COMBINED MODALITY TREATMENT OF ADDUCTOR SPASMODIC DYSPHONIA.

By

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To my daughter Molly.
You are my greatest accomplishment and your love,
my sweetest reward.

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Adductor type spasmodic dysphonia (ADSD) is a neurogenic voice disorder which directly affects muscles within the human larynx that are responsible for the production of voice. The hallmark characteristic of this disorder is the presence of irregular and uncontrollable spasms within these muscles, resulting in erratic disruption of normal voicing. The purpose of the present study was to determine the effect of voice therapy following botulinum toxin type A (BTX-A) injections for ADSD on duration of injection benefit, perceived vocal quality of life, and various acoustic measures of vocal instability. The study also sought to compare these effects with those observed in participants who had only received BTX-A injections, and those who had received BTX-A injections followed by a “sham” voice therapy.

Thirty-one individuals with ADSD participated in this study. None of the participants had ever had prior BTX-A injections. All participants had elected to receive BTX-A injections for ADSD. Following enrollment, one-third received no further intervention following injection, one-third received a standard five-week course of voice therapy following injection, and one-third received a five week course of sham voice therapy following injection. Variables of interest were duration of injection benefit, quality of life as indicated by standard scores from the Voice-Related Quality of Life (V-RQOL) battery, as well as acoustic measures of vocal instability.

Measures of these variables were collected prior to initial injection, three weeks post injection, seven weeks post injection, 12 weeks post injection, and immediately prior to reinjection.

Results suggested significant effects on participants' perceived quality of life and acoustic variables, over time, for all participants. These effects were observed to have a curvilinear relationship to time. Participants who received voice therapy following BTX-A injection did not experience longer injection effect duration or significantly greater improvements in V-RQOL or acoustic variables than participants in BTX-A only or BTX-A plus sham therapy groups. The results provide additional information on changes to acoustic and voice-related quality of life variables following BTX-A injection.

CHAPTER 1
INTRODUCTION AND REVIEW OF THE LITERATURE

Origins of Spasmodic Dysphonia

Spasmodic dysphonia (SD) is a neurogenic voice disorder which directly affects muscles within the human larynx that are responsible for the production of voice. The hallmark characteristic of this disorder is the presence of irregular and uncontrollable spasms within these muscles, resulting in erratic disruption of normal voicing.

Two varieties of SD exist. The first, known as abductor SD (ABSD), makes up only around 15% of SD cases and involves uncontrollable opening or *abduction* of the vocal folds during voicing tasks (Merson & Ginsberg, 1979). These uncontrollable vocal abductions typically produce an excessively breathy and irregular voice. The second, more common, subtype is known as adductor SD (ADSD) and features frequent and irregular closure or *adduction* of the vocal folds, producing characteristic "strain and strangle" type voicing (Miller & Woodson, 1991; Van Pelt, Ludlow, & Smith, 1994) that arises from aberrant acoustic events (Sapienza, Murry, & Brown, 1998). ADSD was first described by Traube (1871) as a "nervous hoarseness" and, over time, became known as "spastic dysphonia."

The etiology of ADSD is unclear. Individuals diagnosed with ADSD are predominately (nearly 80%) female (Adler, Edwards, & Bansberg, 1997), with onset typically occurring during the fourth decade of life (Schweinfurth, Billante, & Courey, 2002). Diagnosis of ADSD has been associated with presence of writer's cramp, essential tremor, and a remote diagnosis of mumps or measles with onset frequently following an upper respiratory illness or major life stress (Schweinfurth et al., 2002). Up until recent decades, ADSD was considered a psychological disorder, primarily affecting anxious individuals, possibly brought about by the "pressures and losses of middle age" (Henschen & Burton, 1978). Although psycho-social

issues are known to co-manifest with ADSD (Aronson, Brown, Litin, & Pearson, 1968; Mirza, Ruiz, Baum, & Staab, 2003; Smith et al., 1998), current theory holds that psycho emotional correlates of ADSD are likely symptoms of the primary voice disorder (Baylor, Yorkston, & Eadie, 2005; Liu et al., 1998), rather than the cause of the disorder itself.

Other investigations have focused on structural abnormalities involving the recurrent laryngeal nerve (RLN) but have failed to identify consistent abnormalities within the RLNs of individuals with ADSD versus healthy controls (Bocchino & Tucker, 1978, Dedo, Townsend, & Izdebski, 1978; Kosaki, Iwamura, & Yamazaki, 1999; Ravits, Aronson, DeSanto & Dyck, 1979).

Current theory classifies ADSD as a *focal dystonia* alongside such disorders as torticollis, blepharospasm, oral mandibular dystonia, and writer's cramp (Ludlow & Connor, 1987). This classification is indicative of a neurogenic etiology, although no clear relationship exists between ADSD and damage to any one particular area of the brain or brainstem (Aronson & Lagerlund, 1991; Devous et al., 1990; Finitzo & Freeman, 1989; Hirano et al., 2001; Schaefer et al., 1985). Other research has focused on the role of sensorimotor pathways in the inhibition of laryngeal response to sensory inputs, and potential dysfunction of these pathways in individuals with ADSD (Deleyiannis, Gillespie, Bielamowicz, Yamashita, & Ludlow, 1999; Ludlow, Schultz, Yamashita, & Deleyiannis, 1995).

ADSD is frequently confused with muscle tension dysphonia (MTD), where voice symptoms are brought about through excessive muscular tension and maladaptive patterns of voicing. The two disorders can be differentiated acoustically (Sapienza, Walton, & Murry, 2000) and, unlike MTD, ADSD appears to be task specific in that voice symptoms will manifest as more severe during connected speech (as opposed to sustained vowel) and voiced (as opposed to voiceless) phonemes. In contrast, individuals with MTD will typically maintain consistent

levels of severity across connected speech, sustained vowel, and during both voiced and voiceless productions (Erickson, 2003; Roy, Gouse, Mauszycki, Merrill, & Smith, 2005; Roy, Mauszycki, Merrill, Gouse, & Smith, 2007). Individuals with ADSD also demonstrate greater variability in mean phonatory airflow compared to those with MTD (Higgins, Chait, & Schulte, 1999).

Treatment Options for Spasmodic Dysphonia

Initially addressed through behavioral therapy alone, today a number of treatment options exist for individuals with ADSD. These include surgical, chemodenervation, alternative, behavioral, and combined modality approaches.

Surgical Treatments

Surgical treatment of ADSD focuses on modifying the mechanics of phonation, reducing vocal fold adduction by altering nervous system control of the larynx. This can be accomplished through resection (Barton, 1979; Dedo, 1976), selective sectioning (Carpenter, Henley-Cohn, & Snyder, 1979), or crushing (Biller, Som, & Lawson, 1979) of the RLN, the nerve responsible for vocal fold adduction. These procedures create a surgically-induced partial or total paralysis of one or both vocal folds, reducing or eliminating the ability of the vocal folds to spasmodically close. Failure rates for this type of surgical procedure appear relatively high with return of symptoms frequently observed anywhere from four months to three years post-surgery (Aronson & DeSanto, 1981; 1983; Fritzell et al., 1993; Izdebski, Dedo, Shipp, & Flower, 1981; Levine, Wood, Batza, Rusnov, & Tucker, 1979; Wilson, Oldring, & Mueller, 1980). Learned compensation in the form of over adduction of the non-paralyzed fold or false vocal fold adduction (Aronson & DeSanto, 1983), and neural regrowth (Fritzell et al., 1993; Ludlow, Naunton, Fujita, & Sedory, 1990; Schiratzki & Fritzell, 1991; Shindo, Herzon, Hanson, Cain, & Sahgal, 1992; Wilson et al., 1980) are frequently implicated as reasons why surgical

interventions for ADSD fail. Adjunctive procedures such as postoperative voice therapy (Dedo & Izdebski, 1983) or RLN avulsion (Netterville, Stone, Rainey, Zealear & Ossoff, 1991) may be successful in reducing the likelihood of symptom return following surgery.

Companion surgical procedures such as vocal fold bulking (Belafsky & Postma, 2004; Izdebski, Dedo, Shipp, & Flower, 1981; Hill, Meyers, & Harris, 1991; Hirano, Tanaka, Tanaka, & Hibi, 1990; Peppas & Benner, 1980; Schramm, May, & Lavorato, 1978) and thinning (Izdebski, et al., 1981) can be used to improve an overly breathy or still-spasmodic vocal quality following RLN procedures.

Selective bilateral denervation reinervation procedures emerged in the early 1990's and were designed to eliminate vocal fold hyperadduction while minimizing the potential undesirable surgical side effects of excessive breathiness, airway compromise, and neural regrowth with symptom return (Allegretto, Morrison, Rammage, & Lau, 2003; Chhetri & Berke, 2006; Sercarz, Berke, Ming, Rothschiller, & Graves, 1992). Here, the RLN is sectioned bilaterally, and then reinnervated by branches of the *Ansa Cervicalis*. This preserves the action of vocal fold adduction for voicing and airway protection while permanently eliminating the capacity for over-adduction, or vocal fold spasming (Allegretto et al., 2003; Berke et al., 1999). This procedure has been successful in long term symptom resolution for some patients (Chhetri, Mendelsohn, Blumin, & Berke, 2006).

Other, less popular, surgical procedures used in the treatment of ADSD include midline lateralization type II thyroplasty (Chan, Baxter, Oates, & Yorkston, 2004; Isshiki, 1998; 2000; Isshiki, Haji, Yamamoto, & Mahieu, 2001; Isshiki, Tsuji, Yamamoto, & Iizuka, 2000), anterior commissure retrusion (Tucker, 1989), autologous replacement of the vocal fold (Tsunoda, Amagai, Kondou, Baer, Kaga, & Niimi, 2005) thermotherapy of terminal RLN branches

(Remacle, Plouin-Gaudon, Lawson, & Abitbol, 2005) thyroarytenoid (TA) muscle myectomy (Su, Chuang, Tsai, & Chiu, 2007; Woo, 1990), and implantation of a RLN stimulator (Friedman, Toriumi, Grybauskas, & Applebaum, 1989; Friedman, Wernicke, & Caldarelli, 1994).

Chemodenervation Treatments

Botulinum toxin type A (BTX-A), known commercially as Botox (©2005 Allergan) acts as a temporary paralytic, inactivating muscle fibers into which it is injected (Blitzer & Sulica, 2001). Successful use of BTX-A with other focal dystonias such as spasmodic torticollis (Boghen & Flanders, 1993) and blepharospasm (Jost & Kohl, 2001) brought about interest in the drug as a potential therapy for ADSD (Blitzer, Brin, Fahn, & Lovelace, 1988; Miller, Woodson, & Jankovic, 1987). BTX-A, injected into one or both TA muscles, paralyzes the muscle fibers to which it comes in contact through blockage of acetylcholine release at the neuromuscular junction (Bielamowicz & Ludlow, 2000). When successful, this chemical denervation of the TA eliminates the uncontrollable spasmodic bursts which bring about the primary voice symptoms of ADSD (Bielamowicz & Ludlow, 2000). The specific mechanisms by which BTX-A achieves these effects remains poorly understood. Some studies suggest that the BTX-A may (Ali et al., 2006) or may not (Haslinger et al., 2005) enhance cortical processing of laryngeal sensory information, preventing the “over reaction” (in the form of spasming) of the true vocal folds in response to normal laryngeal sensory inputs. BTX-A injections can also be used as a secondary treatment approach, should surgical intervention fail (Ludlow, et al., 1990; Sulica, Blitzer, Brin, & Stewart, 2003).

Observed physiologic changes following BTX-A chemodenervation include reduced airway impedance and increases in airflow rates and stability during phonation (Adams, Durkin, Irish, Wong, & Hunt, 1996; Cantarelle, Berlusconi, Maraschi, Ghio, & Barbieri, 2006; Finnegan, Luschei, Gordon, Barkmeier, & Hoffman, 1999; Fisher, Scherer, Guo, & Owen, 1996; Mehta,

Goldman, & Orloff, 2001; Miller, Woodson, & Jankovic, 1987; Wong et al., 1995; Zwirner, Murry, Swenson, & Woodson, 1992). Perceptual and acoustic effects of BTX-A injection include improvements in voice quality, reduced presence of voice breaks, reduced aperiodicity, and reductions in shifts in vocal fundamental frequency (F_0) with less effect on noise to harmonic ratio, jitter, and shimmer (Blitzer, Brin, & Stewart, 1998; Boutsen, Cannito, Taylor, & Bender, 2002; Cannito, Woodson, Murry, & Bender, 2004; Damrose, Goldman, Groessl, & Orloff, 2004; Langeveld et al., 2001; Mehta, et al., 2001; Sapienza, Cannito, Murry, Branski, & Woodson, 2002; Whurr, Nye, & Lorch, 1998; Zwirner, Murry, & Woodson, 1997). Speech effects of BTX-A include increased speech intelligibility (Bender, Cannito, Murry, & Woodson, 2004). BTX-A also appears to exert beneficial effects on quality of life (Baylor, Yorkston, Eadie, & Maronian, 2007; Bhattacharyya & Taray, 2001; Courey et al., 2000; Epstein, Stygall, & Newman, 1997; Hogikyan, Wodchis, Spak, & Kileny, 2001; Langeveld, Luteijn, van Rossum, Drost, & Baatenburg de Jong, 2001; Rubin, Wodchis, Spak, Kileny, & Hogikyan, 2004; Wingate et al., 2005). Over time (typically a matter of months), the toxin is eliminated from the muscle fibers, and symptoms return.

In spite of its widespread clinical use, there are very few studies which have examined the effects of BTX-A within the context of a randomized, clinically controlled trial (Boutsen et al., 2002; Watts, Nye, & Whurr, 2006; Watts, Whurr, & Nye, 2004). As previously discussed, BTX-A has the potential to exert a wide array of positive effects on both physical and quality of life variables. However, injection failure rates have been documented as high as twenty nine percent (Galardi et al., 2001), Also, given that BTX-A injections must be administered repeatedly in order to achieve lasting symptom relief, the issue of acquired immunoresistence to BTX-A has

emerged within the research literature (Park, Simpson, Anderson, & Sataloff, 2003; Smith & Ford, 2000).

Alternative Treatments

Acupuncture has been used as an alternative treatment for ADSD and has, anecdotally, been associated with improvements in acoustic (F_0, F_0 variability, vocal intensity, jitter, shimmer, noise to harmonic ratio), qualitative (Voice Handicap Index) as well as speech and voice performance (maximum phonation time, number of words per minute, number of words per breath) tasks (Crevier-Buchman, Laccourreye, Papon, Nurit & Brasnu, 1997; Lee et al., 2003).

These changes do not necessarily translate into improvements in perceptual measures of voice symptom severity (Unified Spasmodic Dysphonia Rating Scale) and continued acupuncture treatment was not desired by a majority of participants in one recent study (Lee et al., 2003).

There exists a single case study examining the effect of chiropractic manipulation of the first and second cervical vertebrae in an individual with ADSD. The author hypothesized that these manipulations reduced vagus nerve compression at the level of the occipital foramen, restoring normal efferent nerve conduction. The subject in this case study was treated five times during a two week period and was reported to display some improvement in phonation after two sessions, with complete symptom resolution by the conclusion of five treatment sessions (Wood, 1991).

Behavioral Treatments

The primary voice symptoms of ADSD are typically reduced during whisper or breathy voice (performed with complete or partial vocal fold abduction), cough, throat clearing, singing, humming, and altered pitch maneuvers (Bloch, Hirano, & Gould, 1985). Observation of these effects has led to the development of various styles of voicing which can be trained

therapeutically to help minimize the primary voice symptoms of ADSD. Other behavioral techniques seek to reduce laryngeal tension, a separate and secondary phenomenon which may contribute to reduced vocal quality.

Use of vocal abductor muscles to counteract the adductor spasms of ADSD is the rationale behind use of inverse phonation. Here, individuals with ADSD are taught to phonate on inhalation, rather than exhalation. There are isolated reports of success with this technique, however difficulty in carryover and habituation of this style of voicing has limited its therapeutic use (Harrison, Davis, Troughear, & Winkworth, 1992; Miller & Woodson, 1991).

General body relaxation, or muscle tension reduction techniques are ineffective at eliminating ADSD symptoms (Henschen & Burton, 1978). Laryngeal massage, or *manual laryngeal tension reduction*, targets extrinsic laryngeal musculature to achieve a lowering of the resting position of the larynx. This technique has not been shown to be an effective treatment for ADSD, but is a useful tool in the differentiation of ADSD from MTD where it can produce substantial and long-term symptom relief (Roy, Ford, & Bless, 1996).

Conventional voice therapy (sometimes referred to as *direct voice rehabilitation*) for ADSD seeks to minimize adverse vocal symptoms through use of easy onset voicing while enhancing breath support for speech. These behaviors are first learned in isolation, and then carried over into conversational contexts through guided practice (Miller & Woodson, 1991). Although this approach has been set forth as an independently effective cure for ADSD (Cooper, 1990), it has largely been abandoned as a stand-alone treatment and is more frequently used as an adjunctive therapy to surgery (Dedo & Izdebski, 1983) or BTX-A injection (Miller & Woodson, 1991; Murry & Woodson, 1995).

Combined Modality Treatments

In a review of treatment options for ADSD, Miller and Woodson (1991) stressed the importance of continued research into the role of voice therapy, in combination with BTX-A injections, in the treatment of ADSD. This is known as a *combined modality* approach. In spite of this, to date there is only one published study, now over a decade old, which addresses the role of voice therapy in a combined modality approach to the treatment of ADSD. The investigation involved twenty-seven participants with ADSD and no prior history of BTX-A treatment. Participants were injected, and then returned to clinic three weeks later where they were offered a course of voice therapy. Those who declined voice therapy were assigned to the BTX-A only group and those who accepted were assigned to the combined modality group. Dependent variables examined were durational (time, in weeks, between initial and repeat BTX-A injection, acoustic (standard deviation of F_0, jitter, shimmer, signal to noise ratio - SNR), aerodynamic (mean airflow rates during /a/) and speech (words per minute) variables. Participants in the combined modality group were observed to go longer between injections (*M* = 27.4 weeks, *range* = 13 to 54 weeks) than the BTX-A only group (*M* = 14.9 weeks, *range* = 9 to 26 weeks). This between groups difference in durational effect rose to the level of statistical significance. Within groups analysis revealed that participants within the combined modality group achieved statistically significant improvements in mean airflow rates, standard deviation of F_0, jitter, shimmer, and SNR following voice therapy compared to the BTX-A only group (Table 1-1).

Combined modality therapy combines the suppression of maladaptive sensorimotor circuits (through paralysis or weakening of the vocal folds following BTX-A injection) with the establishment of new patterns of voicing. These include the *unlearning* of hyperfunctional voice behaviors, sometimes developed as means of compensating for the primary, spasmodic

symptoms of the disorder. This suppression-reacquisition loop has been previously examined in the treatment of writer's cramp (Kaji et al., 1995)

Statement of the Problem

An exhaustive meta-analysis of research literature dealing with BTX-A injections for ADSD concluded that an important and overlooked treatment factor was the development of adverse compensatory strategies following injection (Boutsen et al., 2002). Compensatory behaviors which occur in response to BTX-A injection are addressed therapeutically through voice therapy. There is insufficient evidence as to the effectiveness of voice therapy following BTX-A injections for ADSD on improved voicing.

Purpose of the Study

The purpose of the present study was to determine the effects of voice therapy following BTX-A injections for ADSD on perceived voice related quality of life, acoustic measures of vocal instability, and duration of injection benefit. The study also sought to compare these effects with those observed in participants who had only received BTX-A injections, and those who had received BTX-A injections followed by a sham voice therapy.

Hypotheses

Hypothesis 1: Participants who receive voice therapy following BTX-A injection for ADSD will experience increased duration of benefit from BTX-A injections compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD. Duration of benefit is defined as the amount of time, in weeks, between initial and repeat BTX-A injection for ADSD and will be determined statistically through use of survival analysis procedures.

Hypothesis 2: Measures of quality of life will improve, for all participants, following BTX-A injections for ADSD. This improvement will confirmed by observation of improved total and subdomain standard scores on the V-RQOL measure.

Hypothesis 3: V-RQOL standard scores will change in a non-linear fashion over time, in response to BTX-A injection, for all participants. Specifically, standard scores will improve following injection, eventually reaching a maximum value, prior to trending downward toward baseline values thereby demonstrating a significant quadratic effect.

Hypothesis 4: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater improvements in voice-related quality of life compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD. This hypothesis will tested by statistical analysis of total and subdomain standard scores on the V-RQOL measure.

Hypothesis 5: All participants who receive BTX-A injections for ADSD will experience significant increases in the relative percentage of Type 1 (periodic) signals during voicing tasks following injection.

Hypothesis 6: Measures of relative percentage of Type 1 signals during voicing will change in a non-linear fashion, over time, in response to BTX-A injection for all participants. Specifically, Type 1 percentages will increase following injection, eventually reaching a maximum value, prior to trending downward toward baseline values thereby demonstrating a significant quadratic effect.

Hypothesis 7: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater increases in the relative percentage of Type 1

(periodic) signals during voicing tasks compared to participants who receive only BTX-A injection and participants who receive BTX-A injection plus a sham voice therapy for ADSD.

Hypothesis 8: All participants who receive BTX-A injections for ADSD will experience significant decreases in the relative percentage of undesirable signals during voicing tasks following injection. These undesirable signals include Type 2 (subharmonic), Type 3 (aperiodic) and voice breaks.

Hypothesis 9: Measures of the relative percentage of undesirable signals during voicing will change in a non-linear fashion, over time, in response to BTX-A injection, for all participants. Specifically, percentage of undesirable signals will decrease following injection, eventually reaching a minimum value, prior to trending upward toward baseline values thereby demonstrating a significant quadratic effect.

Hypothesis 10: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater decreases in the relative percentage of undesirable signals during voicing tasks compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD.

Hypotheses 1, 4, 7, and 10 are based on the presumed ability of voice therapy to minimize the adverse laryngeal and superlaryngeal compensatory behaviors which may counteract the beneficial effects of BTX-A injection.

Table 1-1. Summarized outcomes from Murry & Woodson (1995). Data presented are from the second assessment period (taken immediately prior to reinjection).

Change in variable between pre-injection and pre-reinjection assessment periods	BTX-A only group	Combined modality group
Mean airflow rates (cc/s)	101.4(22.6)	125.8(20.4)
F_0 (Hz)	131→ 118	141 →148
Standard deviation of F_0 (Hz)	21.8 → 18.1	23.7 → 11.2*
Jitter	[a.]	[a.]*
Shimmer	[a.]	[a.]*
SNR	[a.]*	[a.]*

[a.] Numerical results unavailable (refer to original article for results figure), * $p < .05$

CHAPTER 2
METHODOLOGY

This study examined the effects of behavioral voice therapy following BTX-A injections for ADSD. These injections were not a direct component of this study, but rather were among the criteria for inclusion. All participants in this study independently chose to undergo BTX-A injections for ADSD. Following injection, participants were randomly assigned to one of three experimental groups. Group 1 received no further intervention following BTX-A injection. Group 2 received a standardized five week, five session, course of voice therapy following injection. Group 3 received a standardized five week, five session, course of sham voice therapy following injection.

Experimental Design

This project featured a prospective, randomized, and placebo-controlled repeated measures parallel arm design. The independent variable was group assignment. The dependent variables were, treatment effect duration, V-RQOL standard scores, and percentage of both desirable (periodic) and undesirable (subharmonic, aperiodic, voice break) acoustic signal types during sustained phonation and connected speech.

Participants

Sample Size Determination

Calculation of the sample size was performed using a single response variable as suggested by Marks (2001). A power analysis was completed using the V-RQOL. This measure was selected for power analysis because it is the primary variable of interest to the study and has the largest reported standard deviation of all dependent variables. The power analysis was performed with a 90% confidence interval and a bound on error of 10. A standard deviation of 25 was used for the V-RQOL. The power analysis revealed that each of the three groups should

contain 17 participants. This number was doubled in order to accommodate a repeated measures parallel arm design, thereby increasing the requirement to 34 participants per group or 102 participants total. Given the available participant pool at each of the study sites, this number was determined to be impractical and the decision was made to carry out the current project as a pilot study for future investigations. A total of 35 participants with ADSD were enrolled in this study. Of these, 31 completed the study and are the source for all study measures. Eleven participants were randomly assigned to Group 1. Ten participants each were randomly assigned to Groups 2 and 3.

Recruitment and Selection

Recruitment for this study took place at each of the five affiliated study centers: Shands at the University of Florida (Gainesville, Florida), Ear, Nose, Throat and Plastic Surgery Associates (Orlando, Florida), University of Miami (Miami, Florida), the Professional Voice Center of Greater Cincinnati (Cincinnati, Ohio), and Emory University (Atlanta, Georgia). Separate Institutional Review Board (IRB) approvals were obtained for the University of Florida, University of Miami, and Emory University. The two non-university affiliated study sites (Cincinnati and Orlando) were included as external research affiliates under University of Florida IRB approval.

Participation in this study was completely voluntary. Only individuals who had no prior history of BTX-A injection were considered for participation. Participants were recruited at the time they presented for BTX-A injection for ADSD at the otolaryngology practices of physicians affiliated with this investigation. Following a diagnosis of ADSD by the attending physician, and prior to BTX-A injection, researchers provided potential participants with information regarding this study including study objectives. If, at that time, the individual expressed interest in participation, the informed consent process was initiated by an affiliated investigator.

Informed consent directly addressed the criteria for participation, purpose of the research, participant rights including the right to withdraw from research at any time without affecting future care, potential benefits, potential risks, and assurance of anonymity. Throughout the informed consent process potential participants were provided with multiple opportunities to seek clarification of all presented information. Following review of the informed consent document, potential participants were asked to accept or decline further participation. Those who accepted indicated their agreement by signing the informed consent document. All participants were provided with a copy of the informed consent document, along with contact information for all affiliated investigators. Data collection commenced immediately following entry into the study. Participants were compensated for their participation in the study at a rate of $25 per data collection session and $25 per treatment (voice or sham) session. These funds were drawn from a small research grant provided by the National Spasmodic Dysphonia Association (NSDA).

Inclusion Criteria

Participants were included based on the following criteria, drawn from written and verbal case histories at the time of initial presentation as well as from a medical questionnaire (Appendix A) designed for the current study:

- Over 18 years of age.
- Willing and capable of providing informed consent.
- Diagnosis of ADSD by otolaryngologist or neurologist.
- Desiring BTX-A injection for treatment of ADSD.
- No prior BTX-A treatment.
- No history of prior surgical or behavioral treatment for ADSD.
- No history of other speech or voice disorder.

- Normal hearing thresholds given participant's age. Alternatively, appropriate aided hearing thresholds.
- ADSD symptoms present for at least six months.
- Medically stable over the preceding year with no major medical changes, surgeries, or hospitalizations.
- No major changes in occupational, social, or behavioral routines during the experimental period.
- No history of other focal or generalized dystonia.

Exclusion Criteria

Participants were excluded from the study if they were unwilling or unable to participate in therapy should they be assigned to either the voice (Group 2) or sham (Group 3) therapy arms.

Assignment of Participants to Groups

Participants were assigned to experimental groups based on a pre-determined, randomized, group assignment order provided to each study site prior to the initiation of participant enrollment at that site.

Participant Demographics

A total of 35 participants were recruited for the current investigation. Of these, three were discontinued from the study for attrition. Researchers were unable to reach each of these participants in order to determine the specific reasons why they left the study. One additional participant was discontinued because she had to move unexpectedly during the middle of the study. A total of 31 participants (5 males and 26 females) were included in the final analyses. Average age of participants was 48.45 years with a range of 23 to 78 years. Average time since symptom onset was 6.31 years with a range of 6 months to 30 years (Table 2-1).

Measures

Baseline measures included V-RQOL and acoustic measures of vocal instability and were sampled prior to initial BTX-A injection. These measures were collected again at approximately 3 weeks post injection, approximately 7 weeks post injection, approximately 12 weeks post injection, and immediately prior to reinjection. Participants in Groups 2 and 3 received a standardized five-session course of voice or sham voice therapy (described later), once per week, beginning at ~3 weeks post injection and concluding at ~7 weeks post injection (Figure 2-1).

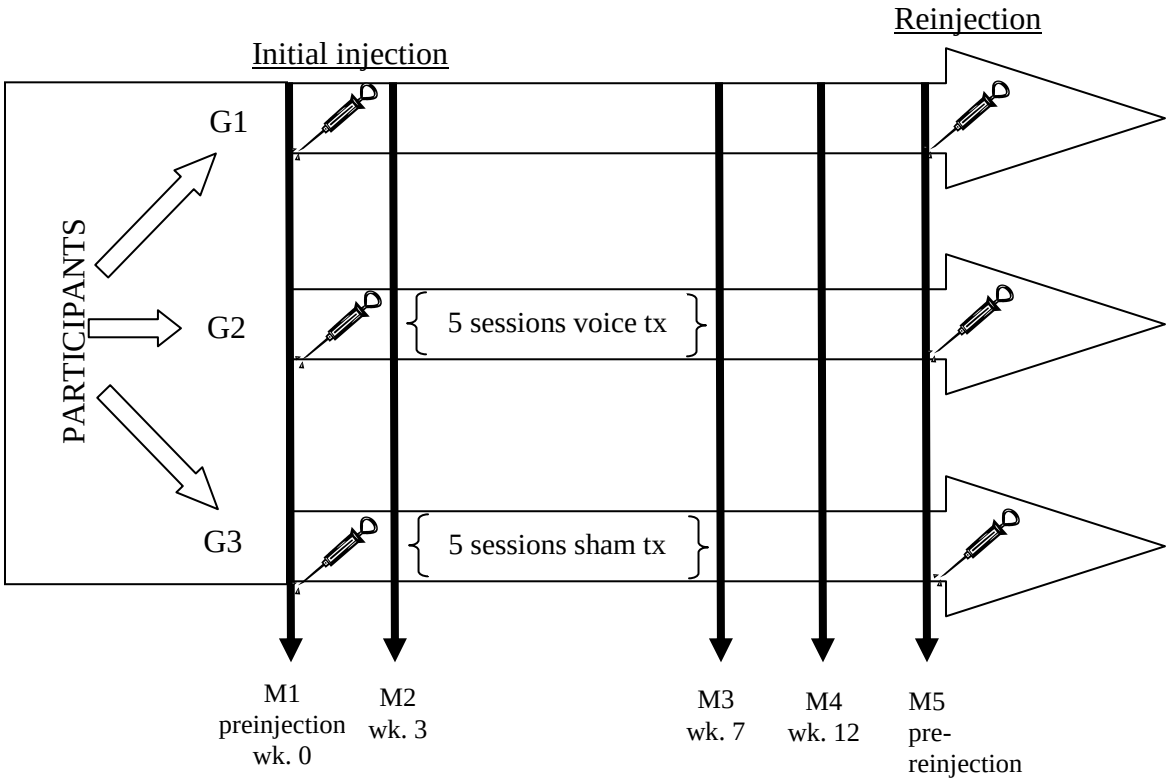

Figure 2-1. Experimental design.

Screening Measures

An endoscopic examination of the vocal folds was performed on each participant prior to acceptance into the study. Each potential participant received a diagnosis of ADSD by the

attending otolaryngologist, as well as met all aforementioned inclusion criteria prior to entrance into the study.

Treatment Effect Duration Measure

Time between initial and repeat BTX-A injection was measured, in weeks, for all participants. In the event that a participant opted to not have a repeat BTX-A injection, that participant was instructed to return for final measures at the time where he or she *would have otherwise* chosen reinjection. That is, the point where the participant perceived his or her voice to have worsened to the point where reinjection would have been requested.

Quality of Life Measures

The V-RQOL (Appendix B) measure is a 10 item graduated Likert-type scale used for assessing quality of life within both physical and social-emotional domains of voice functioning. Respondents are instructed to read each statement (for example, "I have trouble speaking loudly or being heard in noisy situations.") and, based on experiences over the preceding two weeks, indicate the amount (or magnitude) of the problem as "1" (none, not a problem), "2" (a small amount), "3" (a moderate or medium amount), "4" (a lot), or "5" (problem is as bad as it can be).

The V-RQOL is reliable, responsive to change, and poses a low burden of administration (Franic, Bramlett, & Bothe, 2005; Hogikyan & Sethuraman, 1999). Additionally, the V-RQOL correlates highly with the Voice Handicap Index (VHI; Jacobsen et al., 1997) and moderately well with GRBAS auditory-perceptual voice scale (Murry, Medrado, Hogikyan, & Aviv, 2004; Portone, Hapner, McGregor, Otto, & Johns, 2006), both of which are widely used within the field of voice disorders. Past studies have used the V-RQOL in investigations of geriatric dysphonia (Golub, Chen, Otto, Hapner, & Johns, 2006), phonation following laryngectomy (Fung et al., 2005; Kazi et al., 2006; Weinstein et al., 2001), phonation in Parkinson Disease (Dias et al., 2006), occupational voice disorders (Gillivan-Murphy, Drinnan, O'Dwyer, Ridha, &

Carding, 2006), functional versus organic voice disorders (Lindman, Gibbons, Morlier, & Wiatrak, 2004; Rasch, Gunther, Hoppe, Eysholdt, & Rosanowski, 2005), velopharyngeal insufficiency (Boseley & Hartnick, 2004), vocal fold paralysis (Hogikyan, Wodchis, Terrell, Bradford, & Esclamado, 2000; Rontal & Rontal, 2003) and as a tool for quantifying the beneficial effects of BTX-A on voice-related quality of life over multiple injection cycles (Hogikyan, et al., 2001; Rubin, et al., 2004).

The V-RQOL was included as a dependent variable in the current project and was to be completed by each participant immediately prior to initial BTX-A injection, ~3 weeks post injection, ~7 weeks post injection, ~12 weeks post injection, and immediately prior to reinjection. This measurement schedule was designed in order to capture changes in voice status and symptoms, over time, following BTX-A injection.

Acoustic Measures

Equipment and procedures

All voice samples were collected with an Audio Technica ATM73a headset cardioid condenser microphone placed approximately one centimeter from the right corner of the mouth (Titze & Winholtz, 1993). The speech samples were pre amplified (Symetrix 302 Dual Microphone Preamplifier), and then recorded (Sony PCM-R300 DAT player / recorder) onto a digital audio tape (Maxell). Identical sets of recording equipment were used at each of the five study sites. Voice samples were recorded in a quiet room. Once recorded, audio samples were extracted using Creative WaveStudio software (version 5.00.20) and were analyzed using TF32 software (Milenkovic, 2002).

Signal typing

Acoustic measures related to vocal instability were obtained from sustained phonation and connected speech tasks. Vowel prolongation samples were obtained by instructing each

participant to take a full breath, and then sustain the phoneme /a/ at a comfortable pitch, for as long as possible. Three repetitions of the vowel prolongation task were completed at each of the five data collection points. Connected speech samples were obtained through reading of the Rainbow Passage (Fairbanks, 1960) at a comfortable rate, with typical loudness and pitch levels. Two repetitions of the connected speech task were completed at each of the five data collection points. Fifteen words were pre-selected from the Rainbow Passage for acoustic analysis (Figure 2-2). These words were chosen because they consist mostly of voiced phonemes and have been used successfully in past investigations of acoustic features of ADSD (Cimino-Knight & Sapienza, 2001; Sapienza et al., 1998; Sapienza et al., 1999; Sapienza et al., 2000; Sapienza et al., 2002). Voiceless segments of these words (for example the frication produced by some speakers at the end of *arch*) were excluded from analysis.

Acoustic samples obtained from sustained phonation and connected speech tasks were labeled according to signal typing methodology as set forth by the National Center for Voice and Speech Workshop on Acoustic Voice Analysis (Titze, 1994):

> Type 1 signals: nearly periodic signals that display no qualitative changes in the analysis segment; if modulating frequencies or sub harmonics are present, their energies are an order of magnitude below the fundamental frequency.
>
> Type 2 signals: signals with qualitative changes (bifurcations) in the analysis segment, or signals with sub harmonic frequencies or modulating frequencies whose energies approach the energy of the fundamental frequency; there is therefore no obvious single fundamental frequency throughout the segment.
>
> Type 3 signals: signals with no apparent periodic structure (p. 19)

Periods of inappropriate absence of phonation or *voice breaks* were also identified during connected speech and vowel prolongation tasks.

Voiced segment duration (VSD). VSD was defined, in milliseconds, from the onset of voicing to voicing offset within sustained /a/ and words selected for connected speech analysis.

If a voice break occurred during the segment its duration was considered as part of the segment provided no audible breath occurred. VSD was included, not as a primary variable of interest, but as a methodological control in order to derive percentage measures for Type 1, 2, and 3 signals as well as voice breaks.

Duration and percentage of Type 1 signals. Type 1 signals (Figure 2-3) were identified visually through use of a narrow band spectrogram and confirmed through observation of a steady pitch trace using TF32. Duration was defined, in milliseconds, from onset of Type 1 signal to offset within both sustained phonation and connected speech segments. Percentage of Type 1 signals was calculated by dividing the Type 1 signal duration by VSD for sustained phonation and connected speech segments.

Duration and percentage of Type 2 signals. Type 2 signals (Figure 2-4) were identified visually through use of a narrow band spectrogram where sub harmonic frequencies presented as lighter, intermediary bands between harmonic frequencies. Duration was defined, in milliseconds, from onset of Type 2 signal to offset within both sustained phonation and connected speech segments. Percentage of Type 2 signals was calculated by dividing the Type 2 signal duration by VSD for sustained phonation and connected speech segments.

Duration and percentage of Type 3 signals. Type 3 signals (Figure 2-5) were identified visually through use of a narrow band spectrogram. Here, aperiodicity appears as a complete loss of harmonic banding and can usually be confirmed through simultaneous observation of erratic or absent pitch traces. Percentage of Type 3 signals was calculated by dividing the Type 3 signal duration by VSD for sustained phonation and connected speech segments.

Duration and percentage of voice breaks. Voice breaks (Figure 2-6) were identified visually through use of a narrow band spectrogram. Voice breaks appear as breaks in harmonic

banding during otherwise voiced productions. Voice stoppages which occur naturally at word or syllable boundaries were ignored. Percentage of voice breaks was calculated by dividing the total duration of voice breaks by VSD for sustained phonation and connected speech segments.

Duration and percentage of undesirable signals. For both sustained phonation and connected speech productions, percentages of Type 2, Type3, and voice breaks were added, creating a summed percentage of "undesirable" signals. This measure was also expressed as a percentage of VSD.

Training Protocol

Each participant was randomly assigned to one of three experimental groups. Participants assigned to Group 1 received no further intervention following BTX-A injection. Participants in Groups 2 or 3 received five standardized weekly sessions of either voice (Group 2) or sham voice (Group 3) therapy beginning at ~3 weeks post BTX-A injection and concluding at ~7 weeks post BTX-A injection.

Group 2: Voice Therapy

The voice therapy program used in this study was based on an existing voice therapy protocol for individuals with ADSD (Verdolini, 1997) and modified into a standardized five session scripted therapy protocol for use at all affiliated study sites (Appendix C). The focus of the program was minimization of voice hyperfunction through voice education, relaxation, laryngeal massage, and *easy onset* type vocal exercises with appropriate carryover tasks for generalization of learned voicing behaviors into conversational speech. An additional focus of the program was on the establishment of easy, continuous breath flow during sustained phonation and (progressively lengthier) speech carryover tasks. These therapeutic targets are well-recognized components of voice therapy for ADSD (Woodson et al., 1992; Zwirner et al., 1992). Sessions one and two focused on establishment of easy vocal onsets. Sessions three and

four emphasized continuity of breath flow. The final, fifth, session focused on easy articulation of connected speech and carryover of all previously entrained behaviors. In addition to the weekly therapy sessions, participants in Group 2 were assigned specific tasks for daily home practice.

Group 3: Sham Voice Therapy

The sham voice therapy program (Appendix C) was designed to mimic the voice therapy with regard to frequency, intensity, and duration of participant-therapist contact, but without therapeutic targeting of easy voice onsets or continuous breath flow. Activities included nonspecific voice education, relaxation, active and passive oral motor tasks, sham laryngeal massage ("laryngeal acupressure"), sustained phonation and speech carryover tasks (though without instruction of vocal behaviors), as well as use of a sham expiratory muscle threshold trainer (Figure 2-7).

This cylindrical device features a mouthpiece and an adjustable dial for setting the device to a desired training level. In normal expiratory muscle threshold trainers, this dial sets an internal spring at a desired threshold level which must then be overcome in order to release the pressure relief valve, thus producing a muscle training effect. The threshold spring was removed from each of the training devices used in the current study, rendering the trainers threshold neutral during exhalation.

Participants in Group 3 were blinded to this modification and, at each session, the sham trainer was set by the therapist at what appeared to be a progressively higher level. Sham trainers were used, in combination with speech tasks, both during weekly sham voice therapy sessions as well as part of the assigned home practice tasks

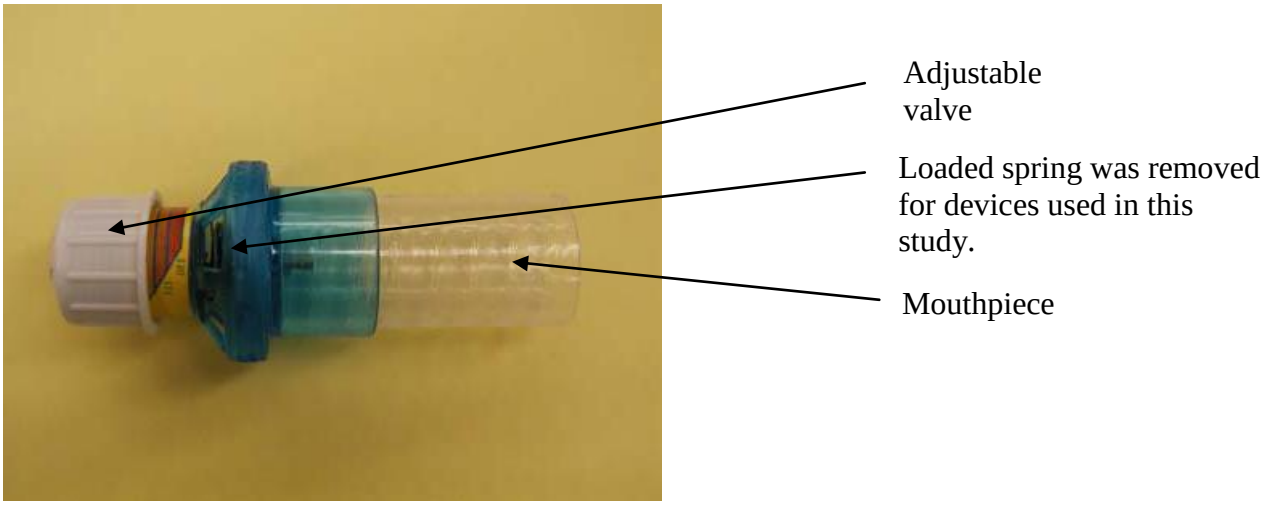

Figure 2-2. Expiratory muscle pressure training device.

Compliance

Participant compliance was document through interview with the treating therapist, as well as through use of practice logs (Appendix C). Participants assigned to Group 2 or 3 were provided with detailed written instructions for home practice assignments (Appendix C) and were instructed to contact the treating therapist if clarification was needed or if problems were encountered during the home practice sessions.

Participants were also interviewed when they returned for therapy sessions. Questions asked at this interview were: (1) Were you able to practice every day? (2) Were you able to practice twice per day? (3) On average, how long were your practice sessions? (4) How did your practice sessions go? Did you have any problems? Problems or concerns were addressed on an as needed basis by the research clinician. Participants were discouraged from both under- and over-practicing the assigned tasks.

Statistical Method

General

Summary statistics were computed and the data graphically displayed to identify outliers and/or impossible or implausible values, to summarize the data, and to check for distributional

forms. Within group comparisons (e.g. percent change from pre-injection to post-injection) were made using Wilcoxon signed rank tests. Groups were compared on numerical data using Kruskal-Wallis tests and on categorical data using chi-square or Fisher's exact tests. A two-sided alpha = 0.05 was used as the level of significance for all tests. SAS version 9.1 (SAS Institute, Cary, NC) was used for all data management and statistical analyses.

Reliability

Intraclass correlation coefficients (ICCs) were calculated to measure intra- and inter- rater agreement. ICCs give a measure of agreement between raters on numeric data that is more informative than Pearson's correlation coefficient (Shrout & Fleiss, 1979). For example, the following pairs: (1, 10), (2, 20) and (3, 30), have a Pearson's correlation coefficient of 1.00. However, the ICC of these pairs is close to zero since this statistic incorporates information about the magnitude of variation between raters. ICCs were performed on approximately 23% of pooled participant data (n=7). V-RQOL and acoustic data was reanalyzed by the initial examiner and by a trained external examiner, both of whom were blinded to participant identifiers, as well as where in the study (i.e. which data collection point) the measures were collected.

For the V-RQOL data, reliability testing involved repeat data entry and calculation of total and sub-domain standard scores based on participant responses indicated on the individual V-RQOL test forms. Scores were manually entered on a Microsoft Excel (2002) workbook from the original participant test forms with standard scores generated automatically based on published formulas (Hogikyan & Sethamuran, 1999).

Acoustic data was reanalyzed using the exact procedures presented earlier under *Signal typing*.

Reliability estimates are expressed in terms of intraclass correlation coefficients (ICCs) and are presented in Chapter 3.

Longitudinal Analysis

Non-normal data were transformed when necessary to stabilize variances and normalize distributional forms. A generalized linear mixed model (GLMM) was used to characterize both fixed (regressor) effects as well as random effects over time. For repeated measures longitudinal data methods were applied (Verbecke & Molenberghs, 2001) that allowed for the correlation of within subject measures (over time) and allowed for mechanisms to correct missing data (e.g., missing at random, missing completely at random). These estimates are valid as long as there is no systematic bias in the missing data such as a pattern of missing data associated with group membership. Statistical analyses to address study hypotheses were based on the following general linear mixed model (Eq. 2-1):

$$Y_{ijk} = \mu + \alpha_i + d_{ij} + \tau_\kappa + (\alpha\tau)_{\iota\kappa} + \tau_\kappa^2 + (\alpha\tau^2)_{\iota\kappa} + e_{ijk} \qquad (2\text{-}1)$$

Here,

- μ, α_i , τ_κ , $(\alpha\tau)_{\iota\kappa}$, τ_κ^2 ,$(\alpha\tau^2)_{\iota\kappa}$ are fixed parameters
- d_{ij} is the random effect associated with the jth participant in group i
- e_{ijk} is the random error associated with the jth participant in group i at sequence time k

with α_i testing for intercept, $(\alpha\tau)_{\iota\kappa}$ testing for linear effect or slope, and $(\alpha\tau^2)_{\iota\kappa}$ assessing quadratic fit. This model was selected because of the hypothesized non-linear behavior of the variables of interest, over time, in response to BTX-A injection. An autoregressive variance-covariance matrix was used to model the correlation of measures presented in Chapter 3.

Survival Analysis of Treatment Duration

The LIFETEST procedure in SAS was used to estimate survival functions and conduct tests for associations between survival time (that is, time between initial and repeat BTX-A injection) and group status.

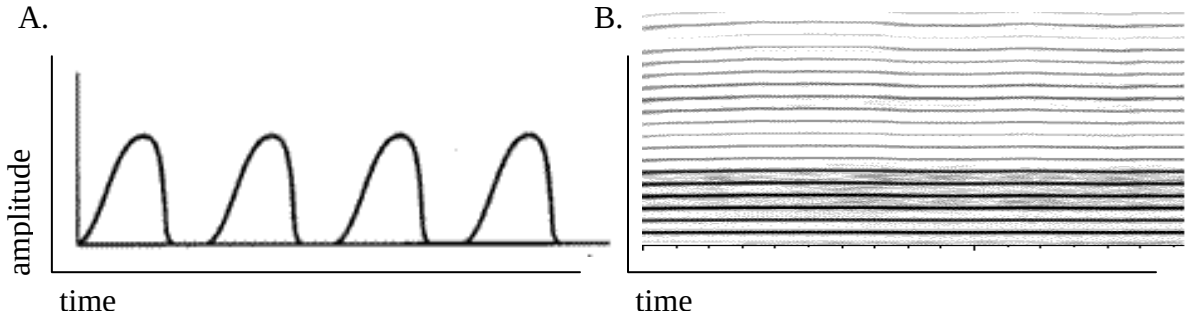

Figure 2-3. Type 1 signals during sustained phonation /a/. Examples include A) diagramatic and B) spectrographic examples of Type 1 signals. Type 1 waveforms are nearly periodic.

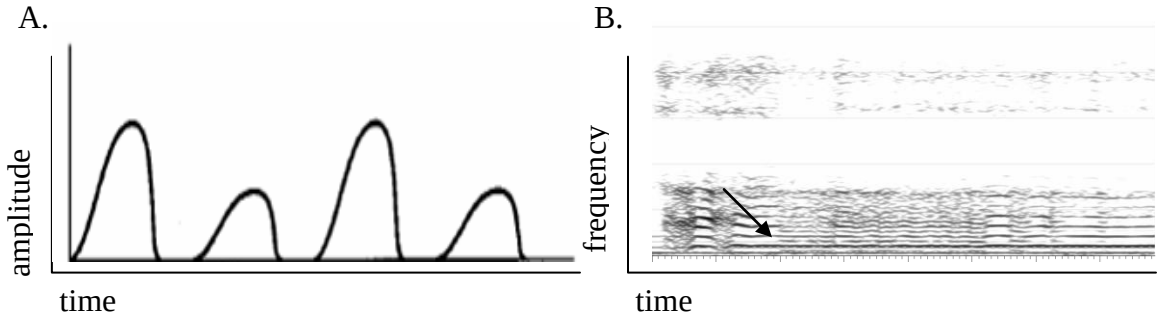

Figure 2-4. Type 2 signals during sustained phonation /a/. Examples include A) diagramatic and B) spectrographic examples of Type 2 signals. As the waveform bifurcates, subharmonic frequencies emerge as intermediary bands on the narrow band spectrogram.

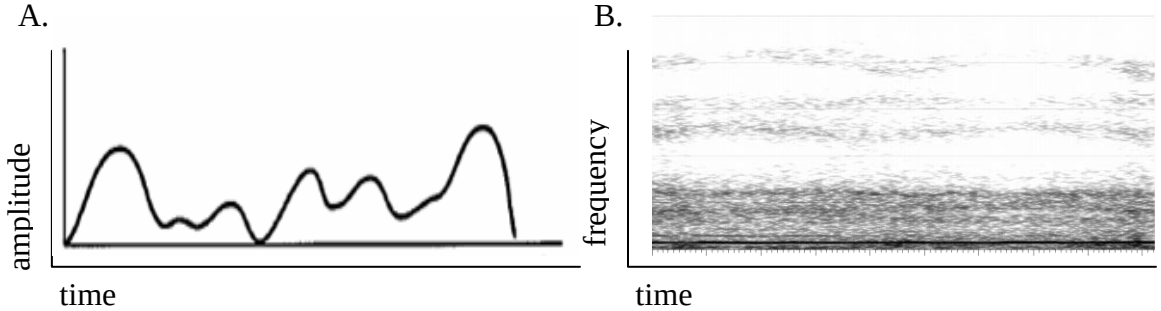

Figure 2-5. Type 3 signals during sustained phonation /a/. Examples include A) diagramatic and B) spectrographic examples of Type 3 signals. Continued bifurcation of the acoustic waveform produces an aperiodic signal which no discernable harmonic banding on a narrow band spectrogram.

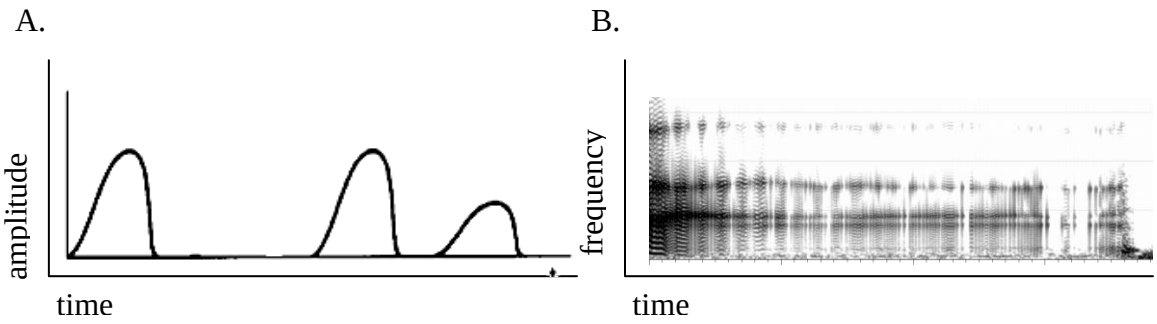

Figure 2-6. Voice breaks during sustained phonation /a/. Examples include A) diagramatic and B) spectrographic examples of voice breaks. Voice breaks are stoppages in vibration and appear as breaks in harmonic banding on a narrow band spectrogram.

Table 2-1. Participant Demographics

Gender	% male	16.13
	% female	83.87
Age (years)	Median	50.00
	Mean	48.45
	SD	15.08
Symptom duration (years)	Median	2.50
	Mean	6.27
	SD	7.62

The Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

Figure 2-7. Rainbow Passage (Fairbanks, 1960). Words used as connected speech measures are indicated through underlining.

CHAPTER 3
RESULTS

The dependent variables for this study were treatment effect duration, V-RQOL standard scores, and acoustic measures of vocal instability including Type 1 signals, Type 2 signals, Type 3 signals, and voice breaks, each expressed as a percentage of VSD. Type 2 signals, Type 3 signals, and voice breaks were summed to produce an additional measure of "undesirable" signals, expressed as a percentage of VSD. Raw data for V-RQOL and acoustic measures across M1 through M5 are presented in Appendix E.

Reliability

Individual V-RQOL forms and all acoustic data were reanalyzed using methods described within Chapter 2. Intra- and interjudge reliability for repeat scoring of the V-RQOL was perfect at 1.00. For acoustic variables, both intra- and interjudge reliability was excellent ranging from 0.93 to 1.00 (intrajudge) 0.95 to 1.00 (interjudge).

Survival Analysis: Treatment Effect Duration Measure

Hypothesis 1: Participants who receive voice therapy following BTX-A injection for ADSD will experience increased duration of benefit from BTX-A injections compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD. Duration of benefit is defined as the amount of time, in weeks, between initial and repeat BTX-A injection for ADSD and will be determined statistically through use of survival analysis procedures.

Of the 31 participants, 27 (87%) elected to repeat BTX-A injection following the initial treatment. Of the four who did not return for injection, three were lost to follow up. The remaining participant declined reinjection due to side effects (specifically, breathiness) experienced following the initial injection. Time between initial and repeat Botox injections

ranged from 7.14 weeks to 41.14 weeks (*M* = 20.03, *SD* = 8.25). The greatest average duration between initial and repeat injection was observed within the BTX-A only group (*M* = 22.19, *SD* = 9.56), followed by the BTX-A plus sham therapy group (*M* = 20.41, *SD* = 9.77 weeks), and the BTX-A plus voice therapy group (*M* = 17.25, *SD* = 4.10 weeks).

Survival analysis procedures model time to event data. In the case of the current investigation, the event of interest was repeat BTX-A injection. Time between initial and repeat injection did not differ by group, χ^2 (2, *N* = 27) = 0.73, $p > .6945$, therefore Hypothesis 1 is rejected. Logistical issues surrounding this measure are discussed in Chapter 4.

Voice Related Quality of Life Measure

Hypothesis 2: Measures of quality of life will improve, for all participants, following BTX-A injections for ADSD. This improvement will be confirmed by observation of improved total and subdomain standard scores on the V-RQOL measure.

Mean total V-RQOL score of 32.18 $\pm$ 18.02 at baseline (preinjection) is consistent with means and standard deviations found in previous investigations (Hogikyan et al., 2001; Rubin et al., 2004). A Wilcoxon signed rank statistic was used to assess the difference in V-RQOL standard scores before and after BTX-A injection. All participants improved significantly following BTX-A injection (*Wilcoxon signed rank*, $p < .0001$; *Table* 3-1). This interval between preinjection and approximately three weeks post injection also marked the interval where the greatest magnitude of improvement was observed, for all participants. Significant ($p < .0001$) linear effects were revealed (Table 3-2) for all three groups. Hypothesis 2 is accepted.

Hypothesis 3: V-RQOL standard scores will change in a non-linear fashion over time, in response to BTX-A injection, for all participants. Specifically, standard scores will improve

following injection, eventually reaching a maximum value, prior to trending downward toward baseline values thereby demonstrating a significant quadratic effect.

Significant quadratic effects were observed for all dependent variables extracted from the V-RQOL (Table 3-2) and are illustrated graphically by Figures 3-2 through 3-4. Following the initial, significant, improvement in mean standard scores, continued gains were observed through M3 (approximately seven weeks post injection). Scores trended downward between M3 and M4 (approximately twelve weeks post injection) with continued decreases observed between M4 and M5 (pre reinjection). At M5 reported mean scores, though decreased from initial gains observed through M3, were still 79% - 83% higher than at baseline, prior to BTX-A injection (Figure 3-1). Hypothesis 3 is accepted.

Hypothesis 4: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater improvements in voice-related quality of life compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD. This hypothesis will be tested by statistical analysis of total and subdomain standard scores on the V-RQOL measure.

Pairwise comparisons of treatment groups (Table 3-3) revealed no differences between groups with regard to change in V-RQOL total or subdomain standard scores following BTX-A injection. Because each of the groups responded in a similar fashion following BTX-A injection, Hypothesis 4 is rejected.

Acoustic Measures

Hypothesis 5: All participants who receive BTX-A injections for ADSD will experience significant increases in the relative percentage of Type 1 (periodic) signals during voicing tasks following injection.

If BTX-A therapy is meant to “normalize” voicing than increases in percentage of Type 1 (periodic) signals are to be expected following injection. A Wilcoxon signed rank statistic was used to assess the difference in percentage of Type 1 signals before and after BTX-A injection. All participants improved significantly following BTX-A injection in percentage of Type 1 signals during both sustained phonation (*Wilcoxon signed rank*, $p < .0001$; *Table* 3-4) and connected speech (*Wilcoxon signed rank*, $p < .0001$; *Table* 3-4) tasks between baseline and approximately 3 weeks post injection. Significant linear effects were observed for all three groups during sustained phonation, but only for Group 1 and Group 2 during connected speech (Table 3-5). Hypothesis 5 is accepted.

Hypothesis 6: Measures of relative percentage of Type 1 signals during voicing will change in a non-linear fashion, over time, in response to BTX-A injection for all participants. Specifically, Type 1 percentages will increase following injection, eventually reaching a maximum value, prior to trending downward toward baseline values thereby demonstrating a significant quadratic effect.

Although all groups displayed similar patterns of increases, then decreases, in Type 1 signals during sustained phonation (Figure 3-5) and connected speech (Figure 3-6) statistically analysis did not reveal uniformly significant effects. During sustained phonation, only Group 3 displayed significant ($p = 0.0347$) quadratic effects. Interestingly, during connected speech tasks Groups 1 and 2 displayed quadratic effects, but not Group 3 (Table 3-5). Quadratic effects are displayed graphically in Figures 3-7 and 3-8.

Hypothesis 7: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater increases in the relative percentage of Type 1

(periodic) signals during voicing tasks compared to participants who receive only BTX-A injection and participants who receive BTX-A injection plus a sham voice therapy for ADSD.

Pairwise comparisons of treatment groups (Table 3-6) revealed significant differences between Groups 2 and 3 with regard to both linear change over time ($\beta = 9.63$, $t(86.1) = 2.61$, $p = 0.0107$) and rate of change (quadratic effect) during connected speech tasks ($\beta = -0.64$, $t(74.6) = -2.31$, $p = 0.0235$). Thus, Group 2 achieved significantly greater increases in relative percentage of Type 1 signals during connected speech tasks compared with Group 3, although those increases also appeared to diminish at a significantly greater rate than Group 3 once maximum benefit was achieved. If participation in voice therapy was responsible for these significant gains in Group 2 compared to Group 3 than we would expect a similar effect to emerge when Group 2 was compared to Group 1, and yet no significant between group effects were revealed when Group 2 was compared to Group 1, the BTX-A only group. Hypothesis 7 is rejected.

Hypothesis 8: All participants who receive BTX-A injections for ADSD will experience significant decreases in the relative percentage of undesirable signals during voicing tasks following injection. These undesirable signals include Type 2 (subharmonic), Type 3 (aperiodic) and voice breaks.

A Wilcoxon signed rank statistic was used to assess the difference in percentage of undesirable signals before and after BTX-A injection. All participants improved significantly following BTX-A injection in percentage of undesirable signals during both sustained phonation (*Wilcoxon signed rank*, $p < .0001$; *Table* 3-7) and connected speech (*Wilcoxon signed rank*, $p = .0042$; *Table* 3-7) tasks between baseline and approximately 3 weeks post injection. When Type 2 signals, Type 3 signals, and voice breaks were pooled into a single measure of undesirable

signals, significant negative linear effects were observed for all Groups over time during sustained phonation tasks although during connected speech tasks no significant changes following BTX-A injection were observed for Group 3 (Table 3-8). Hypothesis 8 is accepted.

Hypothesis 9: Measures of the relative percentage of undesirable signals during voicing will change in a non-linear fashion, over time, in response to BTX-A injection, for all participants. Specifically, percentage of undesirable signals will decrease following injection, eventually reaching a minimum value, prior to trending upward toward baseline values thereby demonstrating a significant quadratic effect.

Although all groups displayed similar patterns of decreases, then increases, in undesirable signals during sustained phonation (Figure 3-9) and connected speech (Figure 3-10) statistical analysis did not reveal uniformly significant effects. During sustained phonation, only Group 3 displayed significant (p = 0.0260) quadratic effects. Interestingly, during connected speech tasks only Group 2 displayed significant (p = 0.0006) quadratic effects (Table 3-8). Quadratic effects are displayed graphically in Figures 3-11 through 3-18. Hypothesis 9 is rejected.

Hypothesis 10: Participants who receive voice therapy following BTX-A injection for ADSD will experience significantly greater decreases in the relative percentage of undesirable signals during voicing tasks compared to participants who receive only BTX-A injection and participants who receive BTX-A injections plus a sham voice therapy for ADSD.

Pairwise comparison of treatment groups during sustained phonation (Table 3-9) revealed a significant difference between Group 1 and Group 3 with regard to linear change in percentage of Type 2 signals over time (β = 0.51, t (86.7) = 2.49, p = 0.0148). During connected speech (Table 3-10) Group 1 and Group 3 varied significantly with regard to linear change in percentage of voice breaks over time (β = - 0.1780, t (78.9) = - 2.09, p = 0.0402) while Groups 2 and 3

varied significantly with regard to change in Type 3 (β = - 9.70, t (86.9) = - 3.04, p = 0.0031) and pooled undesirable (β = - 10.27, t (91) = - 2.83, p = 0.0057) signals over time. These differences continued when examining for quadratic effects with Group 1 and Group 3 varying significantly with regard to the rate of change of voice breaks (β = 0.01, t (68.3) = 2.05, p = 0.0443) and Groups 2 and 3 varying significantly with regard to rate of change of Type 3 (β = 0.6349, t (75.1) = 2.63, p = 0.0103) and pooled undesirable (β = 0.6891, t (80.1) = 2.47, p = 0.0156) signals. Although during connected speech tasks Group 2 had significantly greater decreases in undesirable signals over time when compared to Group 3, there was no significant difference between Groups 1 and 2 therefore Hypothesis 10 is rejected.

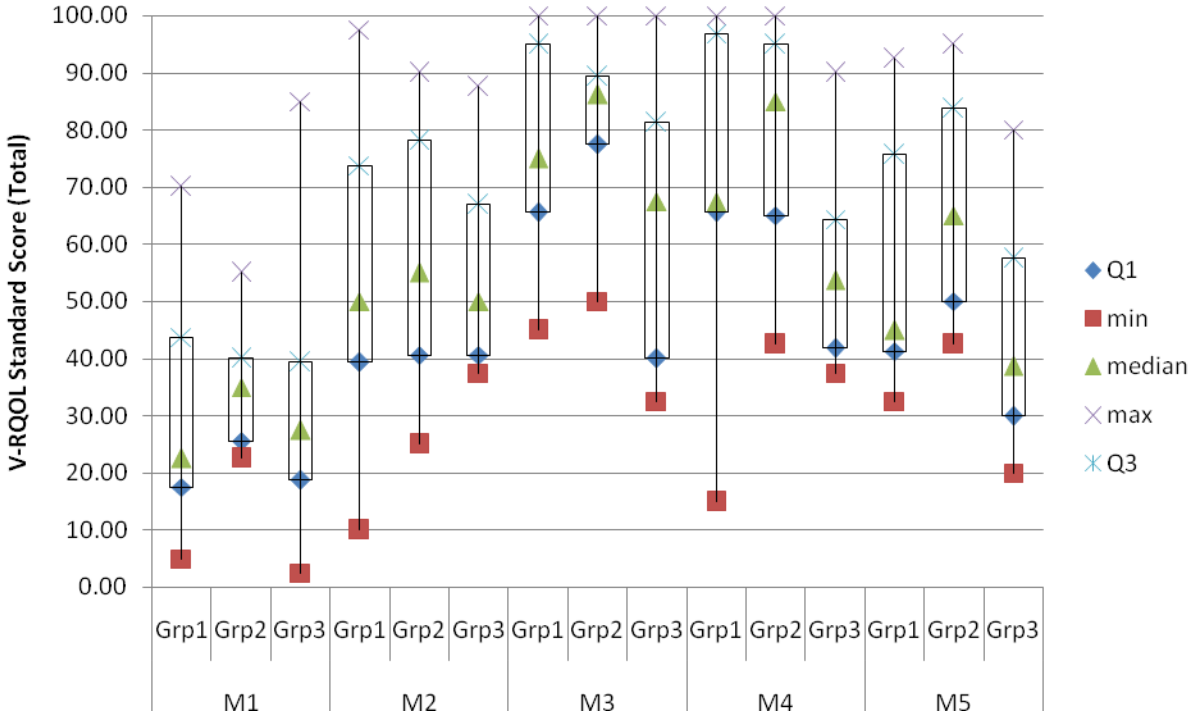

Figure 3-1. V-RQOL box plot. Data pictured represent total scores. M1 = preinjection; M2 = ~3 weeks post injection; M3 = ~7 weeks post injection; M4 = ~12 weeks post injection; M5 = prior to reinjection.

Table 3-1 . Change in V-RQOL standard scores following BTX-A injection (all participants).

V-RQOL Standard Score		% change from baseline (M1)	*p*-value
Social-emotional	Median	73.21	**<.0001**
	Mean(SD)	123.52(1.89)	
Physical	Median	90.91	**<.0001**
	Mean(SD)	181.54(3.27)	
Total	Median	83.33	**<.0001**
	Mean(SD)	215.11(4.53)	

Table 3-2. Solution for fixed effects - V-RQOL. Total score as well as social-emotional and physical subscales

		Social-emotional			Physical			Total		
		β	*SE(β)*	*P*	*β*	*SE(β)*	*p*	*β*	*SE(β)*	*P*
Grp	1	36.14	7.35	**<.0001**	27.08	6.35	**<.0001**	30.70	6.31	**<.0001**
	2	46.29	7.69	**<.0001**	25.76	6.65	**0.0002**	33.90	6.61	**<.0001**
	3	31.72	7.69	**<.0001**	32.33	6.65	**<.0001**	32.34	6.61	**<.0001**
Grp*time	1	10.50	2.85	**0.0004**	11.31	2.47	**<.0001**	11.01	2.48	**<.0001**
	2	9.81	2.91	**0.0011**	11.31	2.52	**<.0001**	10.74	2.53	**<.0001**
	3	10.06	2.92	**0.0009**	7.67	2.53	**0.0032**	8.64	2.54	**0.0010**
Grp*time^2	1	-0.58	0.22	**0.0097**	-0.63	0.19	**0.0016**	-0.61	0.19	**0.0020**
	2	-0.57	0.23	**0.0141**	-0.60	0.20	**0.0030**	-0.59	0.20	**0.0037**
	3	-0.59	0.23	**0.0117**	-0.51	0.20	**0.0121**	-0.54	0.20	**0.0077**

Grp = intercept; Grp*time = linear effect; Grp*time^2 = quadratic effect.

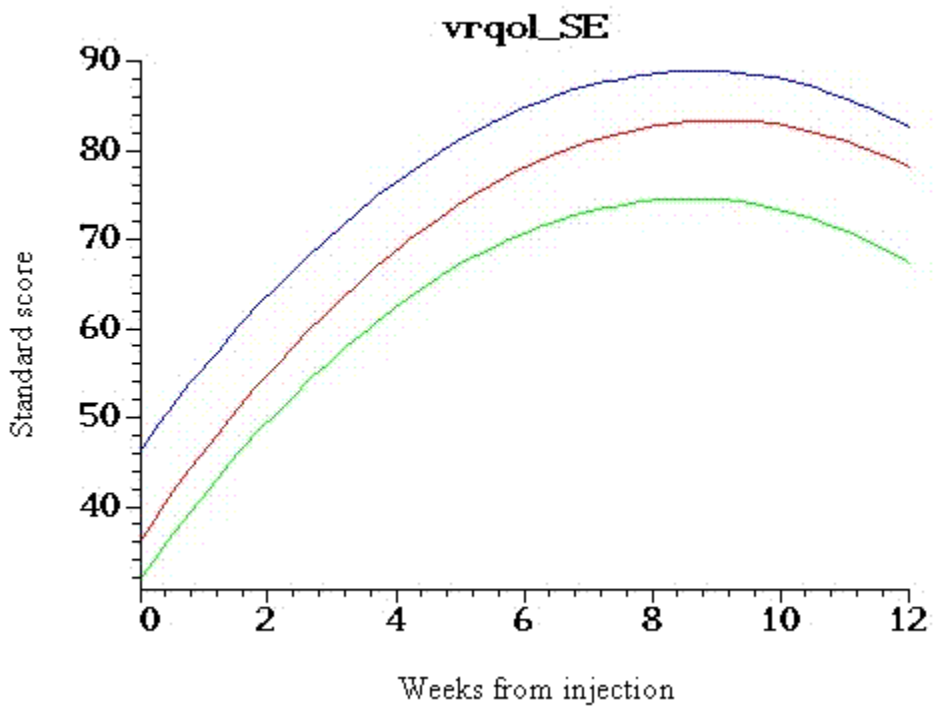

Figure 3-2. Social-emotional subdomain (V-RQOL) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy).

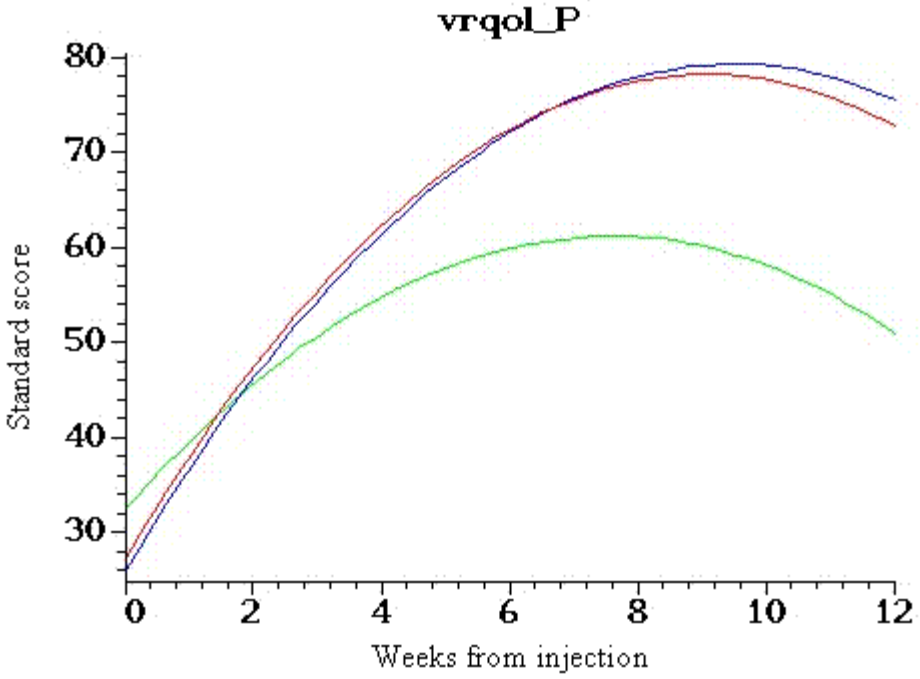

Figure 3-3. Physical subdomain (V-RQOL) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy).

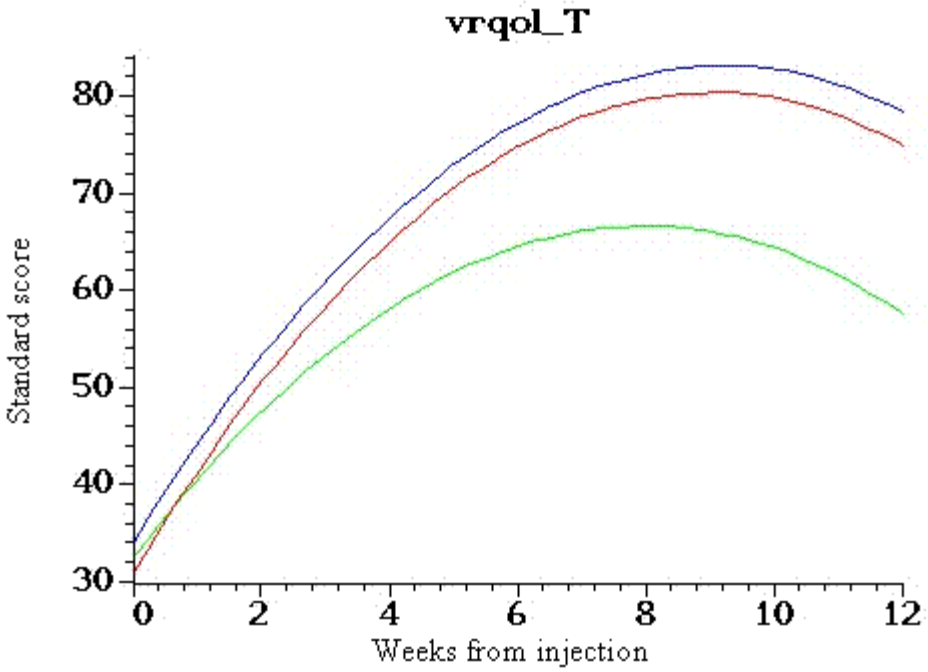

Figure 3-4. V-RQOL quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy).

Table 3-3. Pairwise comparisons V-RQOL

			G1			G2			G3		
			β	*SE(β)*	*p*	*β*	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Intercept	G1	So-Em				-10.15	10.64	0.3426	4.42	10.64	0.6785
		P				1.32	9.20	0.8863	-5.25	9.20	0.5696
		T				-3.21	9.14	0.7267	-1.64	9.14	0.8576
	G2	So-Em	-10.15	10.64	0.3426				14.57	10.88	0.1839
		P	1.32	9.20	0.8863				-6.57	9.41	0.4868
		T	-3.21	9.14	0.7267				1.56	9.35	0.8678
	G3	So-Em	4.42	10.64	0.6785	14.57	10.88	0.1839			
		P	-5.25	9.20	0.5696	-6.57	9.41	0.4868			
		T	-1.64	9.14	0.8576	1.56	9.35	0.8678			
Linear	G1	So-Em				0.69	4.07	0.8668	0.44	4.08	0.9135
		P				0.01	3.53	0.9987	3.65	3.54	0.3113
		T				0.28	3.54	0.9372	2.38	3.55	0.5043
	G2	So-Em	0.69	4.07	0.8668				-0.24	4.12	0.9536
		P	0.01	3.53	0.9987				3.64	3.58	0.3056
		T	0.28	3.54	0.9372				2.10	3.58	0.5598
	G3	So-Em	0.44	4.08	0.9135	-0.24	4.12	0.9536			
		P	3.65	3.54	0.3056	3.64	3.58	0.3113			
		T	2.38	3.55	0.5043	2.10	3.58	0.5598			
Quadratic	G1	So-Em				-0.02	0.32	0.9533	0.01	0.32	0.9848
		P				-0.03	0.27	0.9170	-0.12	0.28	0.6744
		T				-0.03	0.27	0.9275	-0.07	0.28	0.8110
	G2	So-Em	-0.02	0.32	0.9533				0.02	0.32	0.9392
		P	-0.03	0.27	0.9170				-0.09	0.28	0.7539
		T	-0.03	0.27	0.9275				-0.04	0.28	0.8829
	G3	So-Em	0.01	0.32	0.9848	0.02	0.32	0.9392			
		P	-0.12	0.28	0.6744	-0.09	0.28	0.7539			
		T	-0.07	0.28	0.8110	-0.04	0.28	0.8829			

G1 = Group 1; G2 = Group 2; G3 = Group 3; So-Em = Social-emotional subdomain score; P = physical subdomain score; T = total subdomain score.

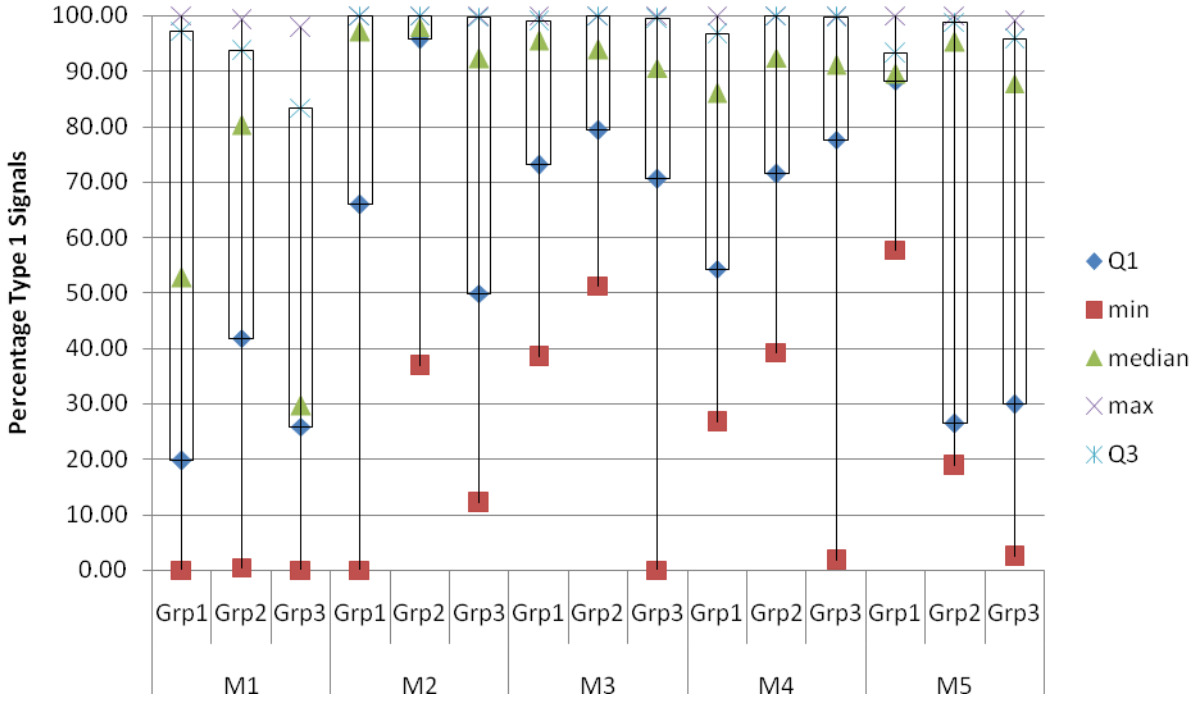

Figure 3-5. Type 1 signals (sustained phonation) box plot. M1 = preinjection; M2 = ~3 weeks post injection; M3 = ~7 weeks post injection; M4 = ~12 weeks post injection; M5 = prior to reinjection.

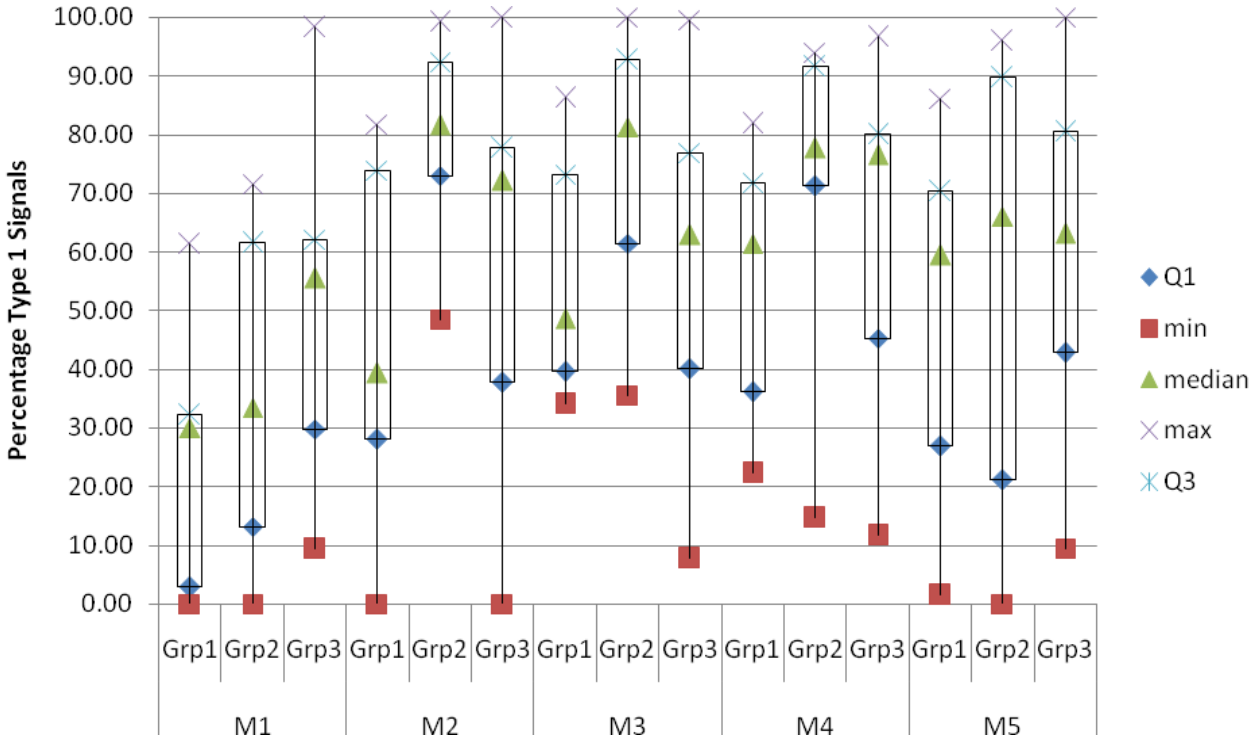

Figure 3-6. Type 1 signals (connected speech) box plot. M1 = preinjection; M2 = ~3 weeks post injection; M3 = ~7 weeks post injection; M4 = ~12 weeks post injection; M5 = prior to reinjection.

Table 3-4. Change in relative percentage of Type 1 signals following BTX-A injection (all participants).

Variable		% change from baseline (M1)	*p*-value
Type 1 - /a/	Median	13.17	**<.0001**
	Mean(SD)	768.54(35.91)	
Type 1 - cs	Median	52.14	**<.0001**
	Mean(SD)	157.11(3.42)	

/a/ = sustained phonation, cs = connected speech (Rainbow Passage)

Table 3-5. Solution for fixed effects for Type 1 signals during sustained phonation (/a/) and connected speech (cs).

		Sustained phonation – /a/			Connected speech - cs		
		β	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Grp	1	60.36	10.24	**<.0001**	26.50	8.40	**0.0023**
	2	68.72	9.92	**<.0001**	38.30	8.10	**<.0001**
	3	50.35	9.93	**<.0001**	50.89	8.11	**<.0001**
Grp*time	1	6.39	3.05	**0.0389**	7.87	2.71	**0.0046**
	2	6.18	2.91	**0.0365**	11.38	2.59	**<.0001**
	3	7.78	2.96	**0.0101**	1.75	2.63	0.5067
Grp*time^2	1	-0.42	0.22	0.0675	-0.47	0.20	**0.0223**
	2	-0.42	0.22	0.0545	-0.72	0.20	**0.0005**
	3	-0.47	0.22	**0.0347**	-0.07	0.20	0.7099

Grp = intercept; Grp*time = linear effect; Grp*time^2 = quadratic effect.

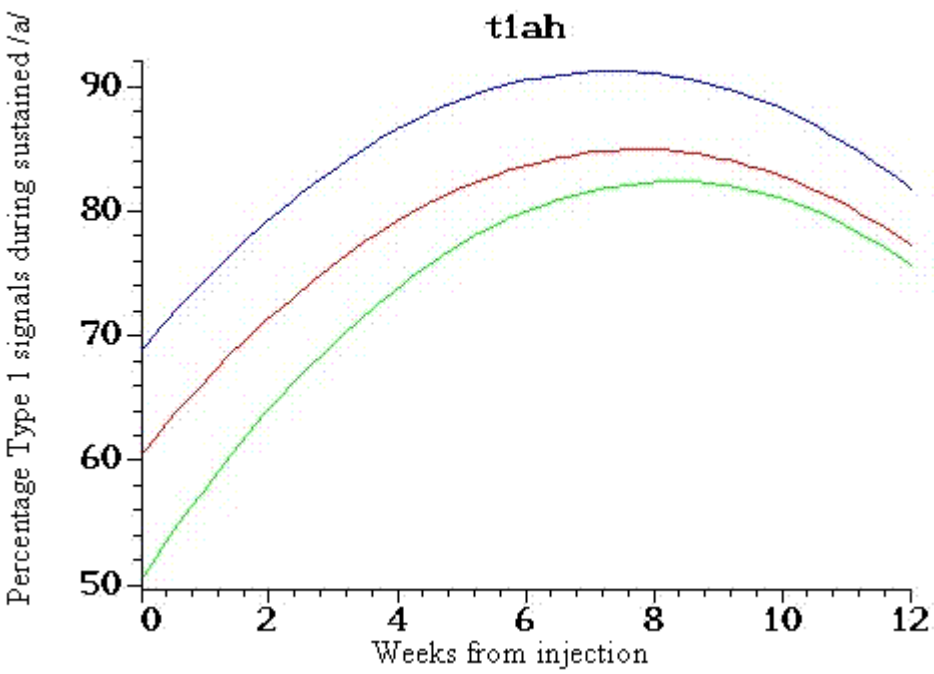

Figure 3-7. Type 1 signals (sustained phonation) quadratic function graph.. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy).

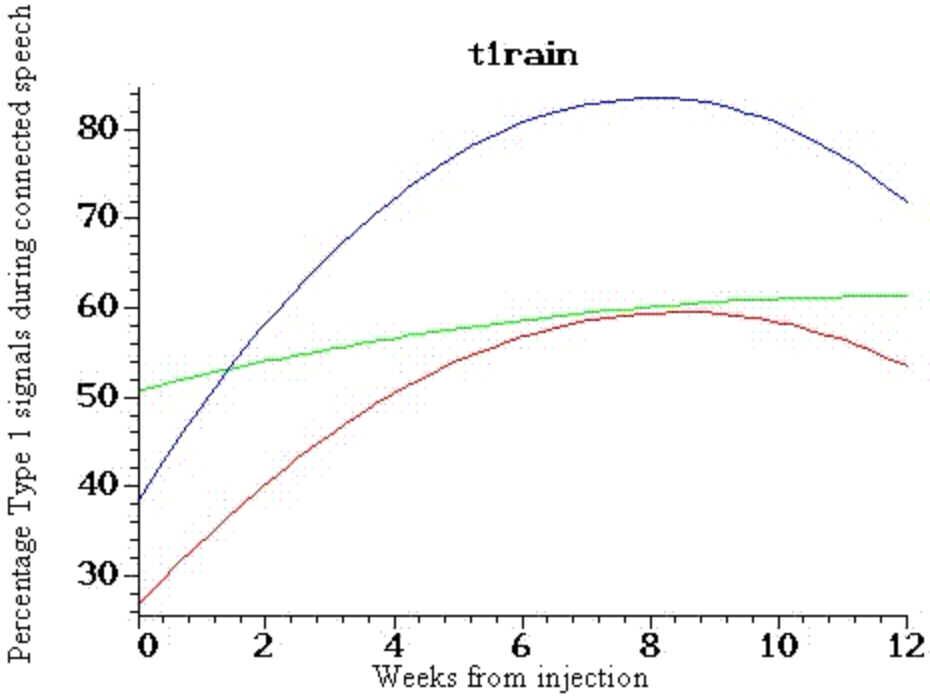

Figure 3-8. Type 1 signals (connected speech) quadratic function graph.. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Group 3 did not demonstrate a quadratic effect.

Table 3-6. Pairwise comparisons for Type 1 signals

			G 1			G 2			G 3		
			β	*SE(β)*	*p*	*β*	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Intercept	G 1	T1-/a/				-8.36	14.26	0.5601	10.01	14.26	0.4855
		T1-cs				-11.79	11.67	0.3157	-24.39	11.67	**0.0403**
	G 2	T1-/a/	-8.36	14.26	0.5601				18.36	14.04	0.1958
		T1-cs	-11.79	11.67	0.3157				-12.60	11.46	0.2756
	G 3	T1-/a/	10.01	14.26	0.4855	18.36	14.04	0.1958			
		T1-cs	-24.39	11.67	**0.0403**	-12.60	11.46	0.2756			
Linear	G 1	T1-/a/				0.21	4.21	0.9608	-1.39	4.24	0.7444
		T1-cs				-3.51	3.74	0.3514	6.12	3.77	0.1085
	G 2	T1-/a/	0.21	4.21	0.9608				-1.60	4.15	0.7013
		T1-cs	-3.51	3.74	0.3514				9.63	3.69	**0.0107**
	G 3	T1-/a/	-1.39	4.24	0.7444	-1.60	4.15	0.7013			
		T1-cs	6.12	3.77	0.1085	9.63	3.69	**0.0107**			
Quadratic	G 1	T1-/a/				0.01	0.31	0.9768	0.06	0.31	0.8561
		T1-cs				0.25	0.28	0.3824	-0.40	0.28	0.1646
	G 2	T1-/a/	0.01	0.31	0.9768				0.05	0.31	0.8770
		T1-cs	0.25	0.28	0.3824				-0.64	0.28	**0.0235**
	G 3	T1-/a/	0.06	0.31	0.8561	0.05	0.31	0.8770			
		T1-cs	-0.40	0.28	0.1646	-0.64	0.28	**0.0235**			

G1 = Group 1; G2 = Group 2; G3 = Group 3; /a/ = sustained phonation; cs = connected speech

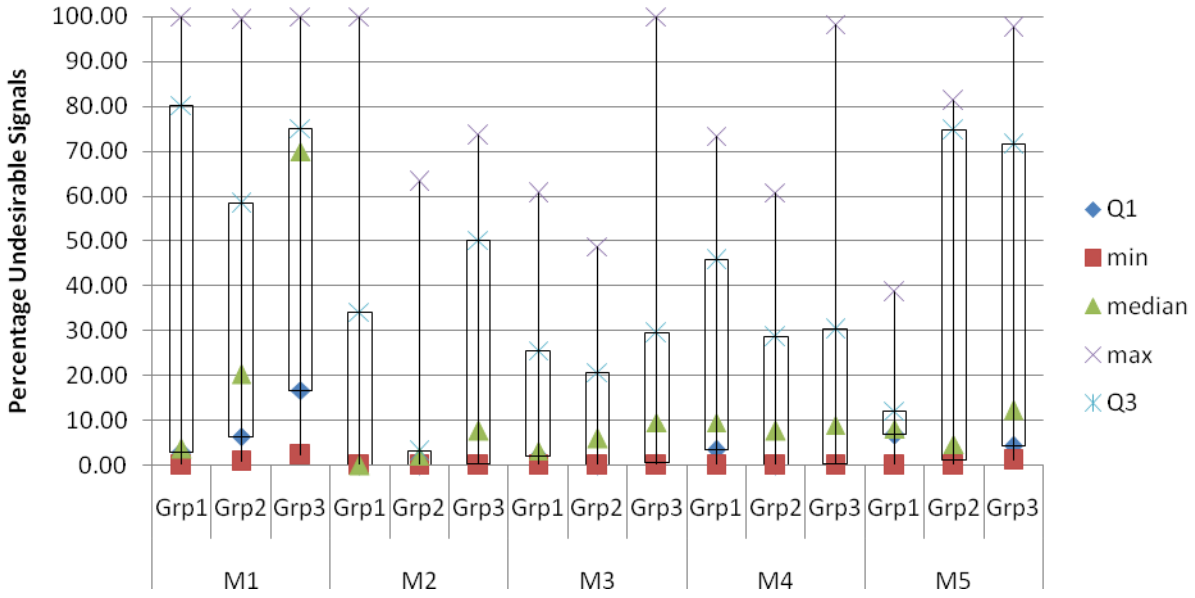

Figure 3-9. Undesirable signals (sustained phonation) box plot. M1 = preinjection; M2 = ~3 weeks post injection; M3 = ~7 weeks post injection; M4 = ~12 weeks post injection; M5 = prior to reinjection.

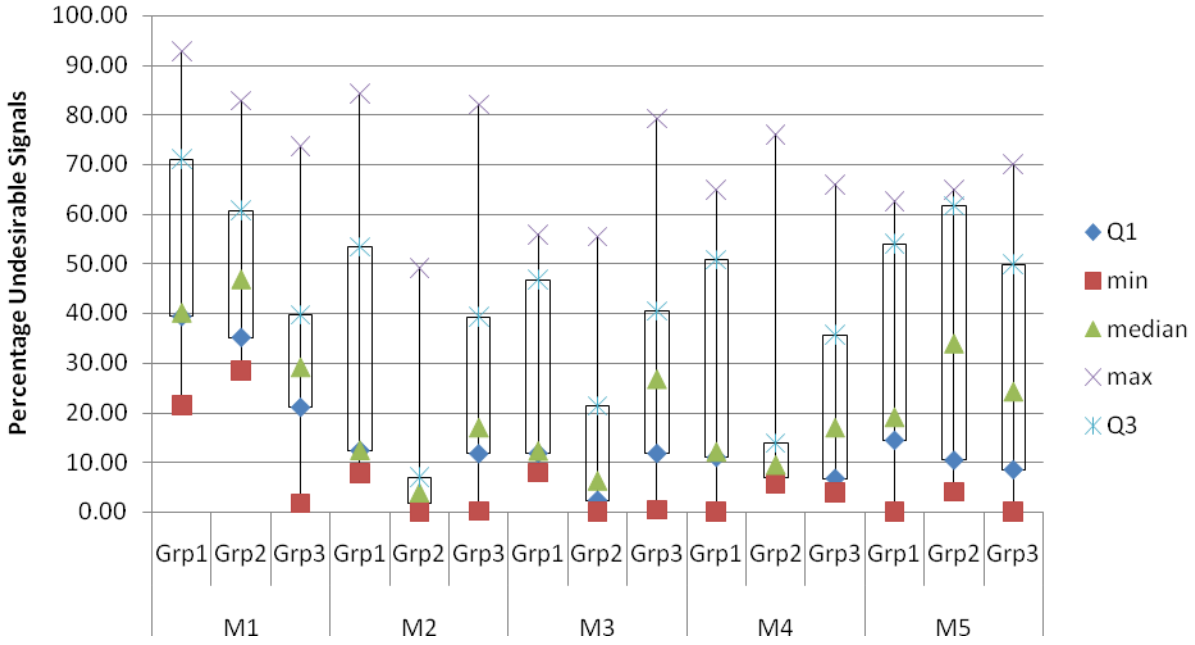

Figure 3-10. Undesirable signals (connected speech) box plot. M1 = preinjection; M2 = ~3 weeks post injection; M3 = ~7 weeks post injection; M4 = ~12 weeks post injection; M5 = prior to reinjection.

Table 3-7. Change in relative percentage of undesirable signals following BTX-A injection (all participants).

Variable		% change from baseline (M1)	*p*-value
Undesirable - /a/	Median	-87.94	**<.0001**
	Mean(SD)	-66.57(0.46)	
Undesirable - cs	Median	-65.62	**0.0042**
	Mean(SD)	8.55(2.97)	
Type 2 - /a/	Median	-100.00	**0.0089**
	Mean(SD)	-30.53(2.06)	
Type 2 - cs	Median	-92.60	0.1441
	Mean(SD)	10.45(2.41)	
Type 3 – /a/	Median	-90.04	**0.0258**
	Mean(SD)	39.24(4.76)	
Type 3 - cs	Median	-73.08	**0.0057**
	Mean(SD)	124.25(8.61)	
Voice breaks - /a/	Median	-100.00	**0.0002**
	Mean(SD)	-89.33(0.28)	
Voice breaks – cs	Median	-100.00	**0.0078**
	Mean(SD)	-80.05(0.31)	

/a/ = sustained phonation, cs = connected speech

Table 3-8. Solution for fixed effects for undesirable, Type 2 signals, Type 3 signals and voice breaks.

			Sustained phonation - /a/			Connected speech - cs		
			β	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Undesirable signals	Grp	1	40.11	10.15	**0.0002**	51.08	7.30	**<.0001**
		2	31.22	9.83	**0.0023**	47.32	7.00	**<.0001**
		3	50.14	9.83	**<.0001**	30.69	7.01	**<.0001**
	Grp*time	1	-6.55	3.12	**0.0387**	-6.28	2.66	**0.0204**
		2	-6.34	2.98	**0.0364**	-10.79	2.54	**<.0001**
		3	-8.23	3.03	**0.0080**	-0.52	2.59	0.8400
	Grp*time^2	1	0.43	0.23	0.0682	0.38	0.20	0.0629
		2	0.44	0.22	0.0541	0.70	0.20	**0.0006**
		3	0.51	0.23	**0.0260**	0.01	0.20	0.9453
Type 2 signals	Grp	1	0.39	0.42	0.3586	0.74	0.36	**0.0443**
		2	1.22	0.40	**0.0034**	0.83	0.35	**0.0212**
		3	1.87	0.40	**<.0001**	0.93	0.35	**0.0098**
	Grp*time	1	0.08	0.15	0.5923	0.01	0.04	0.7875
		2	-0.18	0.14	0.2138	0.02	0.04	0.6542
		3	-0.43	0.14	**0.0034**	0.02	0.04	0.7032
	Grp*time^2	1	0.00	0.01	0.9576			
		2	0.02	0.01	0.1468			
		3	0.03	0.01	**0.0076**			
Type 3 signals	Grp	1	2.05	0.48	**<.0001**	45.42	6.99	**<.0001**
		2	1.80	0.47	**0.0003**	40.99	6.74	**<.0001**
		3	2.43	0.47	**<.0001**	25.57	6.74	**0.0003**
	Grp*time	1	-0.05	0.05	0.3565	-6.22	2.34	**0.0093**
		2	-0.12	0.05	**0.0208**	-10.29	2.23	**<.0001**
		3	-0.08	0.05	0.1240	-0.59	2.27	0.7957
	Grp*time^2	1				0.38	0.17	**0.0322**
		2				0.65	0.17	**0.0003**
		3				0.02	0.17	0.9258
Voice breaks	Grp	1	0.89	0.35	**0.0142**	0.59	0.25	**0.0220**
		2	0.65	0.34	0.0663	0.73	0.24	**0.0046**
		3	0.98	0.34	**0.0062**	0.25	0.24	0.3071
	Grp*time	1	-0.28	0.09	**0.0039**	-0.18	0.06	**0.0039**
		2	-0.07	0.09	0.4632	-0.09	0.06	0.1311
		3	-0.20	0.09	**0.0341**	0.00	0.06	0.9446
	Grp*time^2	1	0.02	0.01	**0.0077**	0.01	0.00	**0.0064**
		2	0.01	0.01	0.3620	0.00	0.00	0.2781
		3	0.01	0.01	0.0570	0.00	0.00	0.9559

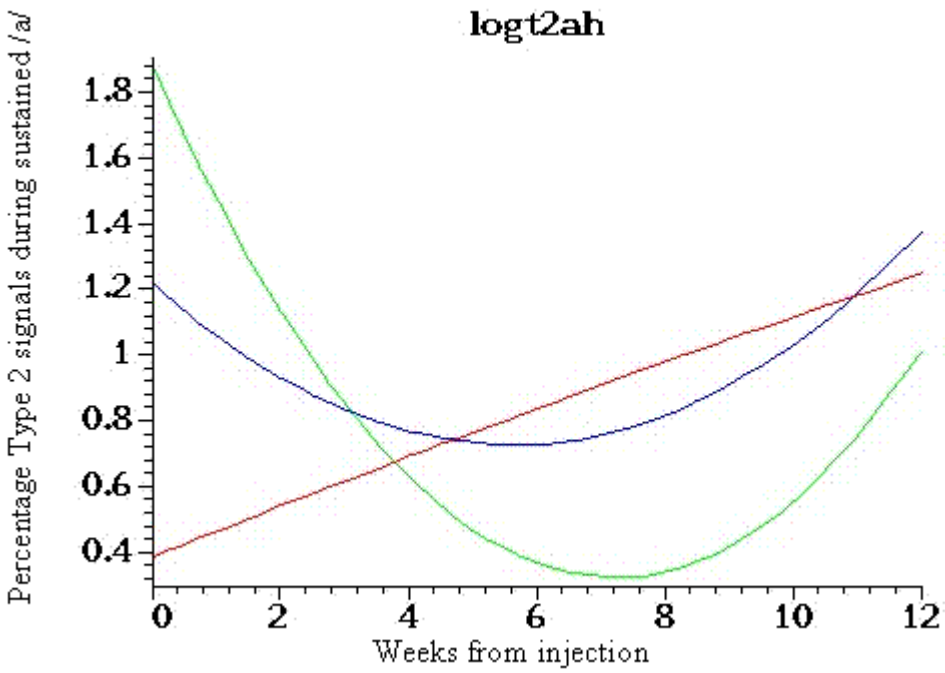

Figure 3-11. Type 2 signals (sustained phonation) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Only Group 3 demonstrates a quadratic effect.

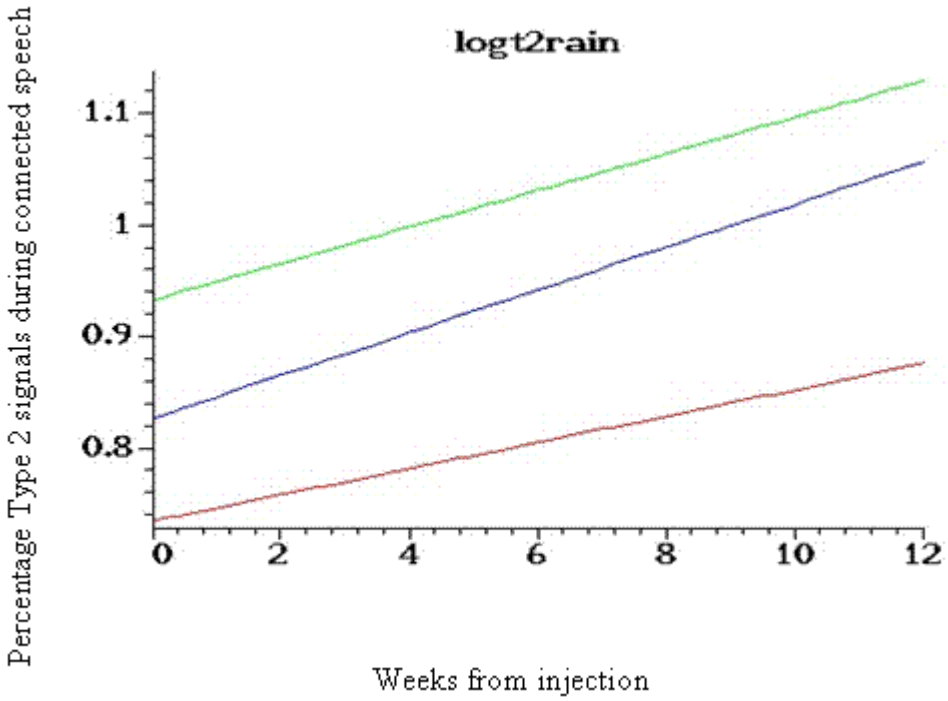

Figure 3-12. Type 2 signals (connected speech) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). No quadratic effects were evidenced for any group.

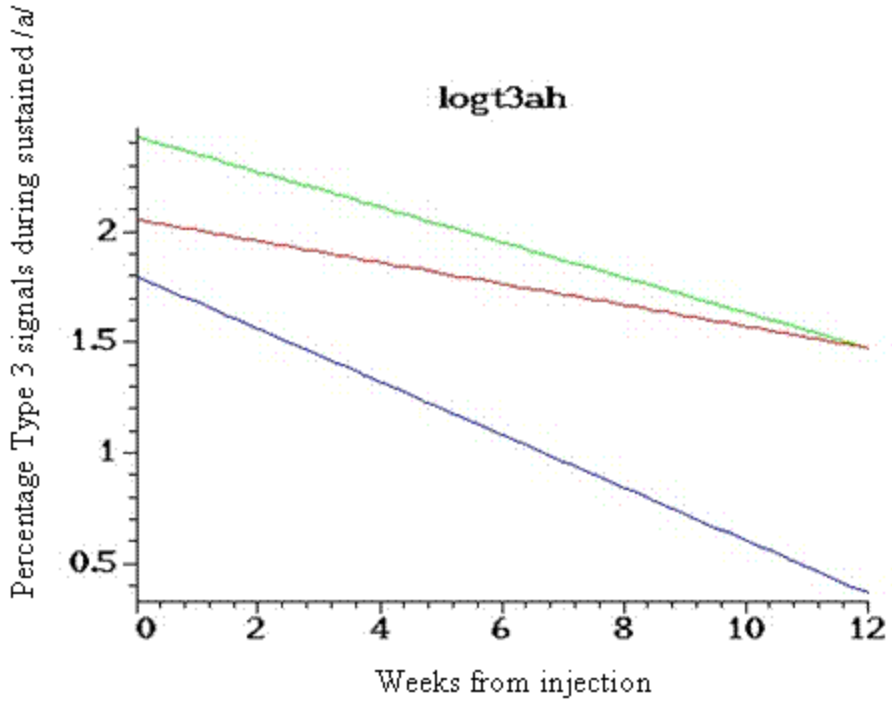

Figure 3-13. Type 3 signals(sustained phonation) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). No quadratic effects were evidenced for any group.

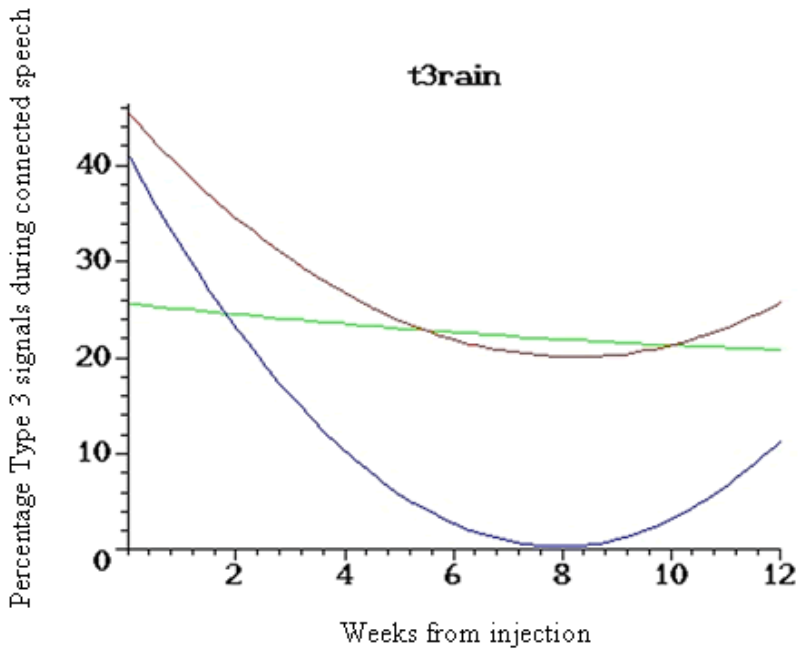

Figure 3-14. Type 3 signals (connected speech) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Group 3 did not demonstrate a quadratic effect.

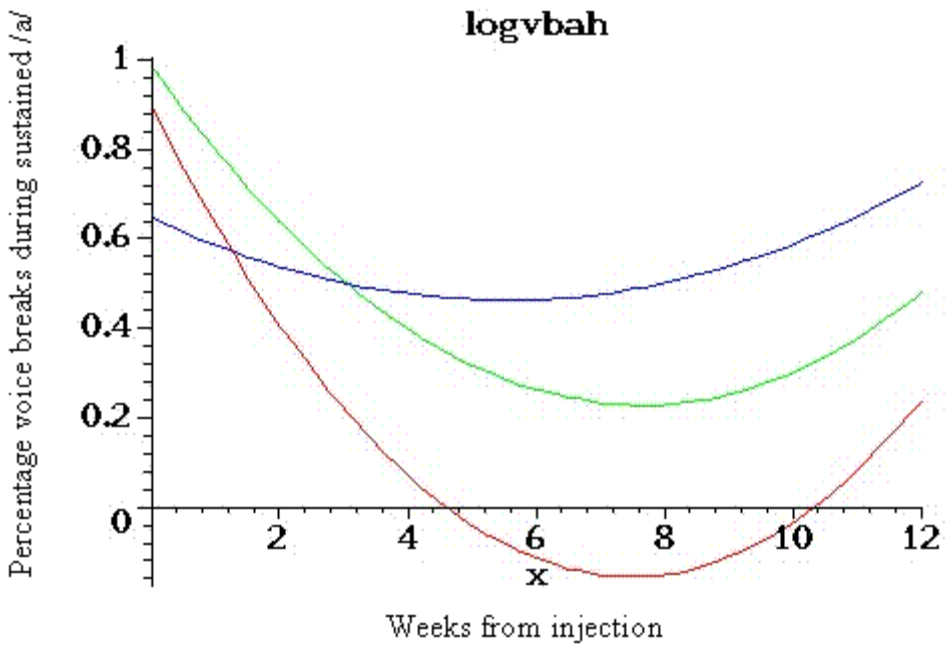

Figure 3-15. Voice breaks (sustained phonation) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Only Group 1 demonstrated a quadratic effect.

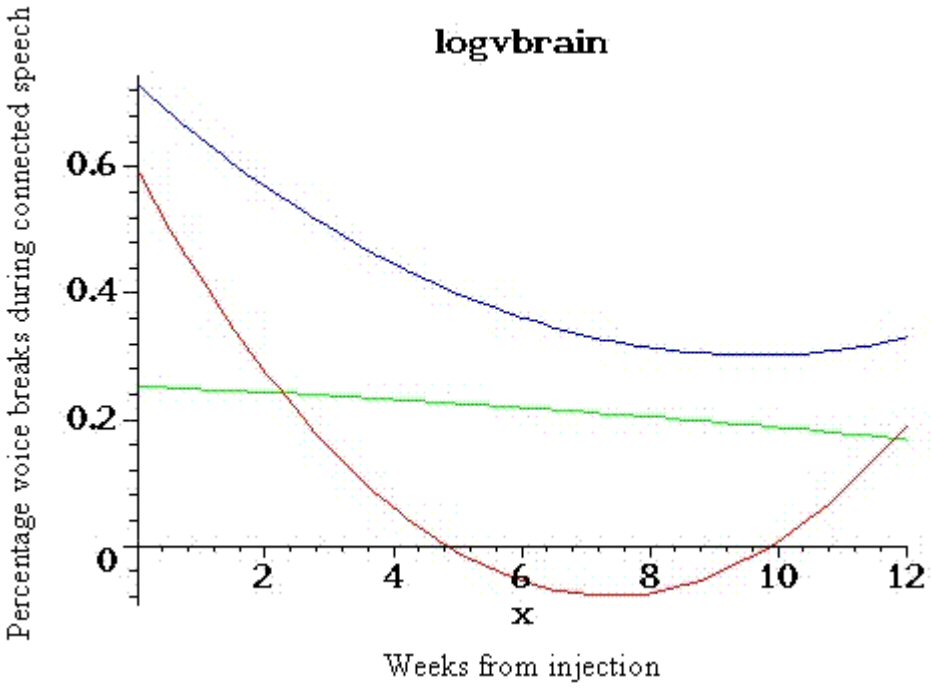

Figure 3-16. Voice breaks (connected speech) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Only Group 1 demonstrated a quadratic effect.

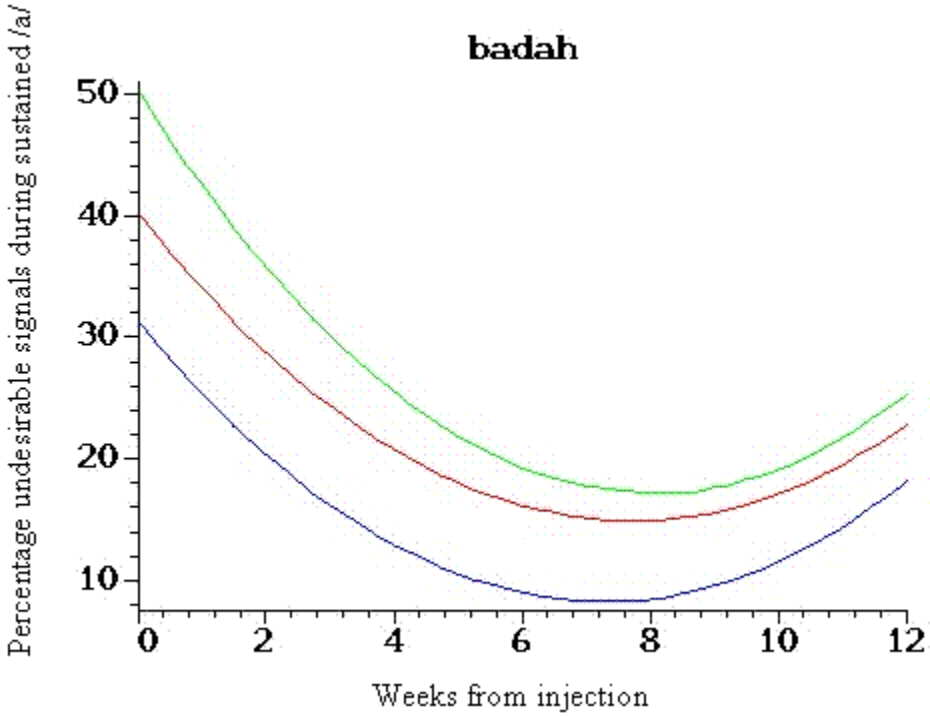

Figure 3-17. Undesirable signals (sustained phonation) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Only Group 3 demonstrated quadratic effects.

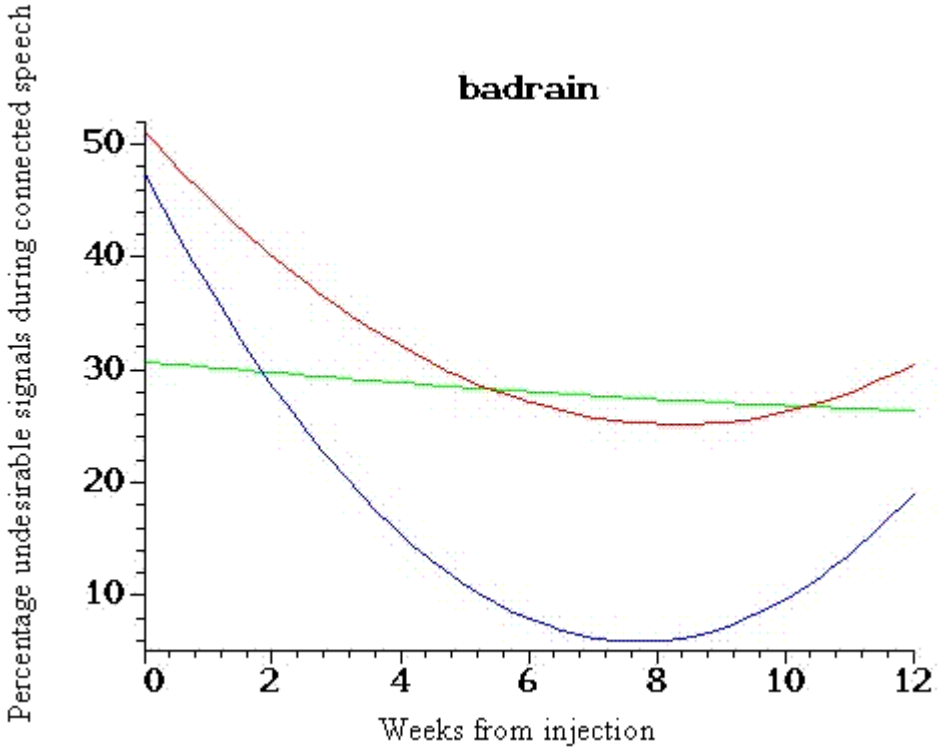

Figure 3-18. Undesirable signals (connected speech) quadratic function graph. Red line = Group 1 (BTX-A only), blue line = Group 2 (BTX-A plus voice therapy), and green line = Group 3 (BTX-A plus sham voice therapy). Only Group 2 demonstrated quadratic effects.

Table 3-9. Pairwise comparisons for undesirable signals (U) including log Type 2 ($T2^L$), log Type 3 ($T3^L$), and log voice breaks (Vb^L) during sustained phonation (/a/).

				G 1			G 2			G 3		
				β	*SE(β)*	*p*	*β*	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Intercept	G 1	U					8.88	14.13	0.5318	-10.04	14.13	0.4801
			$T2^L$				-0.83	0.58	0.1570	-1.49	0.58	**0.0126**
			$T3^L$				0.25	0.67	0.7040	-0.38	0.67	0.5756
			Vb^L				0.25	0.49	0.6147	-0.09	0.49	0.8590
	G 2	U		8.88	14.13	0.5318				-18.92	13.90	0.1783
			$T2^L$	-0.83	0.58	0.1570				-0.66	0.57	0.2534
			$T3^L$	0.25	0.67	0.7040				-0.63	0.66	0.3442
			Vb^L	0.25	0.49	0.6147				-0.34	0.49	0.4908
	G 3	U		-10.04	14.13	0.4801	-18.92	13.90	0.1783			
			$T2^L$	-1.49	0.58	**0.0126**	-0.66	0.57	0.2534			
			$T3^L$	-0.38	0.67	0.5756	-0.63	0.66	0.3442			
			Vb^L	-0.09	0.49	0.8590	-0.34	0.49	0.4908			
Linear	G 1	U					-0.22	4.32	0.9599	1.68	4.35	0.7012
			$T2^L$				0.25	0.20	0.2133	0.51	0.20	**0.0148**
			$T3^L$				0.07	0.07	0.3301	0.03	0.07	0.6688
			Vb^L				-0.22	0.13	0.1050	-0.08	0.13	0.5294
	G 2	U		-0.22	4.32	0.9599				1.89	4.25	0.6572
			$T2^L$	0.25	0.20	0.2133				0.25	0.20	0.2068
			$T3^L$	0.07	0.07	0.3301				-0.04	0.07	0.5823
			Vb^L	-0.22	0.13	0.1050				0.13	0.13	0.3110
	G 3	U		1.68	4.35	0.7012	1.89	4.25	0.6572			
			$T2^L$	0.51	0.20	**0.0148**	0.25	0.20	0.2068			
			$T3^L$	0.03	0.07	0.6688	-0.04	0.07	0.5823			
			Vb^L	-0.08	0.13	0.5294	0.13	0.13	0.3110			
Quadratic	G 1	U					-0.01	0.32	0.9727	-0.09	0.32	0.7874
			$T2^L$				-0.02	0.02	0.2932	-0.03	0.02	0.0535
			$T3^L$				-	-	-	-	-	-
			Vb^L				0.01	0.01	0.1870	0.01	0.01	0.5450
	G 2	U		-0.01	0.32	0.9727				-0.08	0.32	0.8109
			$T2^L$	-0.02	0.02	0.2932				-0.01	0.02	0.3579
			$T3^L$	-	-	-				-	-	-
			Vb^L	0.01	0.01	0.1870				-0.01	0.01	0.4683
	G 3	U		-0.09	0.32	0.7874	-0.08	0.32	0.8109			
			$T2^L$	-0.03	0.02	0.0535	-0.01	0.02	0.3579			
			$T3^L$	-	-	-	-	-	-			
			Vb^L	0.01	0.01	0.5450	-0.01	0.01	0.4683			

G1 = Group 1; G2 = Group 2; G3 = Group 3; No quadratic effect denoted by (-)

Table 3-10. Pairwise comparisons for undesirable signals (U) including log Type 2 ($T2^L$), Type 3 (T3), and log voice breaks (Vb^L) during connected speech (Rainbow Passage).

				G 1			G 2			G 3		
				β	*SE(β)*	*p*	*β*	*SE(β)*	*p*	*β*	*SE(β)*	*p*
Intercept	G 1	U					3.76	10.12	0.7112	20.40	10.12	**0.0471**
			$T2^L$				-0.09	0.50	0.8540	-0.20	0.50	0.6931
			T3				4.44	9.71	0.6491	19.85	9.71	**0.0445**
			Vb^L				-0.14	0.35	0.6953	0.34	0.35	0.3370
	G 2	U		3.76	10.12	0.7112				16.64	9.91	0.0969
			$T2^L$	-0.09	0.50	0.8540				-0.11	0.49	0.8309
			T3	4.44	9.71	0.6491				15.42	9.53	0.1100
			Vb^L	-0.14	0.35	0.6953				0.48	0.34	0.1744
	G 3	U		20.40	10.12	**0.0471**	16.64	9.91	0.0969			
			$T2^L$	-0.20	0.50	0.6931	-0.11	0.49	0.8309			
			T3	19.85	9.71	**0.0445**	15.42	9.53	0.1100			
			Vb^L	0.34	0.35	0.3370	0.48	0.34	0.1744			
Linear	G 1	U					4.51	3.68	0.2238	-5.76	3.71	0.1244
			$T2^L$				-0.01	0.06	0.9039	0.00	0.06	0.9400
			T3				4.06	3.24	0.2124	-5.63	3.26	0.0878
			Vb^L				-0.09	0.08	0.2761	-0.18	0.09	**0.0402**
	G 2	U		4.51	3.68	0.2238				-10.27	3.63	**0.0057**
			$T2^L$	-0.01	0.06	0.9039				0.00	0.06	0.9636
			T3	4.06	3.24	0.2124				-9.70	3.19	**0.0031**
			Vb^L	-0.09	0.08	0.2761				-0.09	0.08	0.3104
	G 3	U		-5.76	3.71	0.1244	-10.27	3.63	**0.0057**			
			$T2^L$	0.00	0.06	0.9400	0.00	0.06	0.9636			
			T3	-5.63	3.26	0.0878	-9.70	3.19	**0.0031**			
			Vb^L	-0.18	0.09	**0.0402**	-0.09	0.08	0.3104			
Quadratic	G 1	U					-0.32	0.28	0.2561	0.37	0.28	0.1983
			$T2^L$				-	-	-	-	-	-
			T3				-0.27	0.24	0.2720	0.37	0.25	0.1399
			Vb^L				0.01	0.01	0.2132	0.01	0.01	**0.0443**
	G 2	U		-0.32	0.28	0.2561				0.69	0.28	**0.0156**
			$T2^L$	-	-	-				-	-	-
			T3	-0.27	0.24	0.2720				0.63	0.24	**0.0103**
			Vb^L	0.01	0.01	0.2132				0.00	0.01	0.4212
	G 3	U		0.37	0.28	0.1983	0.69	0.28	**0.0156**			
			$T2^L$	-	-	-	-	-	-			
			T3	0.37	0.25	0.1399	0.63	0.24	**0.0103**			
			Vb^L	0.01	0.01	**0.0443**	0.00	0.01	0.4212			

G1 = Group 1; G2 = Group 2; G3 = Group 3; No quadratic effect denoted by (-)

CHAPTER 4
DISCUSSION

The objective of the current study was to further explore the effects of BTX-A, both alone and with voice therapy, on voice-related quality of life and acoustic measures of vocal instability. Prior anecdotal, as well as research-based evidence, has suggested that voice therapy may enhance the beneficial effects of BTX-A injections. This study sought to further explore this phenomenon, hypothesizing that, within a study population of individuals with ADSD who had received first time BTX-A injection, those who then received voice therapy would demonstrate significantly greater gains on dependent variables of interest than those who did not. A sham voice therapy arm was added in order to control for potential non-specific treatment effects which may emerge during the close clinical interactions of patient and therapist. Main effects were revealed that support the effectiveness of BTX-A injections on both voice-related quality of life and acoustic variables. On the whole, these effects were observed to increase, then decrease over time following the injection, forming a curvilinear trajectory. No evidence emerged to suggest that those individuals who received voice therapy following injection experienced enhanced benefits above or beyond those experienced by participants within the BTX-A only and BTX-A plus sham therapy groups.

Treatment Effect Duration Measure

The prior investigation of combined modality treatment of ADSD (Murry & Woodson, 1995) included a measure of *duration effect* between initial and repeat BTX-A injection. In this earlier investigation, participants were instructed to return for reinjection when they perceived the return of spasmodic symptoms, specifically strain-strangle phonation with voice breaks. At that point they were reinjected and the interval between initial and repeat injection was calculated (in weeks) as an approximate measure of treatment benefit duration. Participants who

received BTX-A plus voice therapy went an average of 27.4 weeks between initial and repeat injections whereas the BTX-A only group went an average of 14.9 weeks. This difference was statistically significant.

Participants in the current investigation were not as free to determine their reinjection date as those in the prior investigation. Because BTX-A, once opened, has a limited window of time during which it must be used or discarded, most otolaryngology clinics administering the injections have chosen to do so during pre-established days and times so as to minimize the waste and expense of having to discard unused BTX-A serum. Each of the five study sites involved in the current investigation used this practice of grouping BTX-A injections, thereby placing considerable time constraints on when participants could be reinjected.

Even given this constraint, time between initial and repeat BTX-A injections was subjected to survival analysis procedures in the event that different "survival" rates existed between groups. No between groups differences were found. Examination of mean length of time, in weeks, between initial and repeat injection actually shows participants in Group 1 with longer duration of time between injections. It is possible that participants in Group 2 and 3, led during the therapy process to focus on finer aspects of their vocal quality, as well as how that quality changed day to day, were more apt to detect vocal deterioration and therefore presented for reinjection earlier than participants in Group 1.

Voice-Related Quality of Life Measure

In the current study, V-RQOL total and sub scores improved significantly following BTX-A injection. Following the initial, significant, "jump" in improvement, V-RQOL standard scores continued to improve gradually, eventually peaking between seven and twelve weeks post injection and declining steadily prior to reinjection.

Prior to study initiation a power analysis using the V-RQOL estimated that, given the repeated measures parallel arm design of this study, 102 participants would be required in order to sufficiently detect between group differences in response to treatment. This number was determined to be impractical and 31 participants completed the current investigation. Given this study's failings with regard to sample size, it is not surprising that between group differences were not realized on the V-RQOL or any of its subdomains.

Rubin et al. (2004) proposed a change in V-RQOL score of 25 to 30 points to be clinically significant. This range was generated by correlating participants' self-rating of voice (poor, fair, good, very good, excellent) with change in V-RQOL score to determine how much change in V-RQOL would typically correspond with a single level of categorical improvement (fair to good, good to very good, etc.). In the current study, 82% of Group 1 participants, 100% of Group 2 participants, and 90% of Group 3 participants achieved at least a 25 point gain in their total V-RQOL standard score following BTX-A injection. Certainly these percentages reveal a trend toward higher V-RQOL standard scores among those participants who received therapy of some kind with highest frequency of clinically significant gains observed within Group 2. From a statistical standpoint, we cannot determine definitively that participants who received therapy felt better about their voices, but data trends would seem to suggest that is the case.

The current study confirms the utility of the V-RQOL as a measure of patient perceptions both before and following BTX-A injection, and during the inter-injection interval as the voice improves, then gradually worsens. This finding should add to existing evidence supporting the usefulness of the V-RQOL when examining this patient population for the determination of treatment outcomes.

Acoustic Measures

The challenge of describing voice quality acoustically is a considerable one. This holds true for normal voices, let alone voices that are exceptionally abnormal, as is the case with ADSD. Acoustic measures of fundamental frequency, variability in fundamental frequency, jitter, shimmer, voice onset time, voice breaks, noise to harmonic ratio, signal to noise ratio, tremor, and other measures have been used to characterize abnormal phonation, with varying success. This study chose to view the voice signals that were gathered in terms of a simple dichotomy. That is, within the voice signal as a whole, there are signals that are desirable and contribute to a perceptually "normal" sounding voice. There are also signals which are undesirable and increase our perception of "abnormal" voicing. No voice is perfect, so the distinction between "normal" and "abnormal" likely exists as some sort of ratio of desirable to undesirable signals, combined with listener expectations and preferences. A summary statement published by the National Center for Voice and Speech (Titze, 1994) has established an acoustic classification scheme which focuses on the dynamic vibratory behavior of voice signals and the ways in which the vibratory behavior changes, or bifurcates, over time. This scheme classifies voice signals as Type 1 (periodic), Type 2 (subharmonic), or Type 3 (aperiodic). In the current investigation, Type 1 signals were the sole "desirable" signal, representing maximum periodicity. As this periodicity decreases, Type 2 and 3 signals emerge. These were two of the three "undesirable" signals measured in this study, as they represented a departure from periodic vibration. The final "undesirable" signal is not a signal actually, but rather the unexpected and unexplained (by linguistic considerations) absence of voicing where voicing would have otherwise occurred.

This study examined sustained phonation (/a/) and connected speech (selected words from the Rainbow Passage) samples separately, and task did appear to play somewhat of a role in

terms of variable expression of acoustic events. Type 1, periodic signals were relatively more frequent during sustained phonation than connected speech, as were voice breaks. Type 3, aperiodic, signals were more prevalent during connected speech tasks and Type 2, subharmonic, signals emerged with roughly the same frequency during sustained phonation and connected speech. These results seem to support earlier findings that the symptoms of ADSD emerge as more severe during connected speech (as opposed to sustained vowel) tasks (Roy et al., 2005).

Voice breaks are frequently used to describe the voices of individuals with ADSD and emerge, perceptually, as a primary feature of the disorder. This study revealed voice breaks to occur with the least frequency of all the undesirable signal types, a finding that is in agreement with prior investigations (Cimino-Knight & Sapienza, 2001; Sapienza et al., 1998; Sapienza et al., 2002). The preeminent undesirable signals, within both sustained phonation and connected speech productions, were Type 3 (aperiodic). This finding also stands in agreement with prior investigations (Cimino-Knight & Sapienza, 2001; Edgar et al., 2001; Sapienza et al., 1998; Sapienza, Walton, & Murry, 1999; Sapienza, Cannito, Murry, Branski, & Woodson, 2002). Type 2 signals were observed to occur less frequently than Type 3, and more frequently than voice breaks.

Voice breaks, a comparatively rare acoustic event (especially with regard to aperiodicity), are still considered the hallmark characteristic of ADSD. More research is needed as to why this perceptual phenomenon exists. Voice stoppages and periodic voicing exist at opposite ends of the acoustic continuum. Perhaps this exists as a sort of auditory contrast effect where perception of voice breaks is enhanced by voicing which both proceeds and follows the stoppages.

BTX-A injections significantly increased the relative percentage of desirable / Type 1 signals while significantly decreasing undesirable signals during voicing, thereby increasing the

ratio of desirable to undesirable signals. In terms of individual signal types, BTX-A had significant beneficial effects on each of the undesirable signals during sustained phonation. During connected speech productions, Type 2 signals were not significantly decreased. The method of signal typing used in this investigation classifies voice signals along a continuum, from most, to least periodic (Figure 4-1).

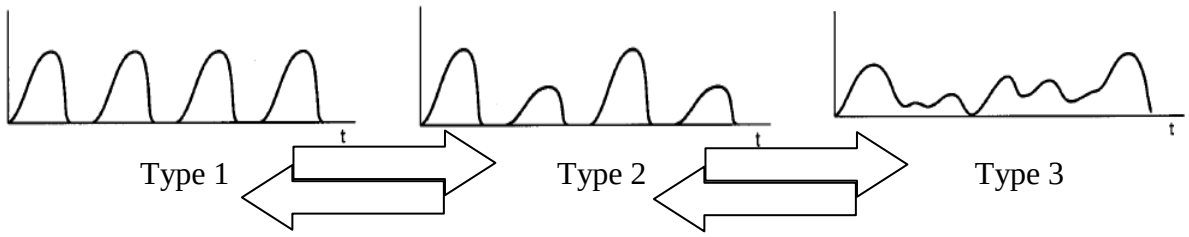

Figure 4-1. Periodicity continuum in signal typing.

It is possible that, as the vibratory behavior of the vocal folds in normalized following injection, some portion of those signals which were aperiodic (Type 3) at baseline stabilize somwhat, though never reaching regular periodicity. Because of this, when the voice signal is reassessed following injection, the total percentage of Type 2 signals may include signals that remain disordered as well as those that are disordered, but improved, from baseline. The Type 2 signal may represent a midpoint of sorts, making it less distinct measure when conducting acoustic outcomes research.

Strengths of the Present Study

Emphasis on Quality of Life Variables

A core strength of the present study was the inclusion of voice-related quality of life as the main dependent variable of interest. The World Health Organization (1948) has characterized quality of life as "...a state of complete physical, mental, and social well-being, and not merely

the absence of disease." In the ensuing decades, quality of life emerged as a variable of increasing interest within healthcare outcomes literature, particularly for disorders which are deemed incurable or difficult to treat, or where treatment carries adverse side effects (Gotay & Moore, 1992). ADSD is considered “incurable” in that it is a neurogenic condition which generally must be managed from onset, over the course of a lifetime. For many individuals with ADSD, the disorder is difficult to treat, with high failure rates for both surgical, chemodenervation, and behavioral treatment approaches. In the case of BTX-A injections, treatment success following a single injection does not seem to be a guarantee of success following future injections, with high rates of intermittent failure. Treatment for ADSD, especially chemodenervation treatment, also carries adverse side effects. Specifically, airway incompetence which frequently leads to “over-breathiness” or increased risk of aspiration.

"Perception is reality" is a popular saying in the business world. Meaning, a customer's perception of the extent to which his needs were met is in fact the degree to which his needs were met, regardless of the opinion of other participants in the transaction. Similarly, a patient's perception of treatment benefit fluctuates relative to subjective and internal perceptions, directly accessible by the patient alone. As noted previously, we have begun to gather information correlating quantitative change on a quality of life battery to qualitative change in the way patients classify their voices. Measures of quality of life are a critical component when determining healthcare outcomes, and should be considered as important as measures of clinical status (biomedical outcomes), patient and customer satisfaction, and cost in determining treatment efficacy (McHorney & Rosenbek, 1998; Relman, 1988).

The V-RQOL appears to be as good as the VHI in detecting changes in patient perceptions following BTX-A injection and, with only 10 questions (compared with 30 on the VHI), may be

more clinically useful. One potential modification of the test would be reworking of question seven: "I have trouble doing my job or practicing my profession (because of my voice)." Many participants who were unemployed, disabled, or retired had some difficulty responding to this question. Shifting the focus of this question from workplace, to community, interaction may allow more comprehensive sampling within the population of interest.

Random Assignment to Treatment Groups

In the only other study of combined modality treatment of ADSD participants returned to clinic two to three weeks following BTX-A injection and were offered a course of voice therapy. Those who declined were assigned to the "BTX-A only" group and those who accepted were assigned to the voice therapy arm. Were the significant effects realized by the BTX-A plus voice therapy group a "true" effect of voice therapy, or rather a non-specific treatment effect brought about when individuals, motivated to engage in voice therapy, volunteered for and underwent voice therapy? At the outset, it seemed that this might be an interesting question and the current study sought to eliminate this potential selection bias in group assignment by randomly assigning participants to each of the three treatment arms based on a predetermined order. In order to accomplish this, each participant had to be willing, though not necessarily motivated, to participate in five sessions of therapy, voice or sham, if assigned.

The idea of random assignment is a central principle of the scientific method. Simply put, random assignment seeks to evenly distribute participant attributes between or among treatment groups. Perfectly executed, random assignment would render the treatment groups indistinguishable at baseline, allowing for greater certainty that any effects observed over the course of treatment were attributable to the treatment itself, rather than any attribute present, at baseline, within the participants. One such attribute might be motivation, or desire, to engage in behavioral therapy. Ideally, in the current study, random assignment produced similar levels of

motivation within each of the three treatment arms, combining individuals with low, moderate, and high motivation to engage in voice therapy into treatment groups of (assumed) average motivational levels. This is a true assumption since participant attitudes and opinions were never assessed beyond basic receptivity to the idea of therapy.

However *if* voice therapy works, the motivation of those who undergo therapy is likely an important part of *why* it works. It is reasonable to assume that those individuals who have belief in the potential benefits of voice therapy will be more attentive during therapy sessions, more compliant with home practice assignments, and more diligent in completing carryover of learned behaviors into functional contexts.

In theory, it is possible to classify any therapy or treatment, for any condition, in terms of what that treatment requires in patient involvement. At one extreme, you have therapies or treatments which require no compliance on the part of the patient in order to achieve a therapeutic objective. Vaccination is perhaps a good example of this. To some extent BTX-A injection applies as well, with the paralytic action of the toxin producing specific effects which, though temporary, are realized without patient involvement beyond seeking the treatment to begin with. The majority of therapies would fall somewhere in the middle of this continuum with medical and behavioral interventions combining to achieve a desired outcome. At the other extreme exist therapies that are completely patient-centered. An example could be weight loss achieved solely through diet and exercise.

Behavioral voice therapy exists on the patient-centered extreme end of the spectrum. Through explicit training, exhaustive repetition, and consistent carryover and practice, voice therapy is able to accomplish specific changes in vocal physiology. In a sense, voice therapy is the process of vocal habit formation – the replacement of one style of voicing with another.

Voice therapy can be used to treat a number of conditions and, and least in theory, can reduce or eliminate the primary symptoms of ADSD.

The most extreme example of this is inverse phonation, discussed briefly in Chapter 1, when patients are trained to speak on inhalation, thereby eliminating glottal adduction during speech tasks as well as the spasms that result from that adduction. The inverse phonation process must be learned, practiced to the level of mastery, and then consistently and constantly implemented in order to achieve symptom relief. This therapy fails because, for the vast majority of individuals, these conditions are too difficult to meet. Alternatively, the "new" style of voicing may be impractical for everyday use. An example of this might be training someone with ADSD to assume whispered speech. While whispered speech is effective at eliminating the symptoms of ADSD, certainly most individuals would find the "cure" for their disorder incompatible with the demands of their environment.

Finally, unlike MTD or dysphonia associated with vocal nodules or edema, the primary voice symptoms of ADSD are not brought about by the *style* of voicing, but rather by the act of voicing itself. For this reason, conventional voice therapy for individuals with ADSD takes place following injection. Patients are trained in the performance of specific voicing behaviors meant to enhance breath support and continuity for speech as well as minimize any adverse compensatory behaviors, either developed in response to the initial spasmodic symptoms or developed as means of compensating for over-breathiness post injection. As with any behavioral therapy, voice therapy requires the highest levels of involvement on the part of the patient. Voice therapy does not work *in spite of* patient motivation and involvement. When voice therapy works, if voice therapy works, it is *because of* patient motivation and involvement.

While random assignment to treatment groups was strength of this study, participant motivation was not specifically addressed as criteria for inclusion.

Inclusion of Behavioral Placebo

The term "placebo" denotes non-specific treatment effects, not attributable to the primary (therapeutic) agent of interest. Here, the therapeutic agent of interest was voice therapy. A prior investigation compared individuals who received voice therapy plus BTX-A injections with those who received BTX-A alone revealed significant benefits in durational, aerodynamic, and acoustic measures for those participants who received voice therapy following injection compared to those who had received injection alone (Murry & Woodson, 1995). This led the authors to "recommend voice therapy as part of the treatment of ADSD in patients who show reduced voice breaks but who exhibit vocal hyperfunction after Botox injection." (Murry & Woodson, 1995, pg. 465) Within the field of communication disorders, this was considered a hallmark study and one of the first studies to directly address treatment efficacy within both the field of speech-language pathology and the subspecialty of voice disorders. The results of this study seemed to lend empirical weight to what many clinicians had felt for years: that voice therapy really did make a difference for individuals with ADSD. Rather than drawing this conclusion themselves, Murry and Woodson (1995) were the first to emphasize the need for continued study of the "relationship between SD variables and voice therapy" (pg. 465).

Voice therapy is, at its heart, an interaction. This interaction occurs between clinician and patient and encompasses the production of discreet, specific behaviors relating to breathing, phonation, resonance, and articulation. It is "physical therapy," though restricted to those areas of the human body directly involved in the production of voice.

Because behavioral placebos are difficult to design and carry out, they are seldom used in research. Unlike pharmacological ("sugar pill") or device placebos where the placebo is designed

primarily to physically resemble the active medicine or device, a behavioral placebo must mimic the duration and quality of a behavioral interaction between clinician and patient, all the while with no therapeutic targeting of relevant behaviors. Participants in the placebo arm of the current study were given the same speech stimuli and carryover material as those in the voice therapy group but were only instructed to perform the speech tasks, then rate the quality of the performance. At no time were they given instruction or feedback as to how to perform the various speech tasks. Dummy expiratory muscle strength trainers were also included as part of the placebo treatment in order to increase the amount of time spent in therapy and home practice sessions to approximate that of the voice therapy arm.

Because participants were randomly assigned to the sham voice therapy arm, we can assume they possessed similar, moderate, levels of desire or motivation for improvement as those individuals in the BTX-A plus voice therapy group, or the BTX-A only group. (Again, we have no way of verifying this assumption and, as previously discussed, the usefulness of this control is subject to question.) In the current investigation the BTX-A plus sham therapy group performed no differently than the BTX-A plus voice therapy, or the BTX-A only group, on most of the dependent variables of interest. Continued use of placebo treatments in the context of behavioral research is a potentially powerful tool for uncovering specific *aspects* of behavioral therapy, beyond those attributable to mere interaction, are able to achieve desired therapeutic outcomes.

Limitations of the Present Study

Sample Size

ADSD is a rare disorder. As with all rare disorders, investigators are limited to examining the study population available to them given time and resource constraints. The current investigation spanned 60 months and five study centers. Unlike prior studies, only individuals

with no prior history of BTX-A injection were considered for inclusion. This criteria was included in order to limit the potential effects of participant expectations. Additionally, only individuals who were willing to participate in behavioral therapies (whether active or sham) were included. These inclusion criteria served to drastically limit the number of potential participants from the population of individuals with ADSD as a whole. This, coupled with the high power demands of a parallel arm design, limited the ability of this investigation to reveal treatment effects, should they exist.

Variability in Presentation at Baseline

Participants were randomly assigned to experimental groups in an effort to normalize the groups with regard to average severity of symptoms, as well as range of severity levels. This point relates to the preceding discussion of sample size in that, even given random assignment, the groups appeared very different at baseline in many respects. ADSD is highly variable in its presentation. For example, Group 2 included one participant who, at baseline, produced voice samples that were composed of anywhere from 72% (during connected speech) to 92% (during "ah") Type 1, periodic signals. This participant displaced moderate (8-28%) aperiodicity, trace (0.2-1%) percentages of signals with subharmonic frequencies, and no voice breaks. Contrast this individual with another participant from Group 2 whose voice consisted of anywhere from 28% (connected speech) to 65% ("ah") voice breaks, or another whose voice consisted almost entirely of Type 3, aperiodic signals.

Variability in participant motivation likely played a role as well. In clinical settings, individuals who are unmotivated to participate in voice therapy never start, miss appointments, or are non compliant with therapy protocols. One can assume that, in the context of research, participants with low levels of motivation behave in much the same way, though data obtained

from these participants is then collected and used to draw conclusions regarding treatment efficacy.

During the data analysis phase, baseline variability was addressed by incorporating initial group differences as part of the longitudinal model. Subsequent tests of differences in groups over time allowed for initial group differences. Had this investigation been able to recruit and run a greater number of participants, baseline variability would have likely been lessened, allowing for more accurate analysis of group differences following treatment. While simply running more participants may improve baseline variability in terms of acoustic and psychometric variables, it may not be as effective an approach to dealing with variability of motivation as it would most likely serve to further bring the motivation levels of the study population into moderate ranges.

Selection Bias

In order to participate in the current study, participants had to be willing to participate in five sessions of therapy, voice or sham, if assigned to Groups 2 or 3. This criteria, meant to eliminate selection bias observed when participants are allowed to volunteer for therapy, actually creates a selection bias in that those individuals enrolled have to be at least minimally receptive to the idea of voice therapy. Eliminating this bias, as discussed previously, may not make good clinical sense and future studies may wish to control for selection bias through a priori assessment of participant motivation levels, then enrolling only those who are ideally suited (that is, highly motivated) to engage in therapy.

Because participants, in many cases, were required to travel to receive the voice and sham therapy, the study design also creates a selection bias in favor of participants with the means and ability to travel and devote necessary time for therapy once per week for five weeks. This study had limited ability to accommodate individuals with inflexible work or other life demands. Though a problem, this factor is by no means specific to this research study and, as such, may

not be critically important to control for in future investigations. Work and lifestyle demands interfere in the clinical setting just as they do in the research setting, perhaps neutralizing this bias a bit.

This was not the case when considering participant compensation as a potential biasing factor. Because participants were compensated for their time, voice improvement was not the sole motivator for participation the way it would be in the clinical setting. Ideally, the intrinsic motivator of vocal improvement would stand as the preeminent motivator for research participation. Inclusion of only highly motivated individuals in future investigations would eliminate this potential bias of desire for monetary gain – a motivator present in research, but rarely in clinical, realms.

Compliance

There are no assurances that participants assigned to voice therapy (or sham voice therapy) were compliant with the assigned home practice tasks beyond what was self-reported to the treating clinician. Regular and repeated practice are core tenants of traditional voice therapy which seeks to replace maladaptive with "healthier" voicing behaviors through processes of behavioral modification. The inability to monitor compliance with home practice, as well as questions regarding how much practice is enough, complicates our examination of behavioral protocols. This challenge is as true in routine clinical practice as it is in research.

Verdolini (1986) has addressed the issue of compliance in voice disorders by combining compliance-related research from a variety of disciplines to create a set of rules for maximizing compliance in voice disorders. These rules include an emphasis on patient-centered interactions, comprehensive evaluation of how severe the patient perceives her voice disorder to be as well as her expectations for improvement through voice therapy. Therapeutic activities should be designed so as to meet those expectations with clear instructions as to how to achieve target

behaviors and then generalize those behaviors to everyday voicing. Verdolini also emphasizes the importance of subjective perceptions of *warmth* and *understanding* in patient-practitioner interactions as well as varying patient preferences for high or low levels of involvement in their own care.

The treatment protocols in the current study were designed to feature simple instructions, straightforward behavioral targets (whether active or sham), and clear progression from basic to more complex carryover tasks. These considerations should serve to increase the likelihood of participant compliance however additional, and perhaps more critical, rules dealing with interaction between therapist and patient are impossible to script and therefore impossible to control systematically across study sites, or even across patients. Controlling for participant motivation may go some length to assuring uniform levels of higher compliance across treatment arms.

This study did not assess Group 2 and 3 participants' confidence in the voice therapy and sham voice therapy protocols. It is possible that compliance was affected by participant non-belief in the therapeutic value of these interactions. The sham therapy protocol, in particular, was designed to appear convincing on the surface, but with no real therapeutic targeting of voice behaviors. Informed consent practices mandate that all potential participants be informed of the presence of a sham group, as well as the likelihood that they will be assigned to that group. It is possible that participants in Group 3, not "fooled" by the sham therapy protocol, perceived their therapy to be of less value and were therefore less compliant. It is also possible that the design of the voice therapy protocol was not engaging to participants, causing participants to become bored or less motivated, and therefore less compliant. Future investigations may wish to employ

repeated assessments of participants' confidence in the therapy protocols being studied as an indirect measure of participant compliance.

Design of Behavioral Placebo

Ideally, a placebo treatment should mirror the active treatment in every regard with the exception of the hypothetical "active" component being studied. The classic example of this is one of the "sugar pill", identical in shape, weight, taste, touch, color, and every other sensory variable to the real pill being studied. The current study tried to mimic the voice therapy process as closely as possible in terms of frequency and duration of patient-therapist interaction, number of activities, and practice time. Still, the active and sham voice therapies were not perfect mirrors of each other. The primary example of this is inclusion of sham expiratory muscle strength training (EMST) devices within the sham, and not voice therapy, treatment arms. Past investigations have demonstrated enhanced effects on measures of vocal effort, vocal handicap, as well as acoustic and aerodynamic variables when EMST devices are used in conjunction with traditional voice therapy approaches (Wingate, Brown, Shrivastav, Davenport, & Sapienza, 2006). The devices used in the current study were sham trainers and measures of respiratory muscle strength were not collected. However, the possibility of a non-specific treatment effect brought about through use of a sham EMST device cannot be completely ruled out.

Scripting of Therapy Sessions

The voice therapy protocol for this study was scripted. Research clinicians were therefore limited in their ability to configure the voice therapy to the specific needs of individual participants. It is possible that some participants would have benefited from additional practice or from therapeutic techniques not included within the standardized program.

Control over Reinjection

As mentioned previously, participants had only limited control over when they were reinjected, thereby rendering the duration measure less meaningful. Because BTX-A administration was not a direct component of the current investigation, we were limited by the clinical schedules of the individual study sites and were unable to assess duration of treatment benefit in a meaningful manner. Rather than examining the duration of time between injection, future investigations may seen to examine the time between injection and maximum treatment benefit (as determined by participant self-assessment), as well as the time between maximum benefit and return to baseline (or near baseline) status (as determined by participant self-assessment).

Future Studies

The V-RQOL is recommended for use in future studies due to its ability to characterize patient perceptions of both the immediate improvement, improvement over time, and decline over time, in voice-related quality of life following BTX-A injection. The measure is brief, consisting of only 10 questions, and easily administered by clinicians or patients themselves.

The process of acoustic signal typing is a straightforward and useful means of characterizing voice samples and, as such, is recommended for future investigations. Traditional, automated, acoustic measures require a certain degree of consistency in vibratory frequency and amplitude in order produce a quantitative result, whether it be fundamental frequency, jitter, shimmer, noise to harmonic ratio, or any number of other variables. While this process is relatively easy to complete on regular and periodic patterns of voicing, the inherently irregular and highly variable voicing of individuals with ADSD is not so readily quantified. The process of signal typing approaches voice analysis from a qualitative perspective, describing segments of voicing based on the extent to which they adhere to regular and predictable patterns of vibration.

This study marks the first time signal typing analysis has been applied to ADSD. Data obtained will be useful in completing power analyses for future investigations which use signal typing variables as acoustic measures of interest.

Because ADSD is a voice disorder of highly variable presentation, and given the difficulty in recruitment of sufficiently large numbers of participants to balance this variability, future studies may wish to introduce a priori limitations on variability. That is, establishing severity ranges for variables of interest, thereby increasing the homogeneity of the population studied at baseline. Overall severity can perhaps be determined via perceptual measures of voice status such as the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V; ASHA, 2002).

Voice therapy is a form of behavioral therapy and, as such, is completely patient-centered and performance driven. Only those individuals who are suitably motivated to meet the high performance demands of behavioral therapy are likely to benefit from voice therapy. Rather than neutralizing levels of desire and motivation across treatment groups, future investigations should seek to quantify aspects of participant motivation so that only those individuals willing and able to complete the therapies as intended are included in investigations of the efficacy of these therapies.

Continued treatment efficacy research is needed in the field of communication disorders and each of its subspecialties, including voice disorders. Future studies should seek to apply basic tenants of the scientific method to research where reasonable, including use of random assignment, placebo controls, and blinded measurement of outcome variables. This study should not be read as “evidence” of the ineffectiveness of voice therapy in the treatment of ADSD any more than prior studies, or anecdotal reports, should be considered “proof” of the beneficial effects of voice therapy. Perception may be reality, but it is also patient-specific. Clinician and

participant treatment logs obtained during the course of this investigation revealed participants in each of the two treatment groups who "believed" in the real and substantial benefits they were receiving as a result of their therapy. Motivational factors do not confound treatment efficacy research, but rather stand at its very core. At the present time, there is no "instant cure" for ADSD, although BTX-A injections certainly require minimal to no patient motivation beyond seeking reinjection. Can behavioral voice therapy, a patient driven process, enhance the effects of BTX-A, a treatment which requires minimal patient involvement? The findings of the current study would seem to disagree with the prior investigation of combined modality treatment of ADSD in that no clear group effects emerged with regard to acoustic and quality of life variables. Modifying inclusion criteria to better identify individuals who desire, and are motivated to assume, an active role in the treatment of their condition should increase assurances of compliance with therapy protocols. Better selection of candidates for behavioral therapy, along with continued development of motivating and engaging (and efficacious) treatment protocols can only serve to enhance public perception of voice therapy as a discipline. Research rarely reaches a stopping point, and the challenge of verifying treatment efficacy – no matter the treatment – is an ongoing one.

APPENDIX A
MEDICAL QUESTIONNAIRE

Participant DOB: _____ / _____ / _____ Age: _____
Diagnosis of ADSD? □ Yes □ No By whom: _____
Symptom duration: _____
Are you electing Botox for treatment of ADSD? □ Yes □ No
Have you had prior Botox treatment? □ Yes □ No
Any previous treatment for ADSD? □ Yes □ No
Any history of other voice or speech disorder? □ Yes □ No
Any history of other movement disorder or dystonia? □ Yes □ No

Have you ever been seen by a doctor for:

Pneumonia? □ Yes □ No
Frequent colds? □ Yes □ No
Other respiratory difficulties? □ Yes □ No
Heart problems? □ Yes □ No
Learning disability? □ Yes □ No
Allergies or asthma? □ Yes □ No
Recurrent ear infections? □ Yes □ No
Neurological disorder? □ Yes □ No
Gastroesophageal reflux disease (GERD)? □ Yes □ No
Hiatal hernia? □ Yes □ No
Do you currently have a cold, the flu, or allergies? □ Yes □ No

What are your current medications?

Are you a trained singer? □ Yes □ No
If you participate in this study, you may be expected to complete a series of exercises on your own time. These exercises should take no longer than 15 – 20 minutes to complete per session. Do you consider yourself good at following through on responsibilities or assignments? □ Yes □ No

Do you have a history of surgery to the head, neck, or respiratory system? If so, when and what?

Have you ever smoked? □ Yes □ No
Do you presently smoke? □ Yes □ No
If no, when did you quit?
If you smoke, how long have you smoked and how much do you smoke?
How much caffeine do you drink per day?
Are you post menopausal? If so, are you on hormone replacement therapy (HRT)?
Is English your first language?
What language is spoken in your home?

APPENDIX B
VOICE-RELATED QUALITY OF LIFE (V-RQOL) MEASURE

We are trying to learn more about how a voice problem can interfere with your day-to-day activities. On this paper, you will find a list of possible voice-related problems. Please answer all questions based upon what you voice has been like over the past two 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 that you have). Use the following scale for rating the amount of the problem:

1 = None, not a problem
2 = A small problem
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

Scoring Algorithm:

Social emotional (SE) domain (items 4, 5, 8, and 10):

$$100 - (\text{Raw score} - 4)/16 * 100$$

Physical (P) domain (items 1, 2, 3, 6, 7, and 9):

$$100 - (\text{Raw score} - 6)/24 * 100$$

Total (T) score:

$$100 - (\text{Raw score} - 10)/40 * 100$$

APPENDIX C
VOICE THERAPY (GROUP 2) AND SHAM VOICE THERAPY (GROUP 3) PROTOCOLS

GROUP 2 VOICE THERAPY: WARM UP & LESSON 1

VOCAL JOURNAL – Keep a journal, as formal or as informal as you wish – dealing with your voice on a daily basis. You may write anything that you wish however pay attention to specific times or places where your voice improves (or worsens). Have you noticed any effects on your voice relating to diet, time of day, etc.?

VOICE FUNCTION –

There are four main components to the production of voice:

- Respiration
- Phonation
- Resonance
- Articulation

Voice therapy (even after Botox injection) may help people with spasmodic dysphonia by:

- Helping to eliminate *hyperfunction*, or "overuse" of muscles associated with voicing. This overuse frequently develops over months, years, or even decades as an individual with ADSD struggles to make his or her voice "work."
- Teaching a new way of voicing which, along with Botox, prevents the vocal folds from contacting each other in a "hard" way. The more the vocal folds are pressed together, the sooner the spasms are likely to return.

WARM UP – Loosen your body

(1) Shoulders
   a. Back strokes while yawning (X 10)
   b. Forward strokes while yawning (X 10)
   c. Roll shoulders back (X 5)
   d. Roll shoulders forward (X 5)
   e. Raise shoulders to ears and drop (X 2)
   f. Swing elbows up to your ears and drop (X 5)
   g. Touch elbows in front, then open up wide (X 5)

(2) Neck
   a. Left ear to left shoulder, hold for 10 seconds
   b. Right ear to right shoulder, hold for 10 seconds
   c. Drop head forward, letting gravity pull your head down, hold for 10 seconds

(3) Jaw – massage your jaw with downward strokes, let your jaw drop (X 5)

(4) Tongue
   a. Stretch! Stick your tongue out as far as you can, hold for 10 seconds
   b. Tongue rolls (X 3)
   c. Open relaxed "laaaaaaa" on a sigh. Release your tongue and jaw. Once you've mastered that, try it on these words:

   LAA, LOT, LAWN, LOCK, LOP, LOB, LAW

(5) Lips – Do lip rolls (X 3)
(6) Throat – Do a yawn sign (X 5)

LARYNGEAL MASSAGE – Therapist will do. Therapist will provide you with an "at home" version of this massage that you can practice.

LESSON 1

After you have warmed up, say the following sounds at a very high pitch, in falsetto. Let your voice fall a little at the end:

(1) Huuu . . . huuu. . . huuu . . . (repeat 5 times)
(2) Hooo . . . hooo. . . hooo . . . (repeat 5 times)
(3) Heee . . . heee . . . heee . . . (repeat 5 times)
(4) Haaa . . . haaa . . . haaa . . . (repeat 5 times)

Say the following sounds, gliding from a very high (falsetto) pitch, to a lower pitch. While lowering your voice, still try and "feel" the falsetto:

(1) Huuuuuuuuuuuuuuuuuuuuuuuuu . . . (repeat 5 times)
(2) Hoooooooooooooooooooooooo , , , (repeat 5 times)
(3) Heeeeeeeeeeeeeeeeeeeeeeeeeee . . . (repeat 5 times)
(4) Haaaaaaaaaaaaaaaaaaaaaaaaaa . . . (repeat 5 times)

This exercise is the same as the previous exercise, but with some words added at the end:

(1) Huuuuuuuuuuuuuuuuuuuuu . . . one two three
(2) Hoooooooooooooooooooo . . . one two three
(3) Heeeeeeeeeeeeeeeeeeeeeee . . . one two three
(4) Haaaaaaaaaaaaaaaaaaaaaa . . . one two three

Repeat the above, starting at a slightly lower pitch:

(1) Huuuuuuuuuuuuuuuuuuuuu . . . one two three
(2) Hoooooooooooooooooooo . . . one two three
(3) Heeeeeeeeeeeeeeeeeeeeeee . . . one two three
(4) Haaaaaaaaaaaaaaaaaaaaaa . . . one two three

Repeat one last time, again at a slightly lower pitch:

(1) Huuuuuuuuuuuuuuuuuuuuu . . . one two three
(2) Hoooooooooooooooooooo . . . one two three
(3) Heeeeeeeeeeeeeeeeeeeeeee . . . one two three
(4) Haaaaaaaaaaaaaaaaaaaaaa . . . one two three

Now, keeping that relaxed and open feel, practice humming on a "mmm" sound:

(1) Mmmmmmmmmmmmm . . . . ma ma ma ma ma ma ma . . .
(2) Mmmmmmmmmmmmm. . . . may may may may may may . . .
(3) Mmmmmmmmmmmmm . . . . me me me me me me me me . . .
(4) Mmmmmmmmmmmmm . . . . moh moh moh moh moh moh , , ,
(5) Mmmmmmmmmmmmm . . . . moo moo moo moo moo moo . . . .

Do you feel a "buzzing" toward the front of your face? Check yourself – the vibrations should stop completely when you plug your nose and waver when you "wiggle" your lips.

Now you can put the easy onset and the hum together. Try these words:

HIM	HOME	HORN	HONE
HAM	HAND	HUME	HARM
HELM	HIM		

GROUP 2 LESSON 1 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS .	MINS .	MINS .	MINS .	MINS .	MINS .	MINS .	MINS .	MINS .

Daily practice:

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Say the following sounds, gliding from a very high (falsetto) pitch, to a lower pitch. While lowering your voice, still try and "feel" the falsetto:

(1) Huuuuuuuuuuuuuuuuuuuuuuuuuu . . . (repeat 5 times)
(2) Hoooooooooooooooooooooooo , , , (repeat 5 times)
(3) Heeeeeeeeeeeeeeeeeeeeeeeeeee . . . (repeat 5 times)
(4) Haaaaaaaaaaaaaaaaaaaaaaaaaa . . . (repeat 5 times)
(5) (Repeat the above starting at a medium pitch)
(6) (Repeat the above starting at a lower pitch)

Repeat exercise #2, but this time add some words at the end. Keep your voice open and relaxed and try and "feel" the falsetto, even as you lower your pitch:

(1) Huuuuuuuuuuuuuuuuuuuuuuuuuu . . . one two three
(2) Hoooooooooooooooooooooo . . . one two three
(3) Heeeeeeeeeeeeeeeeeeeeeeeeee . . . one two three
(4) Haaaaaaaaaaaaaaaaaaaaaaaaa . . . one two three

Hum (repeat 5 times)

Yawn sigh single words ending in a hum:

HIM	HOME	HORN	HONE
HAM	HAND	HUME	HARM
HELM	HIM		

GROUP 2 VOICE THERAPY: WARM UP & LESSON 2

QUESTIONS / COMMENTS FROM VOCAL JOURNAL

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – massage your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Stretch! Stick your tongue out as far as you can, hold for 10 seconds
    b. Tongue rolls (X 3)
    c. Open relaxed "laaaaaaa" on a sigh. Release your tongue and jaw. Once you've mastered that, try it on these words:

LAA	LOT
LAWN	LOCK
LOP	LOB
LAW	

(5) Lips – Do lip rolls (X 3)
(6) Throat – Do a yawn sign (X 5)

LARYNGEAL MASSAGE - Therapist will do.

LESSON 2

Yawn sigh on "ah" (X5):

Yawn sigh single words:

HOT	HOME	HIT	WHOSE
HAT	HE'S	HART	HERB
HOP	HEDGE	HACK	HELEN

HOLE	HIKE	HATE	HIVE
HEART	HOE	HAWK	HILL
HIP	HIS	HAIR	HABIT
HORN	HIGH	HOPE	HOWL
HALE	HER	HALL	HER
HEIGHT	HUT		

Yawn sigh contrast pairs:

WHOSE	OOZE	HOWL	OWL
HALL	ALL	HERE	EAR
HATE	ATE	HER	ER
HALE	ALE	HERB (name)	HERB (plant)
HE'S	EASE	HIGH	EYE
HEDGE	EDGE	HOW	OW
HELEN	ELLEN	HABIT	ABBOT
HIKE	IKE	HAS	AS
HIVE	I'VE	HIS	IS
HOE	OH	HILL	ILL

Repeat:

(1) How are you?
(2) How dare you!
(3) He's back!
(4) Hole in one
(5) Homespun
(6) Hemingway
(7) Happy Birthday!
(8) How is he?
(9) How many are there?

Start with a big yawn before each phrase. Feel the falsetto voice:

(1) Huuuu . . . 1- 2- 3- 4- 5
(2) Huuuu . . . 6- 7- 8- 9- 10
(3) Huuuu . . . Monday – Tuesday – Wednesday
(4) Huuuu . . . Thursday – Friday – Saturday – Sunday
(5) Huuuu . . . January – February – March – April
(6) Huuuu . . . May – June – July – August – September
(7) Huuuu . . . October – November – December – January
(8) Huuuu . . . Who is that?
(9) Huuuu . . . Who are they?
(10) Huuuu . . . Who is she?
(11) Huuuu . . . Who is coming?
(12) Huuuu . . . Who has some?
(13) Huuuu . . . Who is he?
(14) Huuuu . . . Who is there?
(15) Huuuu . . . Who am I?

Start with another big yawn before each phrase:

(1) Ha – 1- 2- 3- 4- 5
(2) Ha – 6- 7- 8- 9- 10
(3) Ha – Monday – Tuesday – Wednesday
(4) Ha – Thursday – Friday – Saturday – Sunday
(5) Ha – January – February – March – April
(6) Ha – May – June – July – August – September
(7) Ha –October – November – December – January
(8) Ha – How are you?
(9) Ha – How old are you?
(10) Ha – What time is it?
(11) Ha – Where are you?
(12) Ha – Happy Birthday!
(13) Ha – How is he?
(14) Ha – How many are there?

Start these with a big yawn and a falsetto voice:

(1) 1 – 2 – 3 – 4 – 5
(2) 6 – 7 – 8 – 9 – 10
(3) Monday – Tuesday - Wednesday
(4) Thursday – Friday – Saturday – Sunday
(5) January – February – March – April
(6) May – June – July – August – September
(7) October – November – December – January
(8) Who is that?
(9) Who is she?

(10) Who is coming?
(11) Who has some?
(12) Who is he?
(13) Who is there?
(14) Who am I?

GROUP 2 LESSON 2 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

[Review this sheet from last week – clear up any confusion on the part of the participant. Emphasize total practice time daily of no more than 10 to 15 minutes. Stress the importance of honest reporting of practice times and frequencies.]

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

Daily practice:

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Yawn sigh single words ending in a hum:

HIM	HOME	HORN	HONE
HAM	HAND	HUME	HARM
HELM	HIM		

Yawn sigh contrast pairs – focus on an easy onset on the second word within the pair:

WHOSE	OOZE	HOWL	OWL
HALL	ALL	HERE	EAR
HATE	ATE	HER	ER
HALE	ALE	HERB (name)	HERB (plant)
HE'S	EASE	HIGH	EYE
HEDGE	EDGE	HOW	OW
HELEN	ELLEN	HABIT	ABBOT

HIKE	IKE	HAS	AS
HIVE	I’VE	HIS	IS
HOE	OH	HILL	ILL

Yawn sigh short phrases:

How are you?	How dare you!	He’s back!
Hole in one	Homespun	Hemingway
Happy Birthday!	How is he?	How many are there?
Who is she?	Who is coming?	Who has some?
Who is he?	Who is there?	Who am I?

GROUP 2 VOICE THERAPY: WARM UP & LESSON 3

WARM UP – Loosen your body

(1) Shoulders
   a. Back strokes while yawning (X 10)
   b. Forward strokes while yawning (X 10)
   c. Roll shoulders back (X 5)
   d. Roll shoulders forward (X 5)
   e. Raise shoulders to ears and drop (X 2)
   f. Swing elbows up to your ears and drop (X 5)
   g. Touch elbows in front, then open up wide (X 5)

(2) Neck
   a. Left ear to left shoulder, hold for 10 seconds
   b. Right ear to right shoulder, hold for 10 seconds
   c. Drop head forward, letting gravity pull your head down, hold for 10 seconds

(3) Jaw – massage your jaw with downward strokes, let your jaw drop (X 5)

(4) Tongue
   a. Stretch! Stick your tongue out as far as you can, hold for 10 seconds
   b. Tongue rolls (X 3)
   c. Open relaxed "laaaaaaa" on a sigh. Release your tongue and jaw. Once you've mastered that, try it on these words:

LAA	LOT
LAWN	LOCK
LOP	LOB
LAW	

(5) Lips – Do lip rolls X 3

(6) Throat – Do a yawn sign X5

LARYNGEAL MASSAGE – Therapist will do.

LESSON 3

Yawn sigh on "ah" (X5)

Yawn sigh single words:

HOT	HOME	HIT	WHOSE
HAT	HE'S	HART	HERB
HOP	HEDGE	HACK	HELEN
HOLE	HIKE	HATE	HIVE

HEART	HOE	HAWK	HILL
HIP	HIS	HAIR	HABIT
HORN	HIGH	HOPE	HOWL
HALE	HERE	HALL	HER
HEIGHT	HUT		

Yawn sigh contrast pairs:

WHOSE	OOZE	HOWL	OWL
HALL	ALL	HERE	EAR
HATE	ATE	HER	ER
HALE	ALE	HERB (name)	HERB (plant)
HE’S	EASE	HIGH	EYE
HEDGE	EDGE	HOW	OW
HELEN	ELLEN	HABIT	ABBOT
HIKE	IKE	HAS	AS
HIVE	I’VE	HIS	IS

Yawn sigh phrases:

How are you?	Hi honey!	How dare you!
Horseshoe	How’re things?	High time
He’s back!	Half time	Hand-me-downs
Hello!	Home stretch	Happy days
Here I am!	Have one	Have a mint
Home spun	Hole-in-one	Hail Mary!
Help me!	Hemingway	Hollywood

Carryover – phrases / sentences of increasing length. Using all that you've learned, concentrate on keeping your voice smooth and resonant while speaking these phrases of increasing length.

GROUP 2 LESSON 3 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

Daily practice:

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Yawn sigh contrast pairs – focus on an easy onset on the second word within the pair:

WHOSE	OOZE	HOWL	OWL
HALL	ALL	HERE	EAR
HATE	ATE	HER	ER
HALE	ALE	HERB (name)	HERB (plant)
HIVE	I'VE	HIS	IS
HOE	OH	HILL	ILL

Yawn sigh short phrases:

How are you?	How dare you!	He's back!
Hole in one	Homespun	Hemingway
Happy Birthday!	How is he?	How many are there?
Who is she?	Who is coming?	Who has some?
Who is he?	Who is there?	Who am I?

Carryover phrases of increasing length:

GROUP 2 VOICE THERAPY: WARM UP & LESSON 4

WARM UP – Loosen your body

(1) Shoulders
   a. Back strokes while yawning (X 10)
   b. Forward strokes while yawning (X 10)
   c. Roll shoulders back (X 5)
   d. Roll shoulders forward (X 5)
   e. Raise shoulders to ears and drop (X 2)
   f. Swing elbows up to your ears and drop (X 5)
   g. Touch elbows in front, then open up wide (X 5)

(2) Neck
   a. Left ear to left shoulder, hold for 10 seconds
   b. Right ear to right shoulder, hold for 10 seconds
   c. Drop head forward, letting gravity pull your head down, hold for 10 seconds

(3) Jaw – massage your jaw with downward strokes, let your jaw drop (X 5)

(4) Tongue
   a. Stretch! Stick your tongue out as far as you can, hold for 10 seconds
   b. Tongue rolls (X 3)
   c. Open relaxed "laaaaaaa" on a sigh. Release your tongue and jaw. Once you've mastered that, try it on these words:

LAA	LOT
LAWN	LOCK
LOP	LOB
LAW	

(5) Lips – Do lip rolls X 3

(6) Throat – Do a yawn sign X5

LARYNGEAL MASSAGE – Therapist will do.

LESSON 4

Yawn sigh on "ah" (X5)

Yawn sigh single words:

HOT	HOME	HIT	WHOSE
HAT	HE'S	HART	HERB
HOP	HEDGE	HACK	HELEN
HOLE	HIKE	HATE	HIVE

Yawn sigh phrases:

How are you?	Hi honey!	How dare you!
Horseshoe	How’re things?	High time
He’s back!	Half time	Hand-me-downs
Hello!	Home stretch	Happy days
Here I am!	Have one	Have a mint
Home spun	Hole-in-one	Hail Mary!
Help me!	Hemingway	Hollywood

Select several carryover sentences (increasing in length):

Select several three sentence paragraphs:

BIG YAWN! FALSETTO! Answer the following questions, using short phrases:

What is your birthdate?
Where do you live?
What is the weather like today?
Where was your mother born?
Where was your father born?
How many years did you attend school?
How tall are you?
What time did you wake up this morning?
What state were you born in?
What was your favorite subject in school?
Who is your ear, nose, and throat doctor?
How many brothers and/or sisters do you have?
What time do you usually go to bed at night?
What is your favorite food?
What is your favorite music?
What is your favorite season?
Do you like to cook?
Do you like to fix cars?
What kind of work do you do?
Do you like to read?

Now answer questions above again, using *complete sentences*.

GROUP 2 LESSON 4 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

Daily practice:

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Yawn sigh short phrases:

How are you?	How dare you!	He's back!
Hole in one	Homespun	Hemingway
Happy Birthday!	How is he?	How many are there?
Who is she?	Who is coming?	Who has some?
Who is he?	Who is there?	Who am I?

Carryover phrases of increasing length:

Carryover: 3 sentence paragraphs:

GROUP 2 VOICE THERAPY: WARM UP & LESSON 5

WARM UP – Loosen your body

(1) Shoulders
   a. Back strokes while yawning (X 10)
   b. Forward strokes while yawning (X 10)
   c. Roll shoulders back (X 5)
   d. Roll shoulders forward (X 5)
   e. Raise shoulders to ears and drop (X 2)
   f. Swing elbows up to your ears and drop (X 5)
   g. Touch elbows in front, then open up wide (X 5)

(2) Neck
   a. Left ear to left shoulder, hold for 10 seconds
   b. Right ear to right shoulder, hold for 10 seconds
   c. Drop head forward, letting gravity pull your head down, hold for 10 seconds

(3) Jaw – massage your jaw with downward strokes, let your jaw drop (X 5)

(4) Tongue
   a. Stretch! Stick your tongue out as far as you can, hold for 10 seconds
   b. Tongue rolls (X 3)
   c. Open relaxed "laaaaaaa" on a sigh. Release your tongue and jaw. Once you've mastered that, try it on these words:

LAA	LOT
LAWN	LOCK
LOP	LOB
LAW	

(5) Lips – Do lip rolls X 3

(6) Throat – Do a yawn sign X5

LARYNGEAL MASSAGE – Therapist will do.

LESSON 5

Yawn sigh on "ah" (X5)

Yawn sigh single words:

HOT	HOME	HIT	WHOSE
HAT	HE'S	HART	HERB
HOP	HEDGE	HACK	HELEN
HOLE	HIKE	HATE	HIVE

Yawn sigh phrases:

How are you?	Hi honey!	How dare you!
Horseshoe	How're things?	High time
He's back!	Half time	Hand-me-downs
Hello!	Home stretch	Happy days
Here I am!	Have one	Have a mint
Home spun	Hole-in-one	Hail Mary!
Help me!	Hemingway	Hollywood

Select several carryover sentences (increasing in length):

Select several three sentence paragraphs:

BIG YAWN! FALSETTO! Answer the following questions, using short phrases:

What is your birthdate?
Where do you live?
What is the weather like today?
Where was your mother born?
Where was your father born?

Select a reading passage to practice:

Pick a topic, or select from the topics below and talk for a few minutes. YAWN! FALSETTO!:

- A wonderful vacation
- The last episode of your favorite TV show
- How you decided on your career
- The pros and cons of living where you do
- Your opinion on a current political debate
- Your dream vacation
- A story about your pet
- Your New Year's Resolutions

Review maintenance program - Congratulations! You've finished voice therapy! You will need to make arrangements to return in about 3 weeks in order to answer another questionnaire about your voice, and have your voice recorded. In the meantime, complete the following tasks, once per day, for around 10 minutes total. Check off those days that you practice *and please be*

honest. Of course it's up to you if you practice or not, but the accuracy of the data we collect depends on your complete honesty.

MAKE ARRANGEMENTS TO SES BACK IN ~4 WEEKS (12 WEEKS POST INJECTION) FOR BASELINE MEASURES . . .

GROUP 2 LESSON 5 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:							
# OF PRACTICES:	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

DATE:							
# OF PRACTICES:	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

DATE:							
# OF PRACTICES:	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0	☐ 1 ☐ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

DATE:							
# OF PRACTICES:	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

Daily practice:

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Yawn sigh short phrases:

How are you?	How dare you!	He's back!
Hole in one	Homespun	Hemingway
Happy Birthday!	How is he?	How many are there?
Who is she?	Who is coming?	Who has some?
Who is he?	Who is there?	Who am I?

Carryover phrases of increasing length:

Carryover: 3 sentence paragraphs:

Carryover: reading passages. For five minutes, read aloud from one of the provided passages (or from material of your choosing). Practice maintaining smooth, resonance voicing throughout.

As additional practice, select 1 or 2 conversations daily. Concentrate on maintaining your best possible voice throughout the conversation. How did you do?

GROUP 3 VOICE THERAPY: WARM UP & LESSON 1

VOCAL JOURNAL – Keep a journal, as formal or as informal as you wish – dealing with your voice on a daily basis. You may write anything that you wish however pay attention to specific times or places where your voice improves (or worsens). Have you noticed any effects on your voice relating to diet, time of day, etc.?

VOICE FUNCTION –

There are four main components to the production of voice:

- Respiration
- Phonation
- Resonance
- Articulation

Voice therapy (even after Botox injection) may help people with spasmodic dysphonia by:

- Helping the four components of voice production work together in a more efficient way.
- Teaching people about their voices.

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – rub your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Press your tongue against the roof of your mouth, hold for 10 seconds
    b. Press your tongue against your lower jaw, hold for 10 seconds
    c. Press your tongue against the inside surface of your teeth on the right side, hold for 10 seconds
    d. Press your tongue against the inside surface of your teeth on the left side, hold for 10 seconds
    e. Tongue rolls (X 3)

(5) Lips – Do lip rolls X 3
(6) Throat – Take a deep breath and let it out.

LARYNGEAL ACUPRESSURE – Therapist will do.

LESSON 1

Because breathing is the first component of voice production, you will be provided with a breath trainer. Your therapist will set the trainer. Complete the following task (your therapist will show you how):

Breath trainer:

(10 reps) – counting 1 – 10
(15 reps) – counting 1 – 15
(20 reps) – counting 1 - 20

GROUP 3 LESSON 1 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.

Daily practice :

Loosen up – go through all the stretches covered during your session. The purpose of these stretches is to help eliminate any extra tension in the muscles near to your voice box.

Using your breath trainer, complete 3 sets of 20 reps. Each rep should consist of one slow breath with 2 seconds of rest before the next breath. Like this:

> Blow – Say “one” – (wait 2 seconds) – blow – Say “two” – (wait 2 seconds) - - - keep repeating until you have finished 20 reps.
> (Rest 30 seconds)
> Repeat
> (Rest 30 seconds)
> Repeat
>
> You should have completed 60 reps total (20 + 20 + 20)

GROUP 3 VOICE THERAPY: WARM UP & LESSON 2

VOCAL JOURNAL – How was your voice this week?

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – rub your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Press your tongue against the roof of your mouth, hold for 10 seconds
    b. Press your tongue against your lower jaw, hold for 10 seconds
    c. Press your tongue against the inside surface of your teeth on the right side, hold for 10 seconds
    d. Press your tongue against the inside surface of your teeth on the left side, hold for 10 seconds
    e. Tongue rolls (X 3)

(5) Lips – Do lip rolls (X 3)
(6) Throat – Take a deep breath and let it out.

LARYNGEAL ACUPRESSURE – Therapist will do.

LESSON 2

Your therapist will set your breath trainer. Complete the following task (your therapist will show you how):

Breath trainer:

(10 reps) – counting 1 – 10
(15 reps) – counting 1 – 15
(20 reps) – counting 1 - 20

Breath trainer max prolongations:

Trial 1: _____
[1 minute rest]
Trial 2: _____
[1 minute rest]
Trial 3:_____
[1 minute rest]
Trial 4:_____
[1 minute rest]
Trial 5:_____
[1 minute rest]

Practice reading the following:

(1) 1 – 2 – 3 – 4 – 5
(2) 6 – 7 – 8 – 9 – 10
(3) Monday – Tuesday - Wednesday
(4) Thursday – Friday – Saturday – Sunday
(5) January – February – March – April
(6) May – June – July – August – September
(7) October – November – December – January
(8) Who is that?
(9) Who is she?
(10) Who is coming?
(11) Who has some?
(12) Who is he?
(13) Who is there?
(14) Who am I?

GROUP 3 LESSON 2 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1								
	Rep 2								
MAX PROLONG Session 2	Rep 1								
	Rep 2								

Daily practice:

Loosen up – go through all the stretches covered during your session.

Using your breath trainer, complete 3 sets of 10 reps. Each rep should consist of one slow breath with 2 seconds of rest before the next breath. Like this:

> Blow – Say "one" – (wait 2 seconds) – blow – Say "two" – (wait 2 seconds) - - - keep repeating until you have finished 10 reps.
> (Rest 30 seconds)
> Repeat
> (Rest 30 seconds)
> Repeat
>
> You should have completed 30 reps total (10 + 10 + 10)

Max prolongations **(you will need a watch)** – Using your breath trainer, take a deep breath in and time how long you are able to exhale into the trainer. Record your times above (twice for each session, two times daily).

GROUP 3 VOICE THERAPY: WARM UP & LESSON 3

VOCAL JOURNAL – How was your voice this week?

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – rub your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Press your tongue against the roof of your mouth, hold for 10 seconds
    b. Press your tongue against your lower jaw, hold for 10 seconds
    c. Press your tongue against the inside surface of your teeth on the right side, hold for 10 seconds
    d. Press your tongue against the inside surface of your teeth on the left side, hold for 10 seconds
    e. Tongue rolls (X 3)

(5) Lips – Do lip rolls (X 3)
(6) Throat – Take a deep breath and let it out.

LARYNGEAL ACUPRESSURE – Therapist will do.

LESSON 3

Breath trainer:

(10 reps) – counting 1 – 10
(15 reps) – counting 1 – 15
(20 reps) – counting 1 - 20

Breath trainer max prolongations:

Trial 1: _____
[1 minute rest]
Trial 2: _____

[1 minute rest]

Trial 3:_____

[1 minute rest]

Carryover: 3 – 15+ syllable phrases. Your therapist will show you how. On each sentence (1) read the phrase of sentence silently while "hearing" your best possible voice in your head. Then (2) read the words aloud, trying to make your voice sound like the "best voice" you imagined. How did you do?

GROUP 3 LESSON 3 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1								
	Rep 2 .								
MAX PROLONG Session 2	Rep 1								
	Rep 2								

Daily practice:

Loosen up – go through all the stretches covered during your session.

Using your breath trainer, complete 2 sets of 10 reps. Each rep should consist of one slow breath with 2 seconds of rest before the next breath. Like this:

> Blow – Say “one” – (wait 2 seconds) – blow – Say “two” – (wait 2 seconds) - - - keep repeating until you have finished 10 reps.
> (Rest 30 seconds)
> Repeat
>
> You should have completed 20 reps total (10 + 10)

Max prolongations **(you will need a watch)** – Using your breath trainer, take a deep breath in and time how long you are able to exhale into the trainer. Record your times above (twice for each session, two times daily).

Carryover phrases: Just like you did in your session, (1) read the words or sentences silently while "hearing" your best possible voice in your head. Then (2) read the words or sentences aloud, making your voice sound as close as possible to the "best" voice your heard in your head. Finally (3) rate how successful you were at making your voice match your "best" possible, ideal voice.

How satisfied were you with your voice when you read aloud?

1 = very unsatisfied
2 = somewhat unsatisfied
3 = neutral
4 = somewhat satisfied
5 = very satisfied

	Day1		Day2		Day3		Day4		Day5		Day6		Day7	
Three syllable phrase 1														
2														
3														
4														
5														
Four syllable phrase 1														
2														
3														
4														
5														
Five syllable phrase 1														
2														
3														
4														
5														
Six syllable phrases 1														
2														
3														
Seven & Eight Syll. 1														
2														
3														
Nine & Ten Syll. 1														
2														
3														
Ten – Twelve Syll. 1														
2														

3														
Fifteen Plus Syll. 1														
2														
3														

GROUP 3 VOICE THERAPY: WARM UP & LESSON 4

VOCAL JOURNAL – How was your voice this week?

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – rub your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Press your tongue against the roof of your mouth, hold for 10 seconds
    b. Press your tongue against your lower jaw, hold for 10 seconds
    c. Press your tongue against the inside surface of your teeth on the right side, hold for 10 seconds
    d. Press your tongue against the inside surface of your teeth on the left side, hold for 10 seconds
    e. Tongue rolls (X 3)

(5) Lips – Do lip rolls X 3
(6) Throat – Take a deep breath and let it out.

LARYNGEAL ACUPRESSURE – Therapist will do

LESSON 4

Breath trainer:

(10 reps) – counting 1 – 10
(15 reps) – counting 1 – 15
(20 reps) – counting 1 - 20

Breath trainer max prolongations:

Trial 1: _____
[1 minute rest]
Trial 2: _____

[1 minute rest]
Trial 3:_____
[1 minute rest]

Carryover: 3 syllable to 3 sentence paragraphs. Just like last week, (1) read the phrase of sentence silently while "hearing" your best possible voice in your head. Then (2) read the words aloud, trying to make your voice sound like the "best voice" you imagined. How did you do?

Conversation: Answer the questions below. Take your time and use short 1 – 3 word answers the first time through:

What is your birthdate?
Where do you live?
What is the weather like today?
Where was your mother born?
Where was your father born?
How many years did you attend school?
How tall are you?
What time did you wake up this morning?
What state were you born in?
What was your favorite subject in school?
Who is your ear, nose, and throat doctor?
How many brothers and/or sisters do you have?
What time do you usually go to bed at night?
What is your favorite food?
What is your favorite music?
What is your favorite season?
Do you like to cook?
Do you like to fix cars?
What kind of work do you do?
Do you like to read?

Now answer questions above again, using complete sentences.

GROUP 3 LESSON 4 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:									
# OF PRACTICES:	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0	□ 2 □ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1								
	Rep 2 .								
MAX PROLONG Session 2	Rep 1								
	Rep 2								

Daily practice:

Loosen up – go through all the stretches covered during your session.

Using your breath trainer, complete 2 sets of 10 reps. Each rep should consist of one slow breath with 2 seconds of rest before the next breath. Like this:

> Blow – Say “one” – (wait 2 seconds) – blow – Say “two” – (wait 2 seconds) - - - keep repeating until you have finished 10 reps.
> (Rest 30 seconds)
> Repeat
>
> You should have completed 20 reps total (10 + 10)

Max prolongations **(you will need a watch)** – Using your breath trainer, take a deep breath in and time how long you are able to exhale into the trainer. Record your times above (twice for each session, two times daily).

Carryover phrases: Just like you did in your session, (1) read the words or sentences silently while "hearing" your best possible voice in your head. Then (2) read the words or sentences aloud, making your voice sound as close as possible to the "best" voice your heard in your head. Finally (3) rate how successful you were at making your voice match your "best" possible, ideal voice.

How satisfied were you with your voice when you read aloud?

1 = very unsatisfied
2 = somewhat unsatisfied
3 = neutral
4 = somewhat satisfied
5 = very satisfied

	Day1		Day2		Day3		Day4		Day5		Day6		Day7	
Three syllable phrase 1														
2														
3														
4														
5														
Four syllable phrase 1														
2														
3														
4														
5														
Five syllable phrase 1														
2														
3														
4														
5														
Six syllable phrases 1														
2														
3														
Seven & Eight Syll. 1														
2														
3														
Nine & Ten Syll. 1														
2														
3														
Ten – Twelve Syll. 1														
2														

3														
Fifteen Plus Syll. 1														
2														
3														
Short paragraphs 1														

GROUP 3 VOICE THERAPY: WARM UP & LESSON 5

VOCAL JOURNAL – How was your voice this week?

WARM UP – Loosen your body

(1) Shoulders
    a. Back strokes while yawning (X 10)
    b. Forward strokes while yawning (X 10)
    c. Roll shoulders back (X 5)
    d. Roll shoulders forward (X 5)
    e. Raise shoulders to ears and drop (X 2)
    f. Swing elbows up to your ears and drop (X 5)
    g. Touch elbows in front, then open up wide (X 5)
(2) Neck
    a. Left ear to left shoulder, hold for 10 seconds
    b. Right ear to right shoulder, hold for 10 seconds
    c. Drop head forward, letting gravity pull your head down, hold for 10 seconds
(3) Jaw – rub your jaw with downward strokes, let your jaw drop (X 5)
(4) Tongue
    a. Press your tongue against the roof of your mouth, hold for 10 seconds
    b. Press your tongue against your lower jaw, hold for 10 seconds
    c. Press your tongue against the inside surface of your teeth on the right side, hold for 10 seconds
    d. Press your tongue against the inside surface of your teeth on the left side, hold for 10 seconds
    e. Tongue rolls (X 3)

(5) Lips – Do lip rolls (X 3)
(6) Throat – Take a deep breath and let it out.

LARYNGEAL ACUPRESSURE – Therapist will do

LESSON 5

Breath trainer:

(10 reps) – counting 1 – 10
(15 reps) – counting 1 – 15
(20 reps) – counting 1 - 20

Breath trainer max prolongations:

Trial 1: _____
[1 minute rest]
Trial 2: _____

[1 minute rest]
Trial 3:_____

Now to practice talking - Start with the following:

Select several carryover sentences (increasing in length):

Select several three sentence paragraphs:

Answer the following questions, using short phrases:

What is your birthdate?
Where do you live?
What is the weather like today?
Where was your mother born?
Where was your father born?

Select a reading passage to practice:

Pick a topic, or select from the topics below and talk for a few minutes:

- A wonderful vacation
- The last episode of your favorite TV show
- How you decided on your career
- The pros and cons of living where you do
- Your opinion on a current political debate
- Your dream vacation
- A story about your pet
- Your New Year's Resolutions

Congratulations! You've finished voice therapy! You will need to make arrangements to return in about 3 weeks in order to answer another questionnaire about your voice, and have your voice recorded.

GROUP 3 LESSON 5 – HOME PRACTICE

For the purposes of this study, it is important that you practice these exercises every day. Practice sessions should last between **10 and 15 minutes** and occur **twice per day** (20 to 30 minutes total). If you are unable to practice twice, or for some reason have to shorten your practice time, please note so below.

DATE:							
# OF PRACTICES:	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1						
	Rep 2 .						
MAX PROLONG Session 2	Rep 1						
	Rep 2						

DATE:							
# OF PRACTICES:	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1						
	Rep 2 .						
MAX PROLONG Session 2	Rep 1						
	Rep 2						

DATE:							
# OF PRACTICES:	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1						
	Rep 2 .						
MAX PROLONG Session 2	Rep 1						
	Rep 2						

DATE:							
# OF PRACTICES:	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0	□ 1 □ 0
TIME SPENT:	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.	MINS.
MAX PROLONG Session 1	Rep1						
	Rep 2 .						
MAX PROLONG Session 2	Rep 1						
	Rep 2						

Daily practice:

Loosen up – go through all the stretches covered during your session.

Using your breath trainer, complete 2 sets of 10 reps. Each rep should consist of one slow breath with 2 seconds of rest before the next breath. Like this:

> Blow – Say "one" – (wait 2 seconds) – blow – Say "two" – (wait 2 seconds) - - - keep repeating until you have finished 10 reps.
> (Rest 30 seconds)
> Repeat
>
> You should have completed 20 reps total (10 + 10)

Max prolongations **(you will need a watch)** – Using your breath trainer, take a deep breath in and time how long you are able to exhale into the trainer. Record your times above (twice for each session, two times daily.

Carryover phrases: (1) Read the words or sentences silently while "hearing" your best possible voice in your head. Then (2) read the words or sentences aloud, making your voice sound as close as possible to the "best" voice your heard in your head.

As additional practice, select 1 or 2 conversations daily. Concentrate on maintaining your best possible voice throughout the conversation. How did you do?

APPENDIX D

CARRYOVER MATERIALS USED IN TX WITH GROUPS 2 AND 3

Three syllable phrases

Put it on.	Tell me how.	Walk around.
Did you know?	Juicy peach.	Yes and no.
Do you know?	Crunchy grape.	Put them down.
What's your name?	You come here.	Not right now.
Time to go.	Close your eyes.	Fine report.
Read the book.	Who is it?	Pick it up.
Take a nap.	Good evening.	

Four syllable phrases

Pleased to meet you.	You'd like it there.	The sun was bright.
Fill it up, please.	How much is it?	He knows the way.
The train was late.	Maybe later.	Cream and sugar.
Bread and butter.	Salt and pepper.	Toast and butter.
Pie and coffee.	Needle and thread.	Turkey and cheese.
Nice to meet you.	That's fine for now.	Don't tease the dog.
Beth arrived late.	This is enough.	

Five syllable phrases

Where are they going?	The concert was great.	Turn off the iron.
The book was stolen.	Tip the waiter well.	When is he finished?
Flowers need water.	Will she be here soon?	The oven is on.
The tea is steeping.	Yes, that's fine with me.	The phone is ringing.
Play the clarinet.	Let's consider it.	They enjoyed the song.
Turn on the TV.	It was time to leave.	He ran to the door.
Whatever you say.	Do you have children?	Where is the bathroom?
They were very sick.	I stood on the scale.	What a lovely dress!
We could see for miles.	Push the door open.	I like apple pie.
I had a flat tire.	Bring me a Kleenex.	Help yourself to more.

Five syllable phrases (cont.)

Let's see the movie.
We stayed in the shade.
The book's on the desk.
She's ready to eat.
Their house needs painting.
The lock was broken.
He sold his old car.
Give me your number.
Please leave me alone.
Do you like to cook?
They should have called first.
What's that man doing?
He's five minutes late.
Does your car need work?

Six syllable phrases

That's a good idea.
They called me late last night.
He can phone us later.
Fill it with unleaded.
He is a millionaire.
Come over and see us.
I need to have it fixed.
The switch is over there.
They moved to the mountains.
Make a grocery list.
I came when you called me.
I can't find your address.
How long will it take you?
What about tomorrow?
Watch out! The floor is wet.
She's a terrible cook.
Put everything away.
They deserve each other.
Molly Elizabeth
Place it down carefully.
I asked you not to go.
The fire alarm rang.
Let me know when he calls.
Do you like to read books?
The puppy is playful.
My shoes are killing me.
I got up before dawn.
It costs too much money.
He offered to help us.
I must be leaving now.
Ted wanted to come along.
Forget about your plans.
She bought it somewhere else.
Leave the window open.
Where did you get that book?
The children were playing.
Did you sleep well last night?
I'll see if she can come.
The spectators were pleased.
How much do I owe you?
You may stay if you like.
They need to paint their house.
I don't think that it is.
Do you like your new job?

Seven and eight syllable phrases

It was a lovely wedding.
Take me to the library.
Do you have an account here?
A Ph.D. can be tiring.
How do you like the East Coast?
Do you know how to play bridge?
He slipped on the kitchen floor.
My son came for a visit.
I belong to a book club.
Will you give me your answer?
Did you enjoy the movie?
Which is the least expensive?
Can I borrow a dollar?
They traveled across Europe.

Seven and eight syllable phrases (cont.)

Did you make the appointment?
They fish aren't biting today.
They will come if you ask them.
Thank you for asking me here.
What is a good time for you?
Don't do it because of me.
Tell me about your mother.
Please pass the salt and pepper.
I want to look at the bill.
I love sleeping late on Sundays.
We will probably start at six.
The top of this jar is stuck.
I can't remember the number.
What shall we have for dessert?
What are you doing after this?
The snowfall was light that year.
She made her dress by herself.
What's for dinner tomorrow.
I ate an apple for lunch.
Read this book if you have time.
We are going with some friends.
I need to get a check cashed.
Have you finished your work yet?
Nothing much has changed lately.
The weather in August is hot.
What time can you come for dinner?
We honeymooned in St. Thomas.
Would you help me open it, please?
Please give it to me again.
Pie and ice cream sounds delicious.
Be careful not to go too fast.
Our guests will arrive at nine.

Nine and ten syllable phrases

Lisa bought some vegetables for dinner.
I will be happy to meet with you.
They all went skiing for the holiday.
There are found bedrooms on the top floor.
Have you been to the theatre lately?
Sally sold her new red car on a whim.
At last, the time of reckoning has come.
Christmas is my favorite holiday.
Mary Poppins had magical powers.
No need to speak, I can read your mind.
Buying in bulk saves money in the end.
I'll always remember that summer night.
He wears a sixteen and a half collar.
I hope to graduate in August.
The bakery smells simply delicious.
After the rain, the air smelled dirty.
Summer at the seashore is popular.
It would be nice to make a decent wage.
The brown puppy played with the tennis ball.
The older you get, the faster time flies.
There are some things that money can't buy.
The telephone bill was lower this month.
Pot roast was Grandpa's favorite dinner.

Ten to twelve syllable phrases

City buses are often crowded and noisy.

He avoided making eye contact while riding the bus.

Don't forget to turn off the lights and lock the door.

Oh no, I think I may have left my keys inside.

We usually go boating each summer.

The car was badly damaged in the crash.

Fortunately, there were no injuries.

Sally loves to go swimming in the lake.

She was reminded not to go too far.

Distilled water tastes much better than tap.

What would I do without my speech pathologist?

I always get heartburn when I eat spicy food.

Most people do not drink enough water.

A yearly physical is vital for good health.

Abraham Lincoln was assassinated.

Her uncle is a senator from Maine.

If I win the lottery, I'd quit my job.

It's difficult to form new speaking habits.

You'd never know she had plastic surgery.

A positive outlook makes all the difference.

I try and keep up with current events.

Two thousand and four is an election year.

Fifteen + syllable phrases

It doesn't take much to get that man to reach his boiling point.

I never thought that I would see a snowstorm in July, but I did.

The house at the end of the road was abandoned two years ago.

When I'm not feeling well, I don't like to get out of my warm bed.

After Billy got home from school, his mother made him mow the lawn.

Since we're all in this together, let's show a little team spirit.

Fifteen + syllable phrases (cont.)

Nothing could be finer than Carolina in the morning.

The world is not going to end if you miss your favorite TV. show.

After the crowd of rowdy people left the party, we had a much better time.

Many people from Massachusetts go to New York for a getaway weekend.

You should know better than to make a mess when Grandma is on her way over for a visit.

When her blind date showed up two hours late, he was wearing a polyester suit that was incredibly tacky.

Would you go to the store and pick up some apples, hot chocolate, a pound of coffee, and some vanilla ice cream?

It never occurred to Harold that it might not be a good idea to go swimming alone after dinner.

It never occurred to Erin that it might not be a good idea to do a longitudinal study for her dissertation.

Since time began, people have been fascinated by beautiful and visually exciting gemstones used for jewelry and adornment.

It is March, and after a long cold winter with more snow than Massachusetts has had in years, you would think that we would have had a warmer, drier spring, but that doesn't seem to be the case.

The early colonial families owed a great deal to the willingness of the Native Americans to share their knowledge of how to make the best use of the materials available in their natural surroundings in the new land.

Three sentence paragraphs

He hit the ball and it flew high, arching against the blue sky. The spectators looked up and squinted. Then they gasped and groaned as the ball suddenly fell to the ground.

Three sentence paragraphs (cont.)

Sam was zipping along the freeway at ninety miles per hour, when he heard the siren behind him. He thought about trying to lose the state trooper, but then thought better of it. He could handle one little speeding ticket.

A mighty herd of elephants was grazing under the hot sun on the open plain. They lumbered slowly in the intense noonday heat. A bull raised his head and listened carefully for any signs of danger. Satisfied that his herd was safe, he went back to eating.

The assassin, dressed in black, slipped through the doorway into the dark night. He moved stealthily and made no sound. He waited silently for his target to approach.

The band played jaunty tunes as the members marched across the green grass. Balloons danced in the air overhead, and a few white wisps of cloud dotted the blue sky. Spectators lounged on the side of the field, and hot dog vendors did a lot of business.

Jane arrived home two hours late. She quietly turned the key in the door, gently opened it, and tiptoed upstairs past her parents' bedroom. She was almost safely to her own room when she heard her father's voice, "Jane, is that you?"

It was the worst night of Jean's life. She should never have let her friend, Diane, fix her up with a blind date. The guy was two hours late, and when he did arrive, he was dressed in a polyester suit that was incredibly tacky.

The house at the end of the road was old and completely run down. So far as anybody knew, no one had lived in it for years. It must have belonged to somebody, but no one claimed it for their own.

It never occurred to Harold that it might not be a good idea to go swimming alone after dinner. He was a fair swimmer, and had never had any trouble before. So, you can imagine his surprise when he got a cramp, and was helped to shore by a passing fisherman in a boat.

Three sentence paragraphs (cont.)

A trip to New York City can be a lot of fun, if you like cities. The theatre district is one of the most popular areas. There's nothing quite like going to see a Broadway musical.

APPENDIX E
RAW DATA

Table E-1. Raw V-RQOL data for all participants – preinjection baseline.

		M1			M2			M3			M4			M5		
Participant	G	S-E	P	T	S-E	P	T	S-E	P	T	S-E	P	T	S-E	P	T
1F	1	56	42	48	44	33	38	100	92	95	100	92	95	94	92	93
2F	1	13	50	35	38	50	45	44	46	45	38	46	43	31	33	33
3F	1	31	21	25	69	63	65	94	96	95	94	100	98	75	63	68
4M	1	81	63	70	75	67	70	88	79	83	75	79	78	75	63	68
5F	1	63	29	43	-	-	-	-	-	-	-	-	-	94	67	78
6F	1	25	17	20	6	25	18	100	100	100	100	100	100	88	92	90
7M	1	13	17	15	56	46	50	50	54	53	19	13	15	-	-	-
8F	1	44	21	30	100	83	90	100	79	88	100	75	85	50	33	40
9M	1	0	8	5	0	17	10	56	67	63	63	67	65	69	71	70
10F	1	63	33	45	94	63	75	100	58	75	88	54	68	69	29	45
11F	1	19	0	8	100	96	98	100	92	95	100	100	100	50	29	38
Group 1 median		31	21	30	63	57	58	97	79	86	91	77	82	72	63	68
Group 1 mean		37	27	31	58	54	56	83	76	79	78	73	75	70	57	62
Group 1 SD		26	19	19	36	25	29	23	19	19	29	29	28	21	25	22
12F	2	50	25	35	75	71	73	81	71	75	63	67	65	-	-	-
13M	2	56	29	40	94	71	80	100	75	85	100	67	80	94	29	55
14F	2	31	17	23	88	83	85	50	50	50	-	-	-	-	-	-
15F	2	56	29	40	100	83	90	94	92	93	38	58	50	-	-	-
16F	2	38	17	25	44	38	40	100	83	90	100	92	95	63	67	65
17F	2	63	25	40	50	33	40	88	88	88	100	100	100	69	29	45
18F	2	63	50	55	50	38	43	100	100	100	100	100	100	100	92	95
19F	2	38	21	28	25	25	25	94	79	85	100	88	93	88	83	85
20F	2	44	13	25	94	38	60	88	50	65	63	29	43	63	29	43
21F	2	31	38	35	63	42	50	94	83	88	88	83	85	88	79	83
Group 2 median		47	25	35	69	40	55	94	81	87	100	83	85	88	67	65
Group 2 mean		47	26	35	68	52	59	89	77	82	84	76	79	81	58	67
Group 2 SD		12	11	10	26	22	22	15	16	15	23	23	22	15	28	21

		M1			M2			M3			M4			M5		
Participant	G	S-E	P	T	S-E	P	T	S-E	P	T	S-E	P	T	S-E	P	T
22F	3	13	38	28	31	50	43	88	79	83	44	42	43	31	38	35
23M	3	63	100	85	100	75	85	88	71	78	-	-	-	-	-	-
24F	3	6	4	5	56	54	55	56	42	48	56	38	45	56	33	43
25F	3	56	29	40	19	54	40	100	83	90	100	83	90	75	33	50
26F	3	50	29	38	50	29	38	25	38	33	81	50	63	-	-	-
27F	3	50	42	45	69	29	45	69	54	60	69	58	63	88	75	80
28F	3	19	25	23	94	83	88	31	33	33	31	42	38	38	25	30
29F	3	13	21	18	44	38	40	75	75	75	88	58	70	88	75	80
30F	3	31	25	28	75	58	65	63	21	38	63	25	40	50	17	30
31F	3	0	4	3	81	58	68	100	100	100	-	-	-	19	21	20
Group 3 median		25	27	28	63	54	50	72	63	68	66	46	54	53	33	39
Group 3 mean		30	32	31	62	53	57	70	60	64	67	50	57	56	40	46
Group 3 SD		23	27	23	27	18	19	26	26	25	23	17	18	26	23	23

Table E-2. Raw acoustic data for all participants – M1 (preinjection baseline)

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
1F	1	19.73	2.83	0.00	0.00	62.71	48.61	17.57	22.91	80.28	71.52
2F	1	100.00	32.18	0.00	1.36	0.00	37.95	0.00	0.00	0.00	39.31
3F	1	14.67	29.23	14.68	15.83	61.74	32.54	8.91	0.00	85.33	48.37
4M	1	95.62	36.18	0.00	0.00	0.00	30.72	4.38	0.00	4.38	30.72
5F	1	-	-	-	-	-	-	-	-	-	-
6F	1	50.28	0.00	0.00	0.00	50.48	69.84	2.78	1.21	53.26	71.05
7M	1	55.13	30.85	0.00	0.00	44.87	62.89	0.00	0.00	44.87	62.89
8F	1	-	-	-	-	-	-	-	-	-	-
9M	1	0.00	0.00	0.00	0.00	100.00	92.73	0.00	0.00	100.00	92.73
10F	1	98.18	31.84	0.00	0.00	1.46	37.62	0.36	2.57	1.82	40.19
11F	1	97.19	61.29	2.81	6.87	0.00	14.62	0.00	0.00	2.81	21.49
Group 1 median		55.13	30.85	0.00	0.00	44.87	37.95	0.36	0.00	44.87	48.37
Group 1 mean		58.98	24.93	1.94	2.67	35.70	47.50	3.78	2.97	41.42	53.14
Group 1 SD		40.46	20.41	4.87	5.42	36.81	23.87	5.99	7.53	40.57	22.93
12F	2	31.44	66.29	2.00	1.00	1.60	4.77	64.98	27.93	68.58	33.70
13M	2	0.46	0.00	0.41	0.00	98.93	81.65	0.00	0.00	99.34	81.65
14F	2	73.34	33.07	24.06	0.00	2.35	58.43	0.25	0.00	26.66	58.43
15F	2	99.23	33.90	0.00	0.00	0.48	39.32	0.29	0.00	0.77	39.32
16F	2	87.16	17.33	0.84	0.00	6.06	33.21	6.85	7.88	13.75	41.09
17F	2	92.30	71.56	0.23	1.06	7.47	27.38	0.00	0.00	7.70	28.44
18F	2	66.46	4.36	8.69	3.35	25.52	79.41	0.00	0.00	34.21	82.76
19F	2	33.57	11.78	23.05	2.36	43.39	58.03	0.00	0.99	66.44	61.38
20F	2	94.08	70.98	4.77	17.23	1.15	11.79	0.00	0.00	5.92	29.02
21F	2	95.24	47.29	0.47	10.98	4.29	39.18	0.00	2.55	4.76	52.71
Group 2 median		80.25	33.49	1.42	1.03	5.18	39.25	0.00	0.00	20.21	46.90
Group 2 mean		67.33	35.66	6.45	3.60	19.12	43.32	7.24	3.94	32.81	50.85
Group 2 SD		34.10	27.44	9.41	5.84	31.24	26.00	20.40	8.79	34.00	20.11

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
22F	3	100	73.51	0	0	0	12.88	0	0	0	12.88
23M	3	89.79	26.07	0	0	10.21	48.04	0	0	10.21	48.04
24F	3	36.54	79.1	0	2.78	51.32	13.21	12.14	4.91	63.46	20.9
25F	3	12.09	28.75	0	3.51	64.94	39.49	1.7	0	66.64	43
26F	3	91.77	0	0	0	8.23	82.03	0	0	8.23	82.03
27F	3	92.81	71.93	0	0	7.19	26.06	0	2.01	7.19	28.07
28F	3	98.95	72.51	0	0	1.05	11.26	0	0	1.05	11.26
29F	3	100	82.58	0	1.43	0	0	0	0	0	1.43
30F	3	33.01	64.86	25.81	13.18	47.76	0	0	0	73.57	13.18
31F	3	100	99.84	0	0.05	0	0.11	0	0	0	0.16
Group 2 median		92.29	72.22	0.00	0.03	7.71	13.05	0.00	0.00	7.71	17.04
Group 3 mean		75.50	59.92	2.58	2.10	19.07	23.31	1.38	0.69	23.04	26.10
Group 3 SD		34.10	31.08	8.16	4.11	25.21	26.48	3.82	1.61	31.27	25.32

G = group; missing data denoted by (-)

Table E-3. Raw acoustic data for all participants – M2 (approximately 3 weeks post injection)

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
1F	1	89.47	19.5	0	10.64	10.53	3.39	0	0	10.53	14.03
2F	1	100	39.35	0	0	0	50.72	0	0	0	50.72
3F	1	100	78.95	0	14.81	0	0	0	0	0	14.81
4M	1	97.05	29.8	2.08	32.13	0.86	25.18	0	0	2.95	57.31
5F	1	-	-	-	-	-	-	-	-	-	-
6F	1	6.05	27.5	0	0	93.95	54.21	0	0	93.95	54.21
7M	1	58.03	81.73	36.57	0	5.4	7.81	0	0	41.97	7.81
8F	1	99.15	66.65	0	0	0.85	11.66	0	0.58	0.85	12.24
9M	1	0	0	0	0	100	84.26	0	0	100	84.26
10F	1	100	55.6	0	0	0	10.6	0	0	0	10.6
11F	1	100	76.33	0	2.76	0	9.73	0	0	0	12.49
Group 1 median		98.1	47.475	0	0	0.855	11.13	0	0	1.9	14.42
Group 1 mean		74.98	47.54	3.87	6.03	21.16	25.76	0.00	0.06	25.03	31.85
Group 1 SD		40.06	28.37	11.51	10.59	40.13	27.94	0.00	0.18	40.06	27.18
12F	2	36.83	50.84	0.59	9.3	39.05	31.68	23.53	8.19	63.17	49.17
13M	2	86.57	73.47	1.89	0	1.09	0	0	0	2.98	0
14F	2	100	93.29	0	0	0	1.95	0	0	0	1.95
15F	2	100	72.86	0	1.81	0	3.01	0	0	0	4.82
16F	2	98.11	48.45	0	0	1.89	1.66	0	0	1.89	1.66
17F	2	97.7	89.56	1.91	3.07	0.39	7.37	0	0	2.3	10.44
18F	2	95.34	74.76	1.02	0	3.64	7.67	0	0	4.66	7.67
19F	2	96.8	88.41	3.2	3.08	0	0	0	0	3.2	3.08
20F	2	100	99.22	0	0	0	0.78	0	0	0	0.78
21F	2	100	95.24	0	0	0	2.63	0	2.14	0	4.77
Group 2 median		97.91	81.59	0.30	0.00	0.20	2.29	0.00	0.00	2.10	3.93
Group 2 mean		91.14	78.61	0.86	1.73	4.61	5.68	2.35	1.03	7.82	8.43
Group 2 SD		19.51	17.91	1.13	2.96	12.16	9.53	7.44	2.60	19.52	14.67

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
22F	3	83.81	75.20	14.57	0.48	1.62	15.86	0.00	0.00	16.19	16.34
23M	3	29.57	27.05	32.38	0.00	37.34	20.90	0.00	0.00	69.72	20.90
24F	3	29.91	54.55	8.25	7.48	49.59	27.38	12.25	10.59	70.09	45.45
25F	3	0.00	18.05	0.00	0.00	49.71	40.41	50.29	0.00	100.00	40.41
26F	3	25.26	9.35	1.42	0.00	71.98	73.65	1.34	0.00	74.74	73.65
27F	3	82.01	98.27	1.01	1.17	3.42	0.56	13.56	0.00	17.99	1.73
28F	3	92.08	62.95	1.08	0.00	12.38	21.37	0.00	0.00	13.46	21.37
29F	3	97.80	59.65	1.29	19.31	0.90	3.96	0.00	0.00	2.19	23.27
30F	3	27.49	38.02	60.33	10.32	14.87	26.93	0.00	0.00	75.20	37.25
31F	3	24.68	56.59	72.40	9.00	2.92	26.12	0.00	0.00	75.32	35.12
Group 2 median		29.74	55.57	4.84	0.83	13.63	23.75	0.00	0.00	69.91	29.20
Group 3 mean		49.26	49.97	19.27	4.78	24.47	25.71	7.74	1.06	51.49	31.55
Group 3 SD		35.43	27.15	26.88	6.58	25.64	20.45	15.86	3.35	34.88	19.71

G = group; missing data denoted by (-)

Table E-4. Raw acoustic data for all participants – M3 (approximately 7 weeks post injection)

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
1F	1	100.00	59.91	0.00	0.00	0.00	7.89	0.00	0.00	0.00	7.89
2F	1	97.20	39.62	0.41	0.00	2.39	46.75	0.00	0.00	2.80	46.75
3F	1	-	-	-	-	-	-	-	-	-	-
4M	1	54.67	34.01	37.24	5.18	8.09	30.69	0.00	0.00	45.33	35.87
5F	1	-	-	-	-	-	-	-	-	-	-
6F	1	98.92	76.03	0.47	0.00	1.39	12.99	0.00	0.00	1.86	12.99
7M	1	38.39	44.14	11.08	1.66	49.46	54.20	0.00	0.00	60.54	55.86
8F	1	94.53	38.79	0.00	29.02	5.47	24.59	0.00	0.00	5.47	53.61
9M	1	73.10	86.20	1.64	0.00	23.94	7.93	0.00	0.00	25.58	7.93
10F	1	100.00	48.58	0.00	0.00	0.00	32.00	0.00	0.00	0.00	32.00
11F	1	96.34	73.18	3.66	1.63	0.00	10.09	0.00	0.00	3.66	11.72
Group 1 median		96.34	48.58	0.47	0.00	2.39	24.59	0.00	0.00	3.66	32.00
Group 1 mean		83.68	55.61	6.06	4.17	10.08	25.24	0.00	0.00	16.14	29.40
Group 1 SD		23.00	18.93	12.23	9.48	16.61	17.17	0.00	0.00	22.60	19.82
12F	2	76.30	77.29	1.79	1.49	6.46	6.41	15.45	14.81	23.70	22.71
13M	2	88.54	85.30	8.19	0.00	3.27	1.92	0.00	0.00	11.46	1.92
14F	2	63.23	66.23	35.10	1.21	1.67	15.79	0.00	0.00	36.77	17.00
15F	2	100.00	85.64	0.00	0.00	0.00	1.44	0.00	0.00	0.00	1.44
16F	2	51.24	59.79	0.00	0.48	30.02	5.88	18.74	1.30	48.76	7.66
17F	2	100.00	100.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
18F	2	88.57	35.55	11.04	34.24	0.04	21.32	0.00	0.00	11.08	55.56
19F	2	99.19	50.13	0.81	18.92	0.00	14.55	0.00	0.00	0.81	33.47
20F	2	100.00	94.98	0.00	1.12	0.00	3.90	0.00	0.00	0.00	5.02
21F	2	100.00	96.62	0.00	0.00	0.00	2.53	0.00	0.85	0.00	3.38
Group 2 median		93.88	81.30	0.41	0.80	0.02	4.89	0.00	0.00	5.95	6.34
Group 2 mean		86.71	75.15	5.69	5.75	4.15	7.37	3.42	1.70	13.26	14.82
Group 2 SD		17.60	21.60	11.06	11.57	9.34	7.26	7.25	4.63	17.60	18.01

22F	3	100.00	62.91	0.00	0.00	0.00	26.79	0.00	0.00	0.00	26.79
23M	3	-	-	-	-	-	-	-	-	-	-
24F	3	51.20	72.33	0.00	1.65	40.95	20.94	7.85	5.08	48.80	27.67
25F	3	0.00	40.10	0.00	0.00	100.00	25.30	0.00	0.00	100.00	25.30
26F	3	70.57	7.72	0.00	0.00	28.62	79.16	0.81	0.00	29.43	79.16
27F	3	90.48	99.52	7.42	0.00	2.10	0.48	0.00	0.00	9.52	0.48
28F	3	95.01	76.87	4.99	0.00	0.00	11.71	0.00	0.00	4.99	11.71
29F	3	99.37	83.72	0.00	2.83	0.00	0.00	0.63	0.00	0.63	2.83
30F	3	80.82	39.34	14.32	18.01	4.86	22.41	0.00	0.00	19.18	40.42
31F	3	100.00	41.42	0.00	43.46	0.00	5.93	0.00	0.00	0.00	49.39
Group 2 median		90.48	62.91	0.00	0.00	2.10	20.94	0.00	0.00	9.52	26.79
Group 3 mean		76.38	58.21	2.97	7.33	19.61	21.41	1.03	0.56	23.62	29.31
Group 3 SD		33.00	28.38	5.07	14.75	33.66	24.01	2.58	1.69	33.00	24.70

G = group; missing data denoted by (-)

Table E-5. Raw acoustic data for all participants – M4 (approximately 12 weeks post injection)

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
1F	1	54.24	37.17	41.44	6.84	4.32	20.79	0	0	45.76	27.63
2F	1	96.63	27.57	0	0	3.37	50.74	0	0	3.37	50.74
3F	1	-	-	-	-	-	-	-	-	-	-
4M	1	43.64	36.19	47.56	5.45	8.81	47.27	0	4.83	56.36	57.56
5F	1	-	-	-	-	-	-	-	-	-	-
6F	1	93.51	72.75	1.9	0	4.59	0	0	0	6.49	0
7M	1	26.69	22.24	0	0	73.31	64.83	0	0	73.31	64.83
8F	1	100	52.47	0	21.46	0	19.11	0	0	0	40.57
9M	1	87.56	81.87	0	0	4.46	9.48	7.98	0	12.44	9.48
10F	1	100	71.77	0	0	0	13.42	0	0	0	13.42
11F	1	84.39	70.32	12.25	0	3.36	10.95	0	0	15.61	10.95
Group 1 median		87.56	52.47	0.00	0.00	4.32	19.11	0.00	0.00	12.44	27.63
Group 1 mean		76.30	52.48	11.46	3.75	11.36	26.29	0.89	0.54	23.70	30.58
Group 1 SD		27.48	22.36	19.21	7.16	23.38	22.30	2.66	1.61	27.48	23.65
12F	2	59.12	90.49	4.14	1.83	1.9	1.99	34.84	5.69	40.88	9.51
13M	2	39.26	71.19	55.07	0	5.67	12.26	0	0	60.74	12.26
14F	2	-	-	-	-	-	-	-	-	-	-
15F	2	100	77.68	0	0	0	5.54	0	0	0	5.54
16F	2	92.37	51.84	4.07	2.28	1.54	16.47	2.03	2.64	7.64	21.39
17F	2	100	93.98	0	0	0	6.02	0	0	0	6.02
18F	2	71.47	14.67	28.53	40.08	0	35.95	0	0	28.53	76.03
19F	2	99.52	73.5	0.47	13.87	0	0	0	0	0.47	13.87
20F	2	92.35	91.54	0	0.59	0	7.86	7.65	0	7.65	8.45
21F	2	100	93.13	0	1.32	0	5.56	0	0	0	6.88
Group 2 median		92.37	77.68	0.47	1.32	0.00	6.02	0.00	0.00	7.64	9.51
Group 2 mean		83.79	73.11	10.25	6.66	1.01	10.18	4.95	0.93	16.21	17.77
Group 2 SD		22.15	25.91	19.15	13.28	1.90	10.86	11.49	1.99	22.15	22.40

22F	3	91.06	80.04	8.94	0	0	8.37	0	0	8.94	8.37
23M	3	-	-	-	-	-	-	-	-	-	-
24F	3	30.98	65.6	0.95	4.18	38.57	26.04	29.5	4.18	69.02	34.4
25F	3	1.71	11.64	0	0	98.29	56.61	0	0	98.29	56.61
26F	3	77.63	18.32	4.57	4.66	17.8	61.34	0	0	22.37	66
27F	3	95.94	96.61	1.98	0	0	3.93	2.09	0	4.07	3.93
28F	3	99.6	87.28	0	0	0.4	4.53	0	0	0.4	4.53
29F	3	100	79.29	0	5.36	0	1.32	0	0	0	6.68
30F	3	78.03	45.3	23.74	17.76	6.47	17.88	0	0	30.21	35.64
31F	3	100	76.54	0	15.38	0	1.66	0	0	0	17.04
Group 2 median		91.06	76.54	0.95	4.18	0.40	8.37	0.00	0.00	8.94	17.04
Group 3 mean		74.99	62.29	4.46	5.26	17.95	20.19	3.51	0.46	25.92	25.91
Group 3 SD		35.14	30.43	7.82	6.81	32.80	23.47	9.77	1.39	35.15	23.49

G = group; missing data denoted by (-)

Table E-6. Raw acoustic data for all participants – M5 (prior to reinjection)

Participant	G	Type 1 /a/	Type 1 Rainbow	Type 2 /a/	Type 2 Rainbow	Type 3 /a/	Type 3 Rainbow	Voice bks /a/	Voice bks Rainbow	Undesirable /a/	Undesirable Rainbow
1F	1	-	-	-	-	-	-	-	-	-	-
2F	1	100	1.5	0	0	0	62.59	0	0	0	62.59
3F	1	-	-	-	-	-	-	-	-	-	-
4M	1	57.77	31.76	18.03	0.83	18.4	43.56	2.1	6.79	38.53	51.18
5F	1	-	-	-	-	-	-	-	-	-	-
6F	1	88.29	22.07	9.05	0.11	3.41	56.74	0	0	12.46	56.85
7M	1	-	-	-	-	-	-	-	-	-	-
8F	1	88.2	52.89	8.99	18.09	2.81	19.82	0	0	11.8	37.91
9M	1	89.5	74.65	0	0	7.43	4.81	3.07	0	10.5	4.81
10F	1	94.39	86.13	3.83	0	1.78	0	0	0	5.61	0
11F	1	91.92	65.92	6.08	0	2	23.94	0	0	8.08	23.94
Group 1 median		89.50	52.89	6.08	0.00	2.81	23.94	0.00	0.00	10.50	37.91
Group 1 mean		87.15	47.85	6.57	2.72	5.12	30.21	0.74	0.97	12.43	33.90
Group 1 SD		13.61	30.57	6.29	6.78	6.29	24.62	1.29	2.57	12.28	25.03
12F	2	18.78	66.03	6.61	1.45	5.36	1.73	69.25	30.79	81.22	33.97
13M	2	20.87	16.77	39.69	4.25	39.19	60.66	0.25	0	79.13	64.91
14F	2	-	-	-	-	-	-	-	-	-	-
15F	2	-	-	-	-	-	-	-	-	-	-
16F	2	-	-	-	-	-	-	-	-	-	-
17F	2	99.02	95.92	0	0	0	4.08	0.98	0	0.98	4.08
18F	2	95.31	25.37	3.87	34.49	0.82	28.61	0	0	4.69	63.1
19F	2	31.89	0	48.6	0	21.66	60.03	0	0	70.26	60.03
20F	2	100	94.98	0	0	0	5.02	0	0	0	5.02
21F	2	98.71	84.3	1.29	10.62	0	5.08	0	0	1.29	15.7
Group 2 median		95.31	66.03	3.87	1.45	0.82	5.08	0.00	0.00	4.69	33.97
Group 2 mean		66.37	54.77	14.29	7.26	9.58	23.60	10.07	4.40	33.94	35.26
Group 2 SD		40.01	40.04	20.69	12.61	15.23	26.69	26.10	11.64	40.32	27.50

22F	3	87.76	85.16	12.24	0	0	10.48	0	0	12.24	10.48
23M	3	-	-	-	-	-	-	-	-	-	-
24F	3	11.92	57.78	4.29	5.09	66.92	27.32	16.86	9.81	88.07	42.22
25F	3	2.42	9.48	0	0	86.31	69.98	11.26	0	97.57	69.98
26F	3	-	-	-	-	-	-	-	-	-	-
27F	3	94.84	100	0.8	0	0	0	4.37	0	5.17	0
28F	3	96.59	75.67	0	0	3.41	6.43	0	0	3.41	6.43
29F	3	98.88	63.15	1.13	19.46	0	4.83	0	0	1.13	24.29
30F	3	48	27.95	24.24	16.73	30.69	40.6	0	0	54.93	57.33
31F	3	-	-	-	-	-	-	-	-	-	-
Group 2 median		87.76	63.15	1.13	0.00	3.41	10.48	0.00	0.00	12.24	24.29
Group 3 mean		62.92	59.88	6.10	5.90	26.76	22.81	4.64	1.40	37.50	30.10
Group 3 SD		41.93	31.81	9.10	8.57	36.21	25.25	6.82	3.71	42.11	26.97

G = group; missing data denoted by (-)

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BIOGRAPHICAL SKETCH

Erin Pearson Silverman was born on April 19, 1976 in Harrisburg, Pennsylvania. She spent her childhood in Montana before moving with her family to Gainesville, Florida in 1991. She graduated from Buchholz High School (Gainesville, Florida) in 1994 and went on to complete her Bachelor of Arts (with Honors) in Communication Sciences and Disorders at the University of Florida in 1997. Following receipt of her bachelor's degree, Erin entered the master of science program in Communication Disorders at Emerson College in Boston, Massachusetts. It was during her time in Boston, and through her practicum experiences at Massachusetts Eye and Ear Infirmary, that her interest in voice disorders first emerged. Following her graduation from Emerson in 1999, Erin began doctoral studies at the University of Florida in rehabilitation sciences prior to transferring to communication sciences and disorders in 2001. Her doctoral studies have focused primarily on voice disorders.

In 2003 Erin was awarded a Ruth Kirschstein Individual Predoctoral Fellowship by the National Institutes of Health in support of her doctoral studies. Also in 2003 Erin and her mentor Christine Sapienza received a research grant from the National Spasmodic Dysphonia Association in support of their research into combined modality treatment of adductor type spasmodic dysphonia.

Erin married Joshua Silverman in Gainesville in October 2004 and their first child, Molly, was born March 30, 2006. Upon completion of her doctorate, Erin will continue to reside in Gainesville with her family. She currently works as an inpatient speech-language pathologist at North Florida Regional Medical Center.