
Shimmer	.324	.172	.200
NHR	.409	.008*	.171
CAPE-V Overall	.161	.004*	.104
CAPE-V Roughness	.441	.054	.218
CAPE-V Breathiness	.062	.013*	.206
CAPE-V Strain	.569	.024*	.106
CAPE-V Pitch	.926	.343	.343
CAPE-V Loudness	.897	.209	.212
VRQoL	.260	.343	.343

* denotes statistically significant value ($p \leq .05$)

Summary of outcome measures. A total of two primary outcome measures and 14 secondary outcome measures were examined in this study at three time points. Overall, the low dose group demonstrated significant change on both primary outcome measures and one secondary outcome measure for a total of three significantly changed measures between baseline and post-intervention. Significant change post-intervention to one-month follow up occurred for one secondary outcome measure for a total of one significant change. Between baseline and one-month follow-up, one primary outcome measure and one secondary outcome measure yielded significant change for a total of two significantly changed measures. The low dose group demonstrated an overall total of six improved measures over the course of the study.

Overall, the traditional dose group demonstrated significant change on both primary outcome measures and two secondary outcome measures for a total of four significantly changed measures between baseline and post-intervention. Significant change post-intervention to one-month follow up occurred for one primary outcome measure, but this value represents a significant decrease (worsening) of that measure. Two secondary outcome measures changed significantly in this time period. A total of three significant changes between post-intervention and one-month follow-up were found. Between baseline and one-month follow-up, one primary outcome measure and three secondary outcome measures yielded significant change for a total of four significantly changed measures. The traditional dose group demonstrated an overall total of eleven significantly changed measures over the course of the study, with ten of those representing significant improvement.

Overall, the high dose group demonstrated significant change on one primary outcome measure for a total of one significantly changed measure between baseline and post-intervention. Significant change post-intervention to one-month follow up occurred for one primary outcome measure, but this value represents a significant decrease (worsening) of that measure. Four secondary outcome measures changed significantly in this time period. A total of five significant changes between post-intervention and one-month follow-up were found. Between baseline and one-month follow-up, one primary outcome measure yielded significant change for a total of one significantly changed measure. The high dose group demonstrated an overall total of seven significantly changed measures over the course of the study, with six of those representing significant improvement. The number of statistically significant changes in primary and secondary outcome measures for each group can be viewed in Table 4.8.

The hypothesis that the high dosage group would demonstrate better maintenance at follow-up was again disproven when examining maintenance in terms of number of significant changes in primary and secondary outcome measures maintained at follow-up.

Table 4.8: Number of Significant Changes in Outcome Measures

	Primary Outcome Measures (2 possible)	Secondary Outcome Measures (14 possible)	Subtotal (16 possible)	Total (48 possible)
Low Dose				
Pre-post	2	1	3	6
Post-month	0	1	1	6 improved
Pre-month	1	1	2	
Traditional Dose				
Pre-post	2	2	4	11
Post-month	1[+]	2	3	10 improved
Pre-month	1	3	4	
High Dose				
Pre-post	1	0	1	7
Post-month	1[+]	4	5	6 improved
Pre-month	1	0	1	

[+] denotes a measure that worsened significantly

Compliance

Participant compliance with weekly check-ins was 99% overall. Only one participant failed to attend a check-in on one occasion. All home practice logs were returned with the exception of three logs from one participant. Compliance was collected via home practice logs and was tabulated in terms of number of practice sessions missed. The average number of missed practice sessions in the low dose group was nine, and the median number of missed practice sessions was one. Two participants in this group missed five or more practice sessions. The average number of missed practice sessions in the traditional dose group was 2.3, and the median number of missed practice sessions was zero. One participant in this group missed five or more practice sessions. The average number of missed practice sessions in the high dose group was 5.8, and the median number of missed practice sessions was one. Two participants in this group missed five or more practice sessions. Compliance with home practice is described below in Table 4.9 by dosage group.

Table 4.9: Home Exercise Compliance by Dosage Group

	Mean Practices Missed	**Median Practices Missed**	**Participants Missing ≥ 5 Practices**
Low Dose	9	1	2
Traditional Dose	2.3	0	1
High Dose	5.8	1	2

Chapter Summary

Chapter four served to present the statistical results of the data analysis. Chapter five will discuss the significance of these findings, study limitations, and future directions for research.

Chapter Five: Discussion

Review of Purpose

Although many areas of speech-language pathology lack precision regarding optimal dose-response relationships, this issue is especially salient in the area of voice due to the potential for toxic effects secondary to vibration over-dose. In addition, optimal dose, or the dose where benefit is maximized without detrimental effects, is essential for efficient and effective treatment (Roy 2012). As Roy mentions, there are many aspects of behavioral therapy, and more specifically voice therapy, which make it difficult to determine dose-response relationships.

The primary purpose of this investigation was to examine the effect of varying doses of VFE home practice on attainment of pre-established MPT goals in individuals with normal voice production. A secondary purpose of this investigation was to observe the presence or absence of observable toxic effects on the vocal folds as a potential result of increased VFE home practice. Finally, this study evaluated a variety of secondary outcome measures including self-assessment, auditory-perceptual, aerodynamic, and acoustic measures before and after VFE intervention in order to determine whether voice assessment parameters change differentially according to dose. That is, which assessment parameters react to low, traditional, and high doses.

Review of Methodology

A total of 28 female participants with normal voice were randomized into one of three dosage groups. All participants attended weekly check-ins and completed home practice twice daily for six weeks. The low dose group did each exercise once, the traditional dose group completed each exercise twice, and the high dose group performed

each exercise four times. Therefore, the low dose group practiced a total of 240 minutes (one repetition of four minutes, twice daily, for 30 days), the traditional group practiced a total of 480 minutes (two repetitions of four minutes, twice daily, for 30 days), and the high dose group practiced a total of 960 minutes (four repetitions of four minutes, twice daily, for 30 days).

After six weeks, VFE practice was discontinued, and participants returned one month later for follow-up. Data was collected at baseline, post VFE protocol, and at one-month follow-up. An additional laryngeal exam with stroboscopy was performed three weeks into the VFE protocol to monitor for observable toxic effects.

Discussion of Results

Group Homogeneity. A series of one-way ANOVAs demonstrated that the three experimental groups were not significantly different at baseline for age, airflow, subglottic pressure, laryngeal airway resistance, range, jitter, shimmer, noise-to-harmonics ratio, acoustic MPT, VFE MPT, CAPE-V scores (overall, roughness, breathiness, strain, pitch, loudness), or VRQoL self-ratings.

Withdrawal rates. A total of eight participants withdrew from the study. Based on withdrawal questionnaires, difficulty tolerating the rigid scope for laryngeal examination did not appear to be a major factor in the decision to discontinue participation. The most frequently cited reason for withdrawal was excessive time commitment, particularly among individuals in the high dose experimental group. Five of the individuals who discontinued the study were from the high dose group, which may indicate that doubling the dose of VFEs represents a sub-optimal course of treatment for the general population. If, by increasing dose, compliance diminishes, one might

ultimately undermine one of many key components underlying treatment efficacy. However, because this study did not examine dose in disordered voice, only speculation about VFE dosing in clinical populations can be presented.

Goal attainment. One question this study attempted to answer was whether altering the dose of VFE home practice affected pre-established VFE MPT goal attainment. Clinically, individuals who complete VFEs are typically discharged from therapy when they reach 80% of their goal. Therefore, the number of participants in each dosage group who reached 80% of their goal was tabulated. In the low dose group, one subject reached 80% of her goal. In the traditional dose group three subjects reached 80% of goal. In the high dose group four subjects reached 80% of goal. It appears that higher doses of VFE home practice may increase the likelihood of reaching MPT goal.

In previous studies examining traditional doses of VFEs in normal voice, all subjects met their goal in approximately two weeks (Stemple et al., 1994). Failure to attain goal in this study may be attributed to exercise technique, to compliance, or to other phenomena such as fatigue. Although compliance was reportedly high, misrepresentations in self-reports may obscure non-compliance that may have contributed to lack of goal attainment. It is unclear whether this was the case, particularly for the low dose group. Based on the Stemple et al. (1994) study where all participants attained goal in two weeks, it may be reasonable to suggest that, at half the dose, participants in the low dose group would have reached goal in less time. However, this was not the case. By performing exercises less frequently, participants may have spent more time in the pre-learning stages than groups who practiced with more

repetitions, meaning that consolidation of technique was delayed, thereby resulting in poorer goal attainment rates (Spielman et al., 2007).

A second question this study addressed was whether altering the dose of VFE home practice affected time to MPT goal attainment. In the high dose group, the median number of check-ins to goal attainment was five, while the average was 4.74. In the traditional dose group, the median number of check-ins to goal attainment was also five, but the mean was 5.33. In the low dose group, where only one subject met 80% of goal, attainment was achieved at her one-month follow-up. The trend suggests that higher doses of VFEs result in decreased goal acquisition times. In the low dose group, it appears that VFE MPT improved after discontinuation of exercises.

Primary outcome measures. For the primary outcome measure of VFE MPT, all three doses of VFEs were sufficient to result in significant changes between baseline and post-intervention, and between baseline and follow-up. The exception was that the low dose group did not demonstrate significant change between post-intervention and follow-up, indicating that MPT did not decline significantly with home practice discontinuation. Interestingly, the low dose group yielded the lowest percentage (11%) of individuals who met 80% of their MPT goal, with only one subject achieving her goal after follow-up. Because this participant did not meet goal during the exercise protocol, this suggests that her VFE MPT increased after exercise discontinuation. For this individual, it may be that she improved on this measure without practice, that for some reason she performed sub-optimally at post-intervention data collection, or that for some reason she performed ideally at follow-up. As a whole, the low dose group VFE MPT decreased slightly between post-intervention and follow-up, but not to a significant

degree. While the low dose group did not improve its VFE MPT as much as the other experimental groups, subjects were better able to maintain that improvement.

The traditional dose group yielded a higher percentage of individuals who met 80% of their VFE MPT goal (33%). The traditional dose group improved more in terms of VFE MPT between baseline and post-intervention and between baseline and follow-up than the low dose group. The traditional dose group experienced a significant reduction in VFE MPT between post-intervention and one-month follow-up, but maintained enough improvement at follow-up to demonstrate better overall outcomes than the low dose group.

The high dose group yielded the highest percentage of individuals who met 80% of their VFE MPT goal (40%). The high dose group improved more in terms of MPT between baseline and post-intervention and between baseline and follow-up than the traditional dose group. Individuals in the high dose group demonstrated a significant reduction in MPT between post-intervention and one-month follow-up. Interestingly, the high dose group seemed to yield diminishing returns. The gap in improvement between the high and traditional dose groups was not as great as the gap in improvement between the traditional and low dose groups. This trend was noted despite the fact that doses were doubled with each successive group. In fact, at follow-up, the traditional dose group had a higher median percentage point change from baseline than did the high dose group, though the average percentage point change was higher in the high dose group. Because medians are less susceptible to being skewed by outliers in the data set, it is reasonable to conclude that high and traditional doses of VFE may lead to similar changes in VFE MPT between baseline and follow-up.

Low doses of VFEs were insufficient to improve vocal function to the same extent as higher doses. Conversely, individuals who completed higher doses of VFEs trained higher in that their percentage point change between pre- and post-intervention indicated greatest improvement, but lost on average 16 (median of 15) percentage points in VFE MPT at one-month follow-up, which represented the largest decline. By comparison, the traditional group lost an average of 11 (median of 9) percentage points and the low dose group lost an average of three (median of two) percentage points at follow-up. Thus, improvement maintenance in MPT was similar for the high and traditional groups when considering mean and median percentage change.

For the primary outcome measure of acoustic MPT, only the low and traditional dose groups significantly improved from pre- to post-intervention. Acoustic MPT refers to MPT taken on the vowel /a/ without use of a semi-occluded vocal tract posture. No other time points demonstrated significant change for any of the three dosage groups. The high dose group, despite improvement in MPT, did not demonstrate significant difference in acoustic MPT. The traditional group demonstrated better outcomes at follow-up in acoustic MPT as compared to any other group, but change in acoustic MPT from baseline to follow-up was not statistically significant.

Toxicity. In this study, no obvious toxic effects to the vocal fold mucosa were observed in any of the intervention groups as visually and subjectively assessed using stroboscopy and through the use of perceptual rating scales. Toxicity was monitored via weekly completion of the VRQoL by each participant and by stroboscopic evaluation after three weeks and six weeks of exercise completion. One participant in the high dose group discontinued the study in the first week, complaining of throat pain and fatigue.

She was interviewed and told the researcher that she was involved in a choral group and that the exercises in addition to her rehearsal schedule likely led to her noticeable discomfort. She refused a follow-up laryngeal examination. No other reports of vocal fatigue, pain, or soreness were made throughout the course of the study for any other participant. It can also be noted from the data that for the individuals who reached goal prior to finishing the six-week protocol, continuing practice past the point of goal attainment did not produce observable toxic effects. All participants continued daily practice for six weeks, yet no observable detrimental effects were observed or reported. Based on the results of this study, high doses of VFEs consisting of four repetitions of each exercise twice daily for six weeks were not found to result in detrimental effects in individuals with normal voice, using the objective and subjective measures previously indicated.

Secondary outcome measures. Another question this study attempted to address was which vocal assessment parameters changed with low doses, traditional doses, and high doses of VFEs. Because the sample in this study consisted of individuals with normal voice, many of the secondary outcome measures demonstrated few statistically significant differences. Of these, low doses produced statistically significant (1) improvement in CAPE-V loudness from baseline to post-intervention, (2) decreased subglottic pressure differences from post-treatment to one-month follow-up, and (3) improved VRQoL self-ratings (significantly decreased) from baseline to one-month follow-up.

Traditional doses produced statistically significant (1) improvement in pitch range between baseline and post-intervention as well as (2) between baseline and one-month

follow-up. Pitch range did not significantly differ as a result of discontinuing daily exercise, suggesting that this variable is more readily maintained with traditional doses of VFEs. (3) Jitter significantly decreased (improvement) between baseline and one-month follow-up. (4) NHR significantly decreased (improvement) between post-intervention data collection and one-month follow-up. The results for jitter and NHR indicate that these variables may continue to improve after discontinuation of practiced exercises. (5) Overall CAPE-V scores improved significantly from baseline to one-month follow-up, with (6) breathiness significantly decreasing (improved) between post-intervention and one-month follow-up, and (7) VRQoL decreasing (improved) significantly from baseline to post-intervention.

High doses produced statistically significant (1) decreases (improvements) in NHR, (2) overall CAPE-V score, (3) breathiness, and (4) strain between post-intervention and follow-up. No other statistically significant changes were made pre-post intervention or baseline to one-month follow-up for secondary outcome measures in this group.

Summary of outcome measures. The low dose group improved on a total of six outcome measures over the course of this study, yet only two measures demonstrated longer-term improvement at one-month follow-up. The traditional dose group improved on a total of ten outcome measures over the course of this study, with only four measures demonstrating continued improvement at one-month follow-up. The high dose group improved on a total of six outcome measures over the course of this study, but only one measure continued to demonstrate improvement at one-month follow-up. Summarizing results using tabulation of total number of improved outcome measures provides some important insights: (1) low and high dose groups demonstrated the same number of

improved measures, (2) the low dose group demonstrated more maintained improvements at follow-up than the high dose group, (3) the traditional dose group demonstrated highest number of improved and maintained measures. While the high dose group may have demonstrated greatest improvement on some outcome measures, the number and maintenance of improved measures were not superior to other groups.

Interestingly, the outcome measures that had significantly improved at one-month follow-up were not always the same outcome measures that improved from baseline to post-intervention. This is particularly true of the secondary outcome measures, indicating a likely interaction between intervention and secondary outcome measures in normal voice. In summary, low doses of VFEs may be sufficient to improve some voice outcome measures, but these gains may be diminished in comparison to the improvement that higher doses yield. In normal voices, higher doses may not intrinsically mean better outcomes or better maintenance. In this study, traditional doses of VFEs appear to have resulted in the best overall maintenance of the practiced tasks.

Compliance. Compliance is the state of an individual adhering to a pattern of treatment. While compliance exists separately from dose, it may have a substantial effect on overall therapeutic outcomes because it represents accumulation of an active ingredient over time. Because compliance, or non-compliance, may affect treatment outcomes, it is a vital consideration in behavioral intervention.

In terms of compliance, high doses of VFEs increased the withdrawal rate of participants to 50%. Given the importance of compliance in voice therapy, increasing dose may undermine one of many key components of the program and reduce its effectiveness. Interestingly, low doses also elicited poorer compliance. Out of the three

groups, the traditional dose group exhibited superior compliance in every form: (1) mean number of missed practice sessions, (2) median number of missed practice sessions, and (3) number of participants who missed five or more practice sessions. This may because fewer repetitions during practice led to longer amounts of time spent in the pre-learning stage, where technique is not yet consolidated. This may have influenced the motivation of individuals in the low dose group, who may have felt less confident in their ability to perform the exercises. It is hypothesized that compliance may influence over all treatment effect and may represent a leading factor in determining outcomes both in basic and in clinical research.

A study by Wenke et. al (2014) described characteristics of individuals who were more likely to attend therapy. Candidates likely to complete voice therapy were young, employed females with fewer laryngeal diagnoses and medical problems, less severe voice disorders, and lower Voice Handicap Index scores at baseline. While the participants in this study were similar to the described population, they were vocally normal and therefore did not have any type of disorder. This may or may not have affected their motivation to be compliant with the intervention protocol. More broadly, this may be an intrinsic flaw in the study of dose in normal subjects.

Limitations and Delimitations

The present study contains certain limitations, one of which is that compliance with home practice was self-reported and could not be verified by the researcher. Non-compliance with home practice could significantly alter the individual's treatment outcomes, particularly at the post-exercise data collection point. Certain aspects of this study's methodology were included specifically to address this limitation. First,

compliance was stressed to all participants, who were provided with face videos to guide and facilitate home practice. Second, participants were reminded to practice twice daily via email. Third, home practice logs were kept and returned weekly.

A second limitation is that research assistants, rather than clinicians specialized in voice, provided guidance for weekly check-ins. Although this study addressed VFE use in individuals with normal voice, research assistants lack the expertise that an experienced voice clinician would have. Less effective or efficient feedback and instruction provided by research assistants may have diminished the efficacy of VFEs and may also have reduced participant compliance. This limitation was addressed by several aspects of the study's design. First, research assistants received training from a speech-language pathologist and expert in voice. Technique was then reviewed individually on two separate occasions. Second, upon initial teaching of VFEs to each participant, voice clinicians with extensive experience using and teaching VFEs confirmed technique with each subject and established VFE MPT baselines. Third, 20% of all weekly check-ins were supervised by experienced voice clinicians, and an additional 20% were monitored by a second year graduate student with experience teaching and using VFEs. Finally, it is important to point out that one attractive quality of the VFE program is that it is fairly simple to teach and practice (Stemple, Glaze, & Gerdeman, 2000).

A number of delimitations were also present in this study. First, this study addressed VFE dosage in individuals with normal voice, and therefore conclusions about pathological populations cannot be drawn. Second, the small sample size used in this study only permits this data to be used for preliminary purposes. Third, only three distinct dosages were examined during this study. Therefore, conclusions about even

higher dosages cannot be drawn. As Baker (2012) points out, when a more intense treatment or a higher dosage does not lead to increased gains, one is left to wonder if one has proof that there is no additional benefit or if the intensity studied simply was not intense enough. Conclusions about the effects of adjusting intensity or dosage in other ways (number of sessions per week, overall length of intervention, etc.) cannot be made. Fourth, there was no attrition component to this study. Given that data collection took place during the fall, upper respiratory infections and allergies could not be avoided. Fifth, although all participants were asked to agree not to engage in vocally harmful behaviors, vocal hygiene was not tracked or reported. Finally, no tapering schedule was used, as recommended following VFE protocols in clinical settings. Typically, after reaching VFE MPT goal, the clinician guides the individual in gradually reducing their practice intensity of VFEs over a number of weeks, with the criterion of maintaining and sustaining 85% of their original MPT goal. In this study, exercises were discontinued completely after six weeks. One-month follow-up data in this study should be interpreted with this in mind, as absence of tapering programs diminishes maintenance.

Implications for Future Research

Due to the aforementioned limitations and delimitations, further research is necessary to determine optimal dose-response relationships for VFEs in normal voice. This would include research using larger sample sizes and a greater variety of dosage groups. If possible, alternate means of compliance tracking, for example a web-based application that would provide instructions, obtain MPT, and send reports to researchers, may be used. Previous studies have demonstrated that groups of participants in compliance-monitored VFE groups improved significantly more on MPT in comparison

to unmonitored groups. Monitored groups were asked to submit audio or video recording of exercises, which presumably increases accountability (Ellis et al., 2011).

Future research should also include additional data, for example confidence self-ratings from clinicians, research assistants, and study participants regarding VFE technique. Additionally, clinicians could rate the accuracy of each subject's technique when performing exercises. This information could be vital in interpreting outcomes, as better technique may correlate with compliance, goal attainment, and time to goal attainment, among other variables. Additionally, superior technique implies a higher dose if technique is an essential active ingredient of VFEs.

The scarcity of research on dose-response relationships in behavioral therapy, particularly in voice therapy, is apparent after an extensive literature review. More research investigating the effects of modifying VFE dosage on outcome measures is necessary for establishing more efficient treatment models. This may include a greater variety of dosage groups or alternate methods of increasing and decreasing dose or intensity. Optimal dose-response relationships in normal voice must be investigated prior to exploration in clinical populations. Data on clinical populations would be useful in determining the window for greatest improvement in the pathological voice, thereby improving efficiency of treatment and accuracy of prognoses. This is especially important in identifying potential thresholds for vibration over-dose or toxicity levels.

Significance of the study

This is a pilot dosage study. It is one of the only studies to examine the effects of varying dose in voice intervention and the first one to systematically examine varying exposure to VFEs. Studying dosage in normal voice is an important first step to research

that examines dosage in clinical populations and serves as a contribution toward defining intervention that is not only effective but also more efficient. Efficiency of treatment is essential to sparing much in the way of time, resources, effort, and money on the part of the healthcare organization, client, clinician, and third party payer.

Contribution to the literature on dosage. Increased dosages of VFEs have not been previously examined, making this study the first to do so. However, there are a number of studies presented in the literature review in chapter two that have examined reduced exposures to VFEs. These studies suggest that lower exposures of VFEs may improve the normal voice, but to a lesser degree. Ellis and Beltyukova (2011) found that in two groups of adult women with normal voice who performed VFEs, both groups improved significantly but the group that was monitored for compliance improved significantly more.

In disordered voice, Pasa et al. (2007) compared groups of teachers with self-reported voice problems who completed either VFEs or vocal hygiene (VH). The treatment delivery model consisted of a group format with reduced clinician contact time. The VH group improved more on measures of voice characteristics and knowledge of vocal health. Berg et al. (2008) examined VRQoL scores in individuals with age-related dysphonia after completion of VFEs. As part of the study, they demonstrated that subjects who were described as "adherent" demonstrated better improvement in comparison to those who were "partially adherent," though definitions for these terms were not provided and compliance did not appear to be explicitly tracked. Nguyen and Kenny (2009) compared two groups of primary teachers with muscles tension dysphonia. One group performed a full VFE protocol, while the other completed a partial protocol

consisting only of the first exercise. The full protocol group demonstrated better outcomes on a variety of outcome measures.

These studies all provide examples of outcomes secondary to reduction of traditional VFE exposure. Previous literature and the present study support the idea that reductions in VFE exposure result in suboptimal outcomes in normal voice. However, specific changes in dosage have never been systematically examined, and dosage and compliance should not be confounded. While dosage, compliance, and even dose are intrinsically related, they must also be carefully separated.

In pharmacology, dose is an amount of an agent given at an instant in time. For VFEs, dose cannot be determined because the agent (active ingredient) remains unknown. Somewhat related to dose is dosage, which refers to a pattern of delivery. In this study, dosage was the independent variable that was systematically manipulated in order to develop a dosage-response curve. Dosage-response curves describe how frequently a given quantity should be administered in order to yield therapeutic effect. However, therapeutic effects are additive in nature and intrinsically affected by compliance. That is, the state of an individual adhering to a pattern of treatment, which is complex in nature. While compliance does not directly affect dose or dosage, it has an important impact on therapeutic effect and cannot be discounted in any intervention, particularly in behavioral interventions.

Dosage as integral to principles of sensory motor learning. In behavioral interventions such as VFEs, dosage takes on another facet, which cannot be accounted for in pharmacology. The important difference is that behavioral interventions may require learning of a motor task. Learning is a process of acquiring a skilled action that results

from experience or practice and produces relatively permanent changes in behavior (Shumway-Cook & Woollacott, 2012). Research indicates that neural plasticity is the basis for motor learning, and that there are specific strategies for enhancing neural plasticity. These strategies are commonly referred to as the principles of sensory motor learning, which dictate key components vital to learning skilled movements. Some of the most salient principles will be discussed in terms of skill acquisition for VFEs.

Specificity. Specific forms of neural plasticity depend on specific experiences. Neural plasticity is facilitated during practice that closely approximates the skill to be learned (Kleim & Jones, 2008). In this study, participants in the high dosage group were asked to perform more repetitions of exercises prior to skill acquisition. This may have diminished the advantage of increased repetition, particularly during early practice, which could partially explain why participants in the high dosage group attained goal only slightly more quickly than subjects in the traditional group. More broadly, demanding higher repetitions prior to skill acquisition may have led to frustration or reduced compliance, and may have increased risk of toxic effects on the vocal mechanism.

Intensity. Intense practice is important in maximizing plasticity. Intensity can be increased by demanding greater effort, accuracy, force, repetition, or frequency (Kleim & Jones, 2008). In this study, intensity was modified by altering the number of repetitions required from each experimental group. Because repetitions were performed successively, without rest, it is likely that participants in the high dosage group expelled more effort as they became fatigued. Intensity is a key principle for establishing a dosage-response curve for VFEs because intensity of intervention affects skill acquisition, and because changes in dosage may also modify intensity.

Repetition. Lasting neural changes require repetition of a newly learned behavior (Kleim & Jones, 2008). In this study, dosage was manipulated by altering the number of repetitions required for each group. Ultimately, the high dosage group demonstrated the greatest improvement in semi-occluded MPT, which may indicate that higher repetitions were advantageous for skill acquisition. Repetition is a key principal for establishing a dosage-response curve for VFEs because repetition affects skill acquisition, and because changes in dosage may be made by altering repetition.

Clinical implications. While this study examined normal voice, pilot data may offer limited clinical perspective as well. Clinically, speech-language pathologists consider a number of elements when designing treatment plans that determine how time is structured within sessions and during independent practice. Decisions regarding treatment are partly based on clinical intuition regarding prognosis, rate of recovery, and extent of improvement required for realization of individual needs. Thus, in instructing clients on home practice schedules, it is important to weigh client-spent effort and time against expected benefits of (extended) practice.

High doses of VFEs may be feasible for select individuals, particularly for those who are highly motivated or who are vocally athletic. It may be feasible to increase dosage after establishing acceptable technique at the traditional dose. Altering dosage after skill acquisition provides the client with ample opportunity to stabilize proper technique and avoids frustration and burdensome time requirements while learning the task. Increasing dosage after skill acquisition also better satisfies the principle of specificity, while incorporating increased repetition and intensity. Another advantage is that, with good technique, concern for toxicity diminishes. For vocal athletes (e.g.

trained singers), higher doses of VFEs might be appropriate when training for specific vocal events or performances.

It is important to mention that dose may not be the most critical factor determining goal attainment or time to goal attainment. As Roy (2012) mentions, efficacy of treatment is dependent on dose, intensity, active therapeutic ingredients, and a host of other variables existing within and without the client. Dose may, however, be a major factor in determining overall improvement, even when effects are not maintained.

Clinically, tapering schedules are used to curb post-treatment decline in MPT by pinpointing the minimal practice required to maintain vocal efficiency. This study did not implement a tapering program, and therefore the data on maintenance must be interpreted with such a design in mind. In this study, successively higher doses of VFEs led to steeper declines in MPT after discontinuation of exercise. This study provides a vivid example of how quickly vocal improvements may dissipate with immediate cessation of exercise.

Clinically, low doses of VFEs may be insufficient to improve the voice, and higher dose may not result in better outcomes or maintenance. However, more research is needed to determine the effects of varying doses of VFE home practice in the pathological voice.

Conclusions

No toxic effects in vocal fold condition or phonation were observed or measured throughout this study of normal voice involving a six-week regimen of VFEs practiced up to four times each, twice daily. Toxic effects of intense voice treatment have not yet been defined, which is in keeping with previous literature.

For physiologic goal, varying the dose of home practice alters MPT attainment in normal voice. Low exposures to VFEs may prevent individuals from reaching MPT goal. High doses may improve time to goal attainment and likelihood of goal attainment. The effects observed in VFE MPT may not transfer to acoustic MPT. Low and traditional dose groups demonstrated similar improvement in acoustic MPT, while the high dose group did not demonstrate significant change in this measure.

For primary and secondary outcome measures, low and high doses resulted in the same number of significant improvements. Traditional doses demonstrated the greatest number of statistically significant changes.

Maintenance can be viewed in terms of decrease in VFE MPT after completion of the intervention protocol. Under the lens of decreased MPT, the low dose group displayed the best maintenance. Alternatively, maintenance may be defined in terms of the number of significantly improved outcome measures at follow-up. In the case of quantity of improved outcome measures, the traditional dose group demonstrated the best maintenance. This may be related to the fact that this group also exhibited highest compliance, which may have affected overall treatment outcomes.

In summary, low doses of VFEs may improve normal voice, though insufficiently. High doses may not produce gains beyond traditional doses, particularly at follow-up. Therefore, blanket alterations of dosage are not likely to be feasible. As in pharmacology, where dose is adjusted according to variables such as age, weight, and gender, it is feasible that dosing in voice must also be individualized to some extent. The variables determining appropriate dosing cannot be enumerated with certainty, but level of motivation, baseline function, and individual goals are likely to be salient.

Chapter Summary

Chapter five served to discus the results of this study, their significance, and their clinical implications. Limitations and delimitations, as well as directions for future research were also outlined in this chapter.

Appendix A: Recruitment Flyer

University of Kentucky Research

Volunteers Needed for a Study of Voice Production

Researchers at the University of Kentucky, College of Health Sciences need participants as a part of a study they are conducting. Testing involves detailed throat examination and voice quality measures. You would need to come in 8 times for about 1 hour.

You may be able to participate if you:

- ✓ Are between 18-25 years old
- ✓ Are female
- ✓ Are a non-smoker
- ✓ Have not had a year or more of classical vocal training
- ✓ Do not have a history of uncontrolled asthma

Appendix B: Consent Form

Combined Consent and Authorization to Participate in a Research Study

VOCAL FUNCTION EXERCISES FOR NORMAL VOICE: THE EFFECTS OF VARYING DOSAGE

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study that will examine the effects of varying dosage of Vocal Function Exercises on the maximum phonation time in individuals with normal voice. You are being invited to take part in this research study as a volunteer in one of three groups, and your group assignment will be determined randomly. If you volunteer to take part in this study, you will be one of about 30 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Maria Bane of the University of Kentucky, Department of Communication Sciences and Disorders. Maria Bane is a graduate student. She is being guided in this research by faculty advisor Joseph Stemple, Ph.D., CCC-SLP. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

With this study, we hope to learn more about how varying the dose of Vocal Function Exercises affects time to maximum phonation goal attainment in the normal voice.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are younger than 18 or older than 25 years of age. If you have a history of uncontrolled asthma, are a smoker, or have a year or more of classical voice training, you should not take part in this study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky Voice and Swallow Clinic in room 116F and 106C of the Charles T. Wethington building and in the University of Kentucky Academic Clinic in room 110 of the Charles T. Wethington building. You will be asked to come in for treatment or assessment a total of 7 times, and each visit will take on average one hour. These sessions will take place over a 4-month period. In addition, you will be asked to do exercises at home in the morning and in the evening, and this will take you about 10 minutes each time.

WHAT WILL YOU BE ASKED TO DO?

At your arrival, we will assess your voice at its current (baseline) functioning, which will include:

- Voice self-assessment: You will be asked to fill out a questionnaire on the quality of your voice.
- Visual imaging of the appearance and movements of vocal/laryngeal structures: An endoscope attached to a digital camera and recorder will be placed into your mouth and a recording will be made of the vocal folds as they produce voice.
- Audio-visual recordings of your voice: These measures will be obtained while you voice or breathe into a microphone and an airflow mask. Researchers will then measure the air pressure and airflow out of your mouth that you use during voice production. Voice samples and airflow measures may be taken several times to ensure consistency.
- Auditory-perceptual rating: A speech-language pathologist who specializes in voice will listen to your speaking voice and rate its quality and characteristics.

Clinical visits:

Date of Visit	Purpose	Procedures
9/25/15	Baseline & Session 1	Full voice assessment; learn Vocal Function Exercises (VFEs)
10/2/15	Session 2	VFEs; complete questionnaire
10/9/15	Session 3	VFEs; complete questionnaire
10/16/15	Session 4 & Midpoint Data Collection	VFEs; complete questionnaire; visual imaging of vocal folds
10/23/15	Session 5	VFEs; complete questionnaire
10/30/15	Session 6	VFEs; complete questionnaire
11/6/15	Data Collection	Full voice assessment
12/4/15	Maintenance Data Collection (1-month follow-up)	Full voice assessment

At home exercises: You will be assigned to one of three groups randomly (by chance). All three groups will be asked to do the same exercises, however the number of times you perform the exercises will vary. The exercises will be performed at each session and also independently at home with the guidance of a smartphone application. See the group descriptions as well as the list of exercises below:

Group	Frequency of Vocal Function Exercises (VFEs)
Low dose group	One time each, twice daily
Traditional dose group	Two times each, twice daily
High dose group	Four times each, twice daily

Exercise	Description
1	Warm up exercise- sustain vowel "ee" as long as possible
2	Stretching exercise- glide upward from lowest to highest note on the word "knoll"
3	Contracting exercise- glide downward from highest to lowest note on the word "knoll"
4	Low impact adductory power exercise- sustain the musical notes C-D-E-F-G for as long as possible on "oll"

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

During the assessment and data collection, the scope will be passed into your mouth to view your vocal folds. This may be momentarily uncomfortable. With the mouth scope, there is a chance of gagging which can be uncomfortable. If your vocal folds show any abnormality, you will be referred to an Ear, Nose and Throat physician in the Kentucky Clinic or another ENT doctor of their choice. There are no known risks associated with audio recording or collecting air coming out of your mouth during speech. There is always a chance that any medical treatment can negatively affect you, and the investigational treatment in this study is no different. Possible minor reversible side effects of Vocal Function Exercises include edema to the vocal fold mucosa and muscular soreness. This may result in temporary decrease in vocal quality, for example hoarseness. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, your willingness to participate may, in the future, help speech-language pathologists more efficiently treat voice disorders.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or grade in any of your classes.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There is no cost to you or your insurance company for you to participate in this study since these procedures are part of research at the University of Kentucky.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your personal information will be accessible only to research personnel. Officials at the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. Any identifiable research information resulting from your participation in this research study prior to the date that you formally withdraw your consent may continue to be used and disclosed by the investigators for the purpose described in the previous section.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe that you have gotten hurt or sick as a result of participation in this study, you should contact Maria Bane at maria.bane@uky.edu and Dr. Joseph Stemple at

jcstem2@uky.edu. In case an abnormality of your voice is found during the assessment you will be referred to the UK Voice and Swallow Clinic. Should you choose to proceed with treatment, you and/or your insurance company will be responsible for the costs of all care and treatment.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are negatively affected by this study. The medical costs related to your care and treatment because of research related discomfort will be your responsibility. Depending on your insurance, you may be paid by Medicare or Medicaid if you are covered (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570. A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Maria Bane, at 859-421-1337. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies: Do you give your permission to be contacted in the future by Maria Bane regarding your willingness to participate in future research studies about how to prevent, detect, or treat voice disorders?

o **Yes** o **No** **_____Initials**

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case data will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.
We have no financial disclosures to include for the present study.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Your name, date of birth, and telephone number
- Visual images from stroboscopic exams
- Averages, time to goal attainment, and data related to Vocal Function Exercise performance at home and during sessions
- Audio-visual recordings of your voice
- Questionnaires and auditory-perceptual ratings regarding your voice

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Your information will be shared with only the research personnel participating in the present study. A list of the personnel is listed below:
  - Maria Bane, B.H.S., graduate student, Principal Investigator
  - Joseph Stemple, Ph.D, CCC-SLP, Faculty Advisor
  - Vrushali Angadi, M.S., Co-investigator

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

Electronic data will be deleted according to University guidelines.

Dates for data collection are from September 25th 2015 to December 4th 2015.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Maria Bane, B.H.S. at 900 South Limestone, Suite 120, Lexington, KY 40503 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.
You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject Date

_____
Name of [authorized] person obtaining informed consent/HIPAA authorization

_____ _____
Signature of Principal Investigator or Sub/Co-Investigator Date

Appendix C: Inclusion/ Exclusion Criteria Checklist

High, Traditional, & Low Exposure Groups

Inclusion criteria	Response to each criterion should be **'<u>yes</u>'** for subject to qualify
Individual >18 and <26 years of age	
Hearing within functional limits	
Agree to avoid abusive vocal behaviors during study participation	
Non-smoker	
Exclusion criteria	Response to each criterion should be **'<u>no</u>'** for subject to qualify
Smoker	
Trained singer (≥1 year of classical voice training)	
Hearing level not functional for instruction	
History of uncontrolled asthma	
Vocal fold pathology identified by laryngeal exam	

Appendix D: Study Checklist

DATE:

Please circle 'yes' for each item that has been completed

Subject #: High/ Traditional/ Low/ (circle 1) **_____ (number)**
(Subjects will be coded as High/ Traditional/ Low 01, 02 etc.)

Informed consent: Yes / No

VRQoL: Yes / No **Score (10-50)**: _____ **Overall Voice Quality: _____**

CAPE-V: Yes / No

Overall quality (> 29 disqualifies)	

Acoustics: Yes/No

Maximum phonation time	
Frequency range	
Noise to harmonics ratio	
Shimmer dB	
Jitter percent	

Aerodynamics: Yes/No

Vital capacity	
Airflow rate	
Mean peak air pressure	
Laryngeal airway resistance	

Strobe: Yes/No **Exam**: Rigid
0= Normal / 1= Abnormal

If abnormal: *(select one)*

Glottic closure	
Mucosal wave	
Supraglottic hyperfunction	
Phase symmetry	

If other, please identify:_____

Appendix E: Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V)

The following parameters of voice quality will be rated upon completion of the following tasks:
1. Sustained vowels, /a/ and /i/ for 3-5 seconds duration each.
2. Sentence production:
   a. The blue spot is on the key again.
   b. How hard did he hit him?
   c. We were away a year ago.
   d. We eat eggs every Easter.
   e. My mama makes lemon muffins.
   f. Peter will keep at the peak.
3. Spontaneous speech in response to: "Tell me about your voice problem." or "Tell me how your voice is functioning."

Legend: C = Consistent I = Intermittent
MI = Mildly Deviant
MO =Moderately Deviant
SE = Severely Deviant

				SCORE
Overall Severity	MI MO SE	C	I	/100
Roughness	MI MO SE	C	I	/100
Breathiness	MI MO SE	C	I	/100
Strain	MI MO SE	C	I	/100
Pitch (Indicate the nature of the abnormality): _____	MI MO SE	C	I	/100
Loudness (Indicate the nature of the abnormality): _____	MI MO SE	C	I	/100
_____	MI MO SE	C	I	/100
_____	MI MO SE	C	I	/100

COMMENTS ABOUT RESONANCE: NORMAL OTHER (Provide description):_____

_____

ADDITIONAL FEATURES (for example, diplophonia, fry, falsetto, asthenia, aphonia, pitch instability, tremor, wet/gurgly, or other relevant terms):

Clinician:_____

Appendix F: Otolaryngology Associates, P.C.
Voice Related Quality of Life (V-RQOL)

Name: _____ **Date:** _____

We are trying to learn more about how a voice problem can interfere with your daily activities. On this paper, you will find a list of possible voice-related problems. Please answer all questions based upon what your voice has been like over the past 2 weeks. There are no "right" or "wrong" answers.

Considering both how severe the problem is when you get it, and how frequently it happens, please rate each item below on how "bad" it is (that is, the amount of each problem you have). Use the following scale for rating the amount of the problem.

1 = None, not a problem
2 = A small amount
3 = A moderate (medium) problem
4 = A lot
5 = Problem is "as bad as it can be"

Because of my voice:	**How much of a problem is this?**
1. I have trouble speaking loudly or being heard in noisy situations.	1 2 3 4 5
2. I run out of air and need to take frequent breaths when talking.	1 2 3 4 5
3. I sometimes do not know what will come out when I begin speaking.	1 2 3 4 5
4. I am sometimes anxious or frustrated (because of my voice).	1 2 3 4 5
5. I sometimes get depressed (because of my voice).	1 2 3 4 5
6. I have trouble using the telephone (because of my voice).	1 2 3 4 5
7. I have trouble doing my job or practicing my profession (because of my voice).	1 2 3 4 5
8. I avoid going out socially (because of my voice).	1 2 3 4 5
9. I have to repeat myself to be understood.	1 2 3 4 5
10. I have become less outgoing (because of my voice).	1 2 3 4 5

The overall quality of my voice during the last two weeks has been (please circle):

Poor Fair Good Very Good Excellent

Hogikyan ND, Sethuraman G. Validation of an instrument to measure voice-related quality of life (V-RQOL). Journal of Voice. 1999. 13:557-569.

LPV 3/10

Appendix G: Vocal Function Exercise Program

The following four exercises are performed twice daily (morning and evening) the prescribed number of times (according to dose) for 6 weeks.

Exercise 1: Warm up exercise- sustain vowel /i/ as long as possible

- Females on musical not F above middle C
- Extreme forward focus "almost but not quite nasal"

Goal- sustained /i/ equal to vital capacity/ 80 mL/s (physiologic goal).

Exercise 2: Stretching exercise- glide upward from lowest to highest note on the word "knoll"

- Extreme forward placement, open pharynx, and sympathetic lip vibration
- Continue the stretch even after phonation has stopped

Goal- No voice breaks

Exercise 3: Contracting exercise- glide downward from highest to lowest note on the word "knoll"

- Open pharynx, slow, no growl at the bottom, no muscling of the tone

Goal- No voice breaks

Exercise 4: Low impact adductory power exercise- sustain the musical notes C-D-E-F-G for as long as possible on the word "knoll" without the "kn"

- Open pharynx, lip vibration

Goal- sustained /o/ equal to vital capacity/ 80 mL/s

Instructions

- Produce all exercises as softly as possible with engaged voice (not breathy). No hard glottal attacks at voice onset.
- Tone placement should be forward with an open pharynx and constricted, vibrating lips (inverted megaphone shape).
- Specific speech stimuli (knoll, oll) are selected to help achieve proper placement and pharyngeal opening.
- The tone should not be muscled at the larynx; rely on interaction between abdominal contraction and breath support.
- Practice consistency is encouraged; the participant charts progress on a record sheet. Face videos are provided to guide practice sessions.

Appendix H: Withdrawal Questionnaire

Please complete the questionnaire honestly. You will not be subject to any penalty or repercussion as a result of withdrawal from this study. We would like to know the reason for withdrawal as it may have implications for our results, data analysis, and continuation of the study.

Please rate how difficult/ uncomfortable your stroboscopic examination (visualization of the vocal folds/ imaging of the larynx) was (circle one):

No discomfort Mild discomfort Moderate discomfort Extreme discomfort

Please check all that apply:

- ☐ I feel that I experienced fatigue, pain, soreness, or discomfort as a result of the exercise practices that I completed.
- ☐ I felt discouraged by the required technique and was not able to achieve it independently.
- ☐ I felt that the time commitment involved became too great to continue participation (if so, please indicate dose):
  - 2x1
  - 2x2
  - 2x4
- ☐ Another personal matter prevented my full participation.
- ☐ I do not wish to give a reason but will not continue my participation.
- ☐ Other (please elaborate):

Appendix I: Average Weekly Phonation Times (s)

	Check-In Week Number								
Subject Number		1	2	3	4	5	6	7	Mo.
	02	17	18	19	22	23	26	28	31
	07	25	27	27	26	25	30	34	25
	08	20	26	25	23	22	26	25	29
	12	13	11	15	15	14	13	18	14
	23	16	17	20	23	21	19	19	19
	24	21	21	19	20	21	21	20	20
	25A	18	19	21	18	22	28	28	24
	27A	16	18	18	20	20	22	19	17
	28	11	12	14	13	15	16	15	14
	29	15	26	24	32	32	32	32	24
	03	17	24	25	27	24	20	28	24
	05	21	22	24	24	24	21	23	19
	20	25	40	36	34	54	43	49	47
	13	19	27	32	35	33	28	31	26
	06	10	18	20	25	21	17	21	13
	30	20	20	26	25	27	34	32	30
	19	27	30	27	27	24	29	30	27
	15A	16	18	20	26	29	31	31	24
	21A	18	17	25	26	29	39	37	26
	14A	15	21	23	28	27	28	28	20
	22A	25	34	33	38	41	44	51	41
	01A	20	24	26	32	27	32	33	26
	17A	22	24	24	28	28	32	37	31
	09	21	49	39	34	35	35	27	25
	16	22	35	26	27	30	32	32	29
	18	21	20	27	33	39	58	60	40
	26	19	20	22	24	25	27	34	23
	10	11	15	15	15	18	16	14	16

Low Dose
Traditional Dose
High Dose

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