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The Effects of Nebulized Saline Treatments on Diphthongal Vowel Production on Female Subjects with Sjögren's Syndrome

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ABSTRACT

The Effects of Nebulized Saline Treatments on Diphthongal
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The purpose of this study was to analyze and quantify the effects of a nebulized saline treatment on speech production in eight females with Primary Sjögren's Syndrome (SS). The duration, formant frequency onset and offset, and slope were measured to determine the quality of participants' production of diphthongal American English vowels. Acoustic data were examined before treatment began, immediately following treatment, and during a one-week follow-up to determine the effects of a laryngeal hydration program that used nebulized saline to increase hydration of structures in the vocal tract. The vowels produced during the initial baseline condition were acoustically relatively similar to the productions of typical speakers not diagnosed with SS. Although some differences in mean vowel duration and formant frequency values were found in the recorded vowel productions, results indicated that the participants' vowel productions remained relatively stable across the different phases of treatment. The absence of large treatment effects, in terms of vowel acoustics, may be due to the possibility that although the dryness associated with SS is an irratant for speakers, it may not affect their ability to produce diphthongal vowels in a significant manner.

Keywords: Sjögren's Syndrome, laryngeal hydration, saline treatments, diphthongs

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DESCRIPTION OF STRUCTURE AND CONTENT

This thesis is part of a larger collaborative project, portions of which may be submitted for publication, with the thesis author being one of multiple coauthors. The body of this thesis was written as a manuscript suitable for submission to a peer-reviewed journal in speech-language pathology. The participant consent form, materials related to the study, and an annotated bibliography are presented as noted in List of Appendices.

Introduction

Sjögren's Syndrome (SS) is an autoimmune disease that affects the lacrimal and salivary glands, causing extreme dryness of the eyes and mouth. These characteristics are also known as sicca symptoms that may potentially affect other parts of the body such as the throat, the lower airway, the vagina, and the intestines (Tanner et al., 2013). SS may be organized into two main categories: Primary and Secondary. When there is no other autoimmune condition present, it is considered Primary SS. When another autoimmune disease occurs, such as lupus, rheumatoid arthritis, or mixed connective tissue disease (Kassan & Moutsopoulos, 2004), the result is Secondary SS. SS is most common in females after menopause; however, the disease may also occur in males. According to recent reports, approximately four million individuals are affected by SS in the United States. However, those who are diagnosed with Primary SS are only four in 100,000 (Kruzka & O'Brian, 2009; Pillemer et al., 2001).

Individuals with SS often experience speech, voice, and swallowing problems (Allec et al., 2010; Wheaton, 2007). Most of the literature describing the symptomology of SS addresses swallowing problems, related primarily to dryness and esophageal motility; however, less research has been conducted regarding speech and voice problems with SS. Allec et al. (2010) reported common communication disorders of those with SS included dysphonia and dysarthria, as well as pharyngeal-palatal and lingual-palatal diglossia. Research has also found that individuals with SS may be more prone to sinus symptoms, pulmonary symptoms, sensorineural hearing loss, neurological symptoms, and throat dryness (Freeman, Sheehan, Thorpe, & Rutka, 2005; Stojan, Baer, & Danoff, 2013; Wheaton, 2007). A significant association also exists among SS and laryngeal pathologies, such as pseudosulcus vocalis, thick mucus, granuloma, posterior commissure hypertrophy, bamboo nodules (Mahony, 2003; Ogut et al., 2005; Stojan et al., 2013), partial or complete ventricular obliteration, arytenoid erythema or hyperemia, and gastroesophageal reflux (Ogut et al., 2005).

Ogut et al. (2005) further explain that saliva, which is not produced as freely in those with SS, is effective in denaturalizing the acidic pH and removing the reflux coming from the stomach. Saliva is also a necessary lubricant for speech. Without the necessary amount of saliva, reflux can become an irritant to the dry laryngeal mucosa. This, along with chronic coughing, can greatly affect the voice (Ogut et al., 2005). Auditory-perceptual voice features such as strain, huskiness, hoarseness, and breathiness occur in SS (Allec et al., 2010; Freeman, Sheehan, Thorpe, & Rutka, 2005). Voice symptoms include increased vocal effort and laryngeal dryness (Tanner et al., 2013). Each of these symptoms may have an effect on the individual’s speech and voice.

Laryngeal dryness—or dehydration in general—has an effect on speech and voice. By increasing the viscosity of the fluid in the vocal folds, dehydration increases the phonation threshold pressure (PTP), or the minimal subglottic pressure required to start vibration of the vocal folds (Finkelhor, Titze, & Durham, 1988; Roy, Tanner, Gray, Blomgren, & Fisher, 2003; Titze, 1994; Verdolini-Marston, Titze, & Druker, 1990). Pulmonary effort for phonation may also increase due to thick, tacky mucus (viscous material) on the surface of the vocal folds (Titze, 1994; Verdolini et al., 2002). Vocal fold fluid, both inside and on the surface, is regulated by systemic and surface tissue hydration mechanisms. Systemic hydration is regulated by the kidneys and affected by drinking fluids, as opposed to surface tissue hydration, which is maintained by ionic transport and grandular mechanisms. These two mechanisms are responsible for maintaining vocal fold hydration (Verdolini et al., 2002) and are key in balancing the depth and viscosity of surface fluid (made up of water and mucus layers) of the vocal folds, larynx, and respiratory airway. The depth and viscosity of this surface fluid influences voice production. Decreases in depth and increases in viscosity may be due to environmental humidity changes, making voice production more difficult. Voice disorders have been shown to develop due to prolonged or repeated exposure to environmental dryness (Hemler, Wieneke, & Dejonckere, 1997).

The surface of the airway is lined with a thin mucus layer. This layer of mucus acts as a protection against inhaled irritants and bacteria and is hydrating to the mucosa (Chretien & Nebut, 1996; Proetz, 1953; Rogers, 1994). Two layers form the airway surface liquid (mucus layer): a deeper aqueous (sol) layer consisting of fluid with low viscosity and a gel layer covering the sol layer. The gel layer effectively traps insoluble particles to allow them to be cleared from the airway (Labiris & Dolovich, 2003; Widdicombe, 1997). The sol layer is susceptible to changes in the environmental humidity within the airway (Yeates, 1991), and reductions in the depth of the sol layer due to low environmental humidity could result in heightened viscosity of the gel layer as well as the fluid within the vocal folds. That in turn could make voice production more demanding by increasing phonatory and pulmonary effort (Titze, 1988). More recently, these gel and water layers, as applied to the vocal fold surface, have been termed vocal fold surface fluid (Sivasankar, Carroll, Kasinski, & Rosen, 2013).

The negative effects of low environmental humidity have been documented in several studies. Phonatory instability has been observed to increase after participants inhale dry air (Hemler, Wieneke, & Dejonckere, 1997), suggesting that voice production could be significantly impacted by the effects of surface laryngeal dehydration, even in normal speakers. Reductions in the depth or increases in viscosity of vocal fold surface fluid may be the cause of these negative effects (Sivasankar, Carroll, Kosinski, & Rosen; 2013). The ease of phonation can be reduced due to evaporated water loss brought on by desiccated (dry) air exposure (Hemler et al., 1997). Inhalation of dry air can also increase acoustic measures of jitter and shimmer (Hemler et al., 1997).

Oral breathing has been proven to increase PTP and self-perceived vocal effort (Sivasankar & Fisher, 2002) in normal healthy subjects. This may be due to increased thickness or viscosity of mucus on the surface of the vocal folds, reducing vibratory efficiency or ease. Increases in PTP in typical speakers, as well as those with SS symptoms who report vocal attrition, have been observed within 15 minutes of oral breathing (Sivasankar & Fisher, 2003). Following the oral breathing challenge, negative effects associated with PTP may persist for 60 minutes following the task (Tanner, Roy, Merrill, & Elstad, 2007). In addition, airway fluid lining the larynx and water loss from the vocal fold surface could adversely affect vocal fold oscillation and voice production (Sivasankar, Erickson, Schneider, & Hawes, 2008).

Other studies have attempted to measure the effectiveness of nebulized substances in the hydration of the vocal folds by measuring the PTP and the self-perceived phonatory effort (PPE) before and after treatment. Roy, et al. (2003) conducted an experiment which measured the effects of nebulized water, Mannitol (an osmotic agent), and Entertainer's Secret Throat Relief™ (a glycerin-based product) on vocal fold hydration in 18 vocally healthy females. The results indicated that Mannitol was the only nebulized treatment to significantly lower the PTP after administration; however, its effects lasted only 20 minutes.

In another study, Tanner, et al. (2007) compared hypertonic, isotonic, and hypotonic (water) saline on 60 vocally healthy women. Although the desiccation challenge consistently raised the participant's PTP, none of the saline concentrations were able to significantly lower the PTP after a desiccation challenge. A subsequent study narrowed hydration comparisons to isotonic saline and nebulized water treatments in classical sopranos (Tanner et al., 2010). Results showed that isotonic saline was able to lessen the effects of the desiccation challenge based on PPE ratings; however, the results were not statistically significant. No significant effects were observed for PTP. Limitations of the aforementioned studies are that treatments were only applied once and not tracked over time to determine long-term effectiveness and the treatment techniques were not evaluated on voice disordered populations.

The pathological conditions that cause problems in the vocal mechanism may also result in difficulties with speech articulation. For example, Roy, Nissen, Dromey, and Sapir (2009) studied the effects of muscle tension dysphonia (MTD) on vowel articulation. Participants with MTD were recorded both pre- and post-therapy, which involved manual circumlaryngeal treatment (MCT). The effect of MCT on the production of the four monophthongal corner vowels /i, æ, ɑ, u/ was examined in terms of the first (F1) and second (F2) formant frequencies, vowel space area, and vowel articulation index. Participant's quadrilateral vowel space area and vowel articulation index increased significantly after MCT, suggesting that MTD may also have impact on both vocal functioning and speech articulation.

In a similar study, Dromey, Nissen, Roy, and Merrill (2008) studied the effects of MTD on the diphthongal vowel productions of /eɪ/ and /ɑɪ/ pre- and post-MCT. Significant post-treatment differences were found for the slope of the F1 for /eɪ/, the slope of the F2 for /eɪ/ and /aɪ/, the transition extent of the F1 for /eɪ/, the transition extent of the F2 for /eɪ/ and /aɪ/, duration, speaking time ratio, and perceptual severity. These differences provide some evidence that MTD has an impact beyond the larynx, extending to the articulation of diphthongal vowel sounds.

Research has shown a strong association between the F1 and F2 and several articulatory movements such as tongue height, tongue advancement, and labial protrusion (Ferrand, 2007; Kent & Read, 2002; Rosner & Pickering, 1994). Dysarthric speakers or speakers with normal speech who have experienced induced fatigue have been seen to have flattened F2 transitions. This flattening in F2 transitions causes reduced intelligibility (Solomon, 2000; Weismer, Martin, Kent, & Kent, 1992). Unlike monophthongal vowels, the perception of diphthongal sounds rely in part on the dynamic movement of the tongue from one articulatory position (onset) to a subsequent position (offset). These articulatory positions and intermediate movements of the tongue can then be extrapolated from the acoustic signal in terms of F1 and F2 values, extent, and slope. Compared to the research conducted on monophthongal vowels the amount of normative data describing diphthongal vowel sounds is relatively limited (Gay, 1964; Lehiste & Peterson, 1961; Reeves, 2009; Weil, Fitch, & Wolfe, 2000; Weismer & Berry, 2003), especially for populations facing the challenges of a disease such as Primary SS. Thus, the purpose of this study was to examine the diphthongal vowel production in female speakers with Primary SS and the effects of a home program of laryngeal hydration treatment using nebulized saline.

Method

This thesis describes one portion of a more comprehensive project on nebulized saline treatment on laryngeal hydration, thus the methodology described below is similar in nature to other studies within the project.

Participants

Participants in this study included 8 females with Primary SS (ages 36 to 74 years, mean age 57 years). A chart review was completed by the University of Utah Division of Rheumatology identifying potential study participants, including the review of sicca symptom clinical presentation, antinuclear antibody testing, and/or lip biopsy. All participants lived in the intermountain region, including Utah and Idaho. Appendix B displays present participant medical history factors. Fourteen years was the mean number of years with sicca symptoms (range 3 to 30 years); eleven years was the mean number of years since Primary SS diagnosis (range 2 to 32 years). No participants reported upper respiratory symptoms at the time of study initiation. The Voice Handicap Index had an average total score of 32.5 (range 12 to 62) (Jacobson et al., 1997) at study initiation. The EULAR (European League Against Rheumatism), Sjgören's Syndrome Patient Reported Index (Serar et al., 2012) and the Sicca Symptoms Inventory (Bowman, et al., 2003) were also completed by participants to quantify disease severity prior to study initiation. The University of Utah and Brigham Young University Institutional Review Boards approved all study-related procedures (IRB_00061835).

Procedures

A within-subjects repeated-measures ABAB experimental design was used in the study. Four phases, each phase two weeks in duration, were conducted. Phase one (baseline) required audio-recordings of each participant in the morning and evening every day at similar times. During the second phase (treatment 1), the required twice-daily audio-recordings were followed by the nebulized saline treatment. The nebulized saline treatment contained 9 mL of nebulized isotonic saline ($Na^{+}Cl$) using the Omron MicroAir Nebulizer (Model NE-U22V). Treatment was administered directly after the completion of the audio-recordings and patient-based visual analog scale (VAS) ratings, twice-daily. The intentional collection of audio-recordings and VAS ratings prior to treatment to avoid detecting only short-term effects of nebulized saline on voice production in SS (Tanner et al., 2013). Therefore measurement of treatment effects over time, if any, were facilitated through the present study design. The third phase (withdrawal) withdrew the nebulized treatment and required continued twice-daily audio-recordings and VAS ratings of participants. During phase four (treatment 2), nebulized treatment was resumed.

Audio Recordings

Lists of consonant-vowel-consonant and consonant-vowel-vowel (diphthong) words were recorded. Each set of words was repeated three times in varied order to prevent list effects (see Appendix C). The first paragraph of the Rainbow Passage (Fairbanks, 1960), without the three Consensus Auditory-Perceptual Evaluation of Voice (Kempster, et al., 2009) sentences and three sustained vowels, were included in the audio-recordings. Participants recorded these speech and voice samples using a Zoom Handy Recorder (Model H1) and a head-mounted Audio-Technica cardioid condenser microphone (ATM75-SP-NP). Recordings were sampled at a rate of 96 kHz, with a quantization of 32 bits, and saved on a SanDisk 32 GB microSD card. Each participant was provided written instructions including photographs to ensure correct microphone placement, recording conditions, and procedures (see Appendix C). Participants completed patient-based VAS ratings of vocal effort, mouth dryness, and throat dryness after each audio-recording (see Appendix D).

Acoustic Analysis

Acoustic measures of the diphthongs /eɪ, ɑɪ, oɪ, ɑʊ, oʊ/ were made from the audio recordings of the words *bay*, *bye*, *boy*, *bough*, and *bow*. Frequency tracks for the F1 and F2 were extracted from the diphthongal vowel targets, using PRAAT® acoustic analysis software, version 5.2.17 (Boersma & Weenink, 2004). A linear predictive coding (LPC) based tracking algorithm (Burg method, 11 coefficients) was used to determine formant values for the vocalic segments at approximately 5 ms intervals. The LPC analysis used a 25 ms Hamming window with 50% overlap and 98% pre-emphasis. Each token was visually and auditory monitored to ensure that there were no audible surrounding speech sounds in the analyzed segment. The extracted formant values and associated time points for each vowel target were then saved as a text file. The extracted formant tracks were also evaluated with custom software designed to detect halving or doubling in the extracted formant tracks.

Following the methods of Dromey, et al. (2008), the average F1 and F2 frequencies were calculated at eight different equidistant measurement points through each vowel's overall duration (t1-t8) using the values of the extracted formant tracks. Thus, the introductory 12.5% of the vowel's duration was defined as the average of the formant values in t1, and the final 12.5% was an average of the formant values in t8. At 25% (t2-t3), onset values for the diphthongs were calculated, and at 75% (t6-t7), offset values were calculated. These points were chosen for computing values in order to limit the influence of the consonantal context. The frequency difference between the onset and offset values as a function of time was used to determine the transition duration and formant slope of the diphthongs.

Results

Due to the limited number of participants in the current work, descriptive statistics were used to analyze the vowel production data. Means and standard deviations were calculated for each diphthong in terms of the overall vowel duration, the onset and offset of the F1 and F2, and the formant frequency slope values. These data as a function of the phase of data collection (i.e., baseline, treatment 1, withdrawal, treatment 2) can be found in Tables 1 through 4, respectively.

As shown in Figure 1, mean duration values were calculated for each diphthong across all four phases of data collection. In general, the pattern of differences in duration was similar

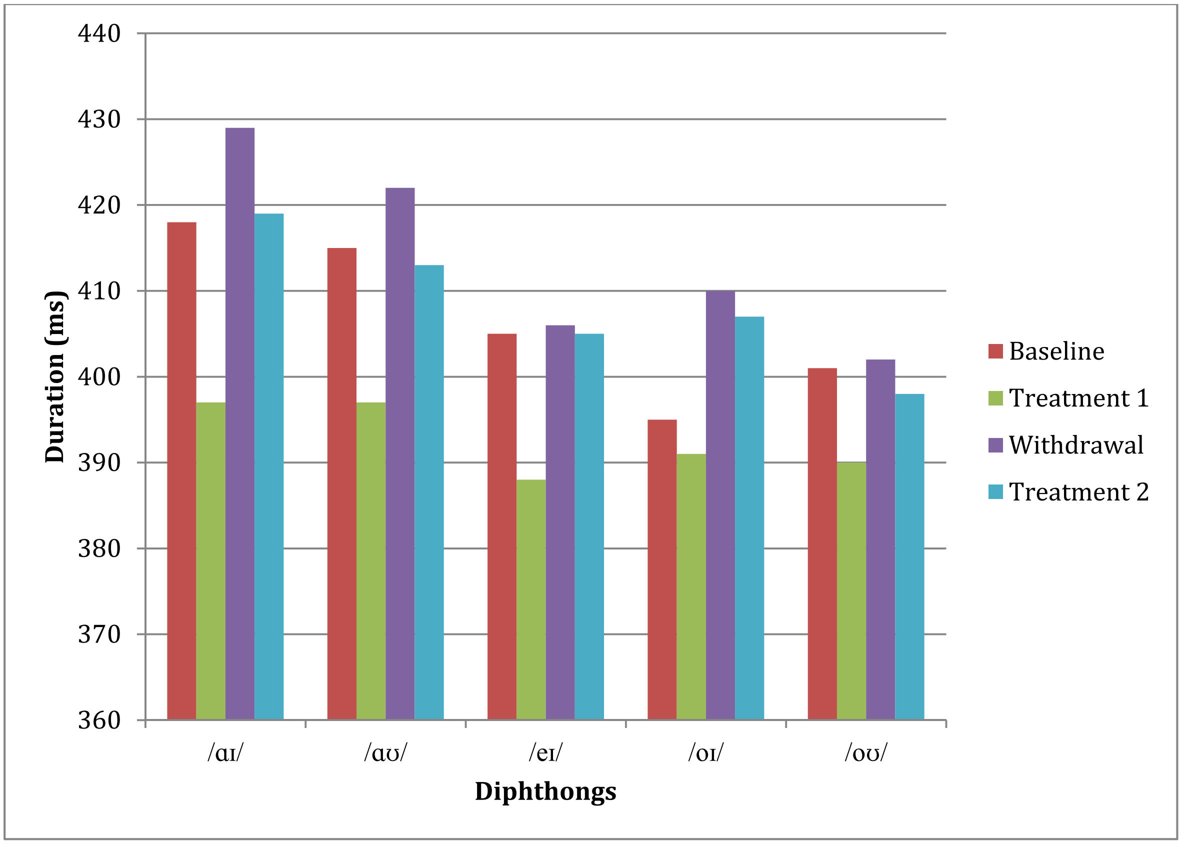

Figure 1. Duration means for the diphthongal vowel productions across the four phases of data collection.

across all five diphthongal vowels. Compared to the mean values collected at baseline (*M* = 407 ms), each of the diphthongs had a decrease in duration during the first treatment phase (*M* = 393 ms), followed by a return to near baseline levels during the withdrawal (*M* = 414 ms) and second treatment phases (*M* = 408 ms). When collapsed across treatment phase, the longest mean duration was found for /ɑɪ/ at (*M* = 416 ms) and the shortest for /oʊ/ at (*M* = 398 ms).

As can be seen by Figures 2 through 4, mean formant frequency onset, offset, and slope measurements were calculated for each diphthong across all four phases of data collection. In general, the mean formant and slope values were relatively similar across the four different phases of data collection. Compared to the values collected at baseline, the largest differences during the first treatment phase were increases in the F2 onset (*M* = 193 Hz) and offset (*M* = 215 Hz) values for the /eɪ/ vowel productions. Across the five different diphthong types, the mean F1 and F2 slope measures differed by less than .19 Hz/ms, respectively.

When comparing the data collected during the withdrawal phase to the baseline values, the largest differences were decreases in the F1 onset (*M* = -79 Hz) and offset (*M* = - 39 Hz) values for /ɑɪ/ vowel productions. Similar mean differences were found in the F1 onset and offset values for /ɑʊ/ at -53 Hz and -66 Hz, respectively. Across the five different diphthong types, the mean F1 and F2 slope measures differed by less than .23 and .28 Hz/ms, respectively.

The largest acoustic differences between the diphthongs produced during the baseline and second treatment phase were decreases in the mean F2 onset (*M* = - 85 Hz) and offset (*M* = - 98 Hz) values for the /eɪ/ vowel productions. The mean differences in the F1 and F2 slope were .06 Hz/ms and .16 Hz/ms, respectively.

Discussion

The impact of the nebulized saline treatment on participants' productions of diphthongs differed across the various acoustic measures analyzed in this study. The pattern of differences in duration was similar across all five diphthongal vowels, with the mean duration decreasing after the first treatment phase, but increasing to near baseline values during the withdrawal and second treatment phase. The formant onset and offset values were relatively similar across the different phases of data collection and types of diphthongal vowels. The largest differences, compared to the baseline values, during both the first and second treatment phases involved the F2 onset and offset values for the /eɪ/ diphthong. The largest difference from baseline during the withdrawal phase was found in the F1 onset and offset values for /ɑɪ/ and /ɑʊ/. The slope remained relatively

Table 1

Duration, Formant Frequency, and Formant Slope Measurements of Diphthong Tokens Produced During the Baseline Phase of Data Collection

Vowel	Duration[a]		F1 onset[b]		F2 onset[b]		F1 offset[b]		F2 offset[b]		F1slope[c]		F2 slope[c]	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
/ɑɪ/	418	77	863	115	1504	174	612	115	2059	235	-1.23	0.52	2.52	1.33
/ɑu/	415	83	843	227	1847	227	611	120	1358	337	-1.07	0.42	-2.18	0.82
/eɪ/	405	73	558	82	2197	260	440	47	2651	162	-0.56	0.23	2.31	1.29
/oɪ/	395	73	520	73	979	131	496	92	2075	244	-0.24	0.38	5.05	0.95
/oʊ/	401	71	645	110	1207	149	461	81	1151	324	-0.89	0.44	-0.29	0.97

Notes: [a]duration is measured in milliseconds, [b]onset and offset are measured in hertz, [c]slope is measured in hertz per millisecond.

Table 2

Duration, Formant Frequency, and Formant Slope Measurements of Diphthong Tokens Produced During the First Treatment Phase of Data Collection

Vowel	Duration[a]		F1 onset[b]		F2 onset[b]		F1 offset[b]		F2 offset[b]		F1slope[c]		F2 slope[c]	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
/ɑɪ/	397	63	842	157	1476	198	608	154	1986	266	-1.15	0.61	2.39	1.16
/ɑu/	397	60	780	185	1781	277	600	146	1378	296	-0.88	0.65	-1.99	0.85
/eɪ/	388	48	535	77	2004	347	434	65	2436	485	-0.51	0.20	2.25	1.59
/oɪ/	391	56	517	80	989	128	498	89	2048	241	-0.23	0.45	4.94	1.34
/oʊ/	390	67	654	68	1221	126	472	86	1179	271	-0.97	0.57	-0.23	0.90

Notes: [a]duration is measured in milliseconds, [b]onset and offset are measured in hertz, [c]slope is measured in hertz per millisecond.

Table 3

Duration, Formant Frequency, and Formant Slope Measurements of Diphthong Tokens Produced During the Withdrawal Phase of Data Collection

Vowel	Duration[a]		F1 onset[b]		F2 onset[b]		F1 offset[b]		F2 offset[b]		F1slope[c]		F2 slope[c]	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
/ɑɪ/	429	91	784	134	1485	162	573	104	2066	185	-1.00	0.48	2.55	1.08
/ɑu/	422	86	790	156	1825	246	555	115	1348	303	-1.05	0.41	-2.12	0.63
/eɪ/	406	66	546	74	2193	264	434	41	2606	225	-0.54	0.21	2.07	1.28
/oɪ/	410	71	525	57	1025	96	461	88	2099	211	-0.35	0.28	4.78	0.77
/oʊ/	402	72	624	88	1187	155	456	64	1188	271	-0.79	0.46	-0.01	0.87

Notes: [a]duration is measured in milliseconds, [b]onset and offset are measured in hertz, [c]slope is measured in hertz per millisecond.

Table 4

Duration, Formant Frequency, and Formant Slope Measurements of Diphthong Tokens Produced During the Second Treatment Phase of Data Collection

Vowel	Duration[a]		F1 onset[b]		F2 onset[b]		F1 offset[b]		F2 offset[b]		F1slope[c]		F2 slope[c]	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
/ɑɪ/	419	87	852	130	1510	161	597	107	2082	215	-1.22	0.50	2.56	1.24
/ɑu/	413	84	803	150	1815	215	601	130	1405	309	-0.90	0.45	-1.89	0.70
/eɪ/	405	75	542	72	2112	251	437	55	2553	254	-0.48	0.20	2.26	1.52
/oɪ/	407	77	508	79	1009	120	475	84	2075	241	-0.24	0.34	4.84	1.03
/oʊ/	398	76	636	114	1195	138	457	77	1176	291	-0.86	0.52	-0.02	1.12

Notes: [a]duration is measured in milliseconds, [b]onset and offset are measured in hertz, [c]slope is measured in hertz per millisecond.

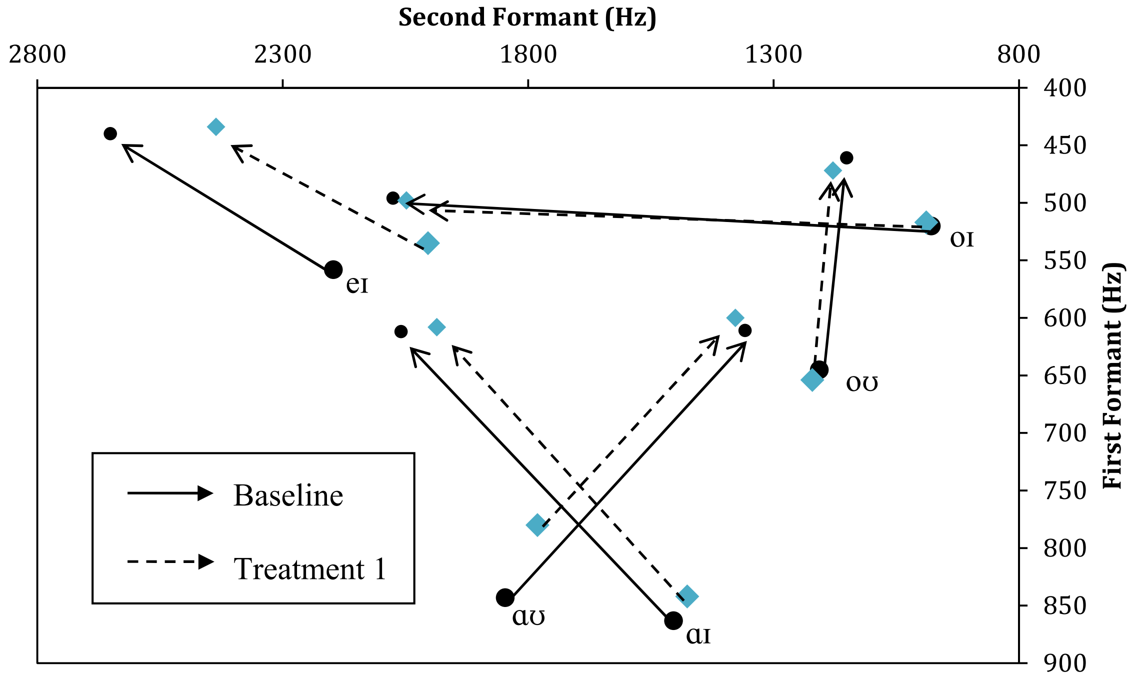

Figure 2. Formant frequency and slope values from the baseline and first treatment phase of data collection.

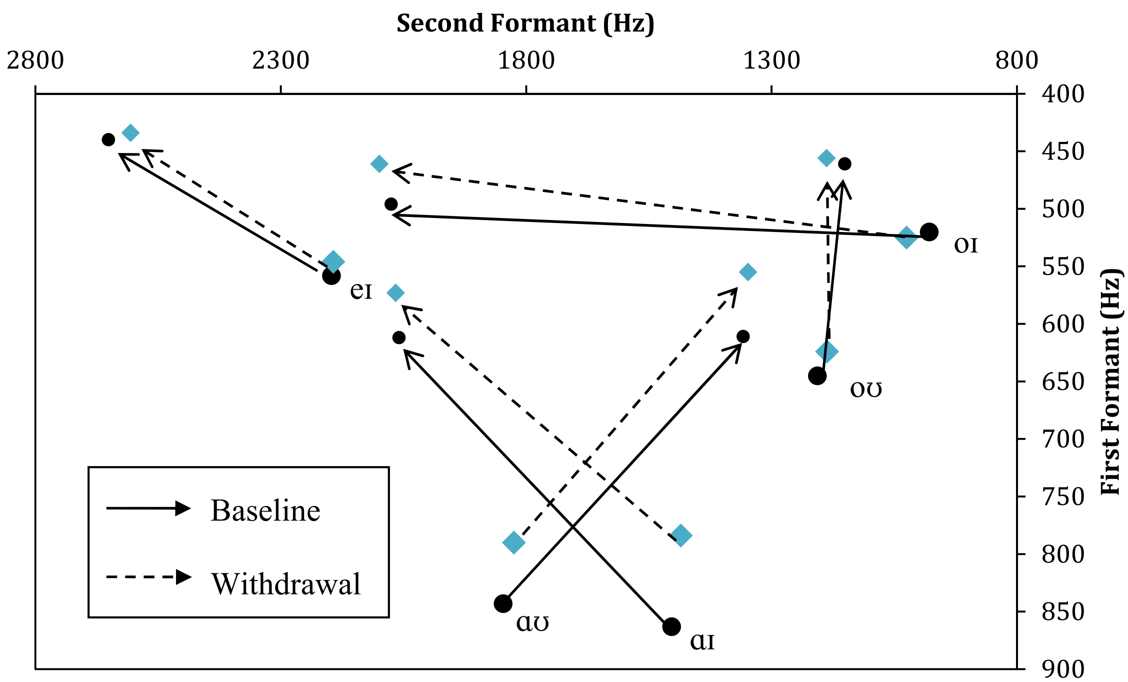

Figure 3. Formant frequency and slope values from the baseline and withdrawal phase of data collection.

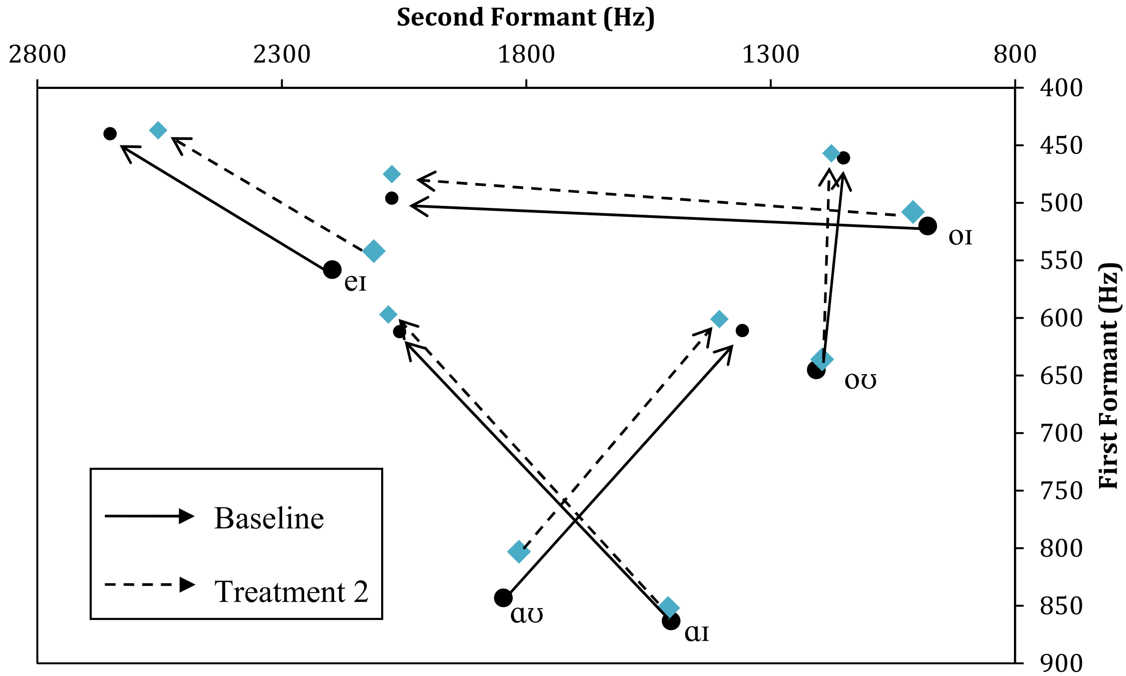

Figure 4. Formant frequency and slope values from the baseline and second treatment phase of data collection.

stable across the different phases of data collection. These relatively small acoustic differences between the initial baseline productions and the data recorded during the treatment and withdrawal periods may be due to the possibility that the participants' vowel production at baseline may be close to those exhibited by typical speakers.

A number of previous studies have described the acoustics of diphthongal vowel productions by typical adult speakers of American English. Weil, et al. (2000) studied the differences in vowel acoustics of /ɑɪ/ as four individuals shifted their style of speaking from Standard American English to a regional dialect of Southern English. Weismer and Berry (2003) provided normative data on the effects of speaking rates on F2 trajectories of the diphthong /oɪ/ from three adult female speakers with a Northern Midwestern dialect of American English (Wisconsin, Minnesota, and Iowa). Additional data on diphthongal durations, formant frequencies, and slopes were also reported in early studies (Gay, 1964; Lehiste & Peterson, 1961). The patterns of diphthong production in the current study are generally similar to the data presented in the research presented previously. However, these comparisons are tenuous considering the demographics of the participant's with SS described in this study (female speakers from the Intermountain region of the United States, i.e. Utah and Idaho).

A more valid comparison may be to an unpublished dataset reported by Reeves (2009), as shown in Figure 5. The study by Reeves examined the diphthongal vowel productions of 35 adult female speakers who originate and have lived in Utah through adulthood. Although the word stimuli in the two studies were different (e.g., /hɑɪd/ vs. /bɑɪ/), the analysis techniques used to extract the formant frequencies and slope values of the recorded diphthongs were the same as those used in the current study. As illustrated in Figure 5, a comparison of the data from the typical speakers in the Reeves study and the baseline data from the current study reveals general

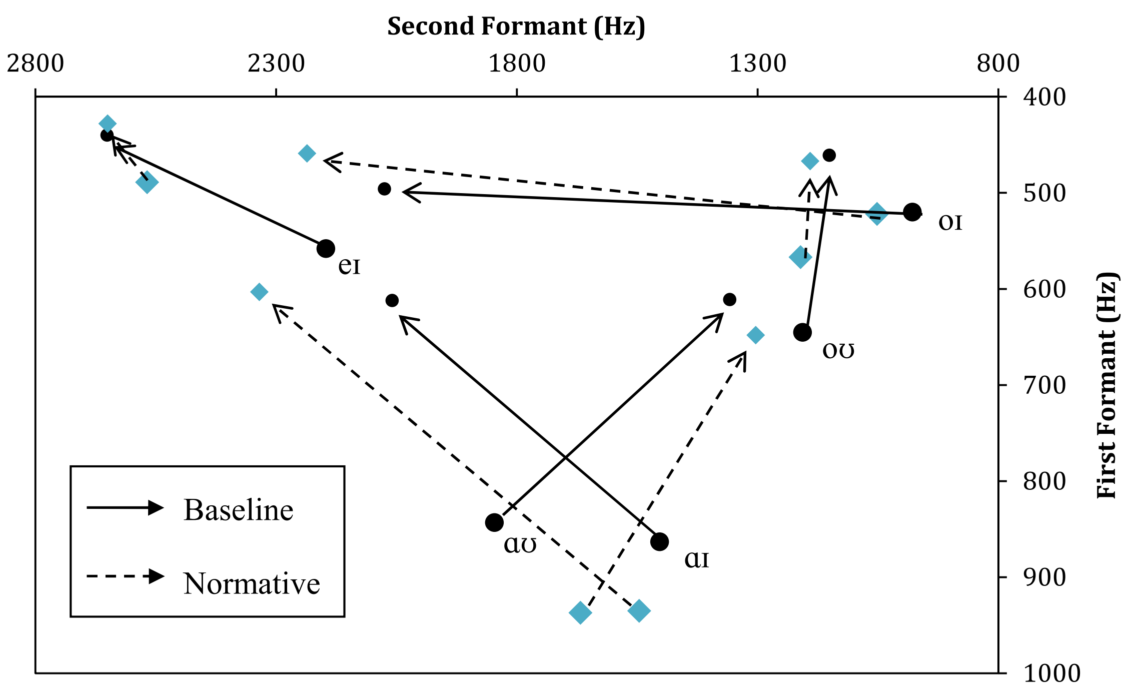

Figure 5. Formant frequency and slope values from the baseline and normative data collection.

similarities in the patterns of vowel productions. Some differences can be seen in the formant frequencies in four of the five diphthong tokens /eɪ, ɑɪ, ɑʊ, oʊ/, thereby also resulting in the decreased transitional extent in the non-phonemic diphthong productions (/eɪ/ and /oʊ/). These differences may be due to the debilitative characteristics of Primary SS, but may also be the result of other uncontrolled factors such as differences in the age of the participants, the data collection (e.g., word type), the speech rate, or the elicitation environment.

The lack of large treatment effects found in the current study varied from the results reported by Dromey et al. (2008), a study which investigated the efficacy of CMT on the diphthong production in individuals with MTD. There are a number of reasons why the results of the two studies may have differed. Although both the study population in the Dromey et al. article and the population in the current work experienced voice disorders, the disorders have differing organic origins. The MTD population experience a voice disorder caused by muscle tension affecting intrinsic muscles of the articulators, whereas a voice disorder caused by Primary SS is often a result of dehydration of superficial tissue in the vocal tract. In addition, it is important to note that the individuals who participated in the current study were diagnosed as having a mild/moderate voice disorder. The effects of the hydration treatment used in the current study may change when used with individuals who exhibit a more severe voice disorder.

This study examined the acoustic characteristics of vowels from individuals with a disorder that results in a mild to moderate impairment of their voice and speech. Considering the complex nature of speech, which may involve a number of different sound sources and separate articulators, it is difficult to causally link the symptoms associated with Primary SS to a particular manner of speech sound productions, such as diphthongal vowels. The general similarities between the data collected in this study and data from typical speakers may indicate that the perception of disordered speech is caused by a misarticulationq of the consonant speech sounds rather than vowels. Thus the measures of disease and severity reported in the patient-based ratings may not be caused by a misarticulation of the diphthongs.

Several limitations in the current work may offer beneficial direction for future research with the SS population. The limited number of participants and range of disease severity examined in the current study makes it difficult to generalize these results to all patients with SS. Although SS is primarily manifested in women, it would also be of value in the future studies to examine the effects of Primary SS and associated hydration treatments on male individuals. It may also be of value to collect more naturalistic speech samples, in an environment that provides the opportunity to obtain a higher quality speech sound recording. For example, recording participant's speech in a sound attenuated booth would provide the basis for more accurate measurement of the formant data, which is highly sensitive to background noise.

Despite these limitations, the present study has much to offer in the clinical description and treatment of Primary SS. As previously stated, Primary SS is a rare disease and compared to previous studies the number of participants and the relatively large number of individual speech tokens examined in this study increases the validity of the reported result. The effects of Primary SS can markedly decrease the quality of life for those individuals with the disease, as well as their friends and family. Although further research is needed, it is hoped that this study will provide a greater understanding of the impact of the disease on speech communication and how it might be more effectively treated in the future.

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Appendix A: Annotated Bibliography

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Objective: The aim of this study was to examine the voice, swallowing, and speech abnormalities in individuals with SS. *Method*: Participants included 31 individuals with a diagnosis of SS without any history of phoniatric alterations or vocal pathologies that were distinct from SS. Interviews were performed and participants were examined physically using video laryngeal stroboscopy and nasolaryngeal endoscope. Analysis of voice and speech were performed using computerized voice spectrographic analysis (software) along with a swallowing evaluation using fiberoptic endoscopy. *Results*: Abnormalities were found principally in: nasopharyngolaryngeal mucosa (77.4%), mucosal wave of vocal folds (90%), cranial nerves (V, VII, IX, X, XII) (67.7%), spectrogram of the vowels /e/ (58.06%) and /i/ (51.61%), swallowing mechanism (90.3%), and rhythm of the *pa-ta-ka* (35.48%). *Discussion*: Significant voice, speech, and swallowing abnormalities are common in individuals with SS. One hypothesis is that xerosis and possible secondary neurological abnormalities in SS are associated with the aforementioned abnormalities. *Relevance to the current study*: The current study examined the voice and speech of individuals with SS and this article proved that individuals with SS experience abnormalities in voice, speech, and swallowing. Further, PRAAT® software was used in the current study to examine the participant's RFF.

Bowman, S. J., Booth, D. A., Platts, R. G., Field, A., Rostron, J., & the UK Sjogren's Interest Group. (2003). Validation of the Sicca Symptoms Inventory for clinical studies of Sjögren's Syndrome. *The Journal of Rheumatology,* 30, 1259-1266.

Objective: This study aimed to create a new measure of symptoms of mucosal surface (sicca) in order to evaluate individuals with Primary SS. *Method*: Participants in this study included groups of patients clinically diagnosed with SS, systematic lupus erythematous, and rheumatoid arthritis, all of whom were Caucasian females. Along with a healthy control group, these groups were assessed for saliva and tear production. They completed a symptoms-profiling inventory that included self-reported and construct-validated items of SS patients. *Results*: About 70 surveys were filled out which showed strong correlations between the domains of long- and short-term. *Discussion*: Strong correlations between the long and short form PROFAD-SSI questionnaires suggesting the validity of the short-form as a tool. This data also implies that an even more concise questionnaire is possible. *Relevance to the current study*: In the current work, participants' symptoms were rated using the short form of the SSI assessment.

Clopper, C. G., & Paolillo, J. C. (2006). North American English vowels: A factor-analytic perspective. *Literary and linguistic computing*, *21*, 445-462. doi: I0.1093/llc/fql039

Objective: The purpose of this study was to compare linguistic features of vowels from varying sets of speakers (dialects) based on measures of vowel space. *Method*: Forty eight speakers from the six dialect regions of the United States (24 men and 24 women split evenly in the six regions) were recorded saying the /i, ɪ, ɑ, æ, u, ʊ, o, ʌ, ɛ/ in h_d contexts. They were also recorded saying /ɔ, ɑɪ, oɪ, ɑu/ in CVC combinations. One factor analysis looked at the relationships of the five acoustic measures. The second analysis looked at the relationship between production and dialect and individual speakers. *Results*: Females have greater variance in F1/F2 scores. Charted data showed typical vowel space for vowels. Gender, minimum F1 and F2, vowel duration, back vowel fronting, and the NCCS were major factors in a group of speakers that vary in gender and dialect and measures of vowel production. *Discussion*: Gender is likely a large factor in vowel variation in NAE. Data also revealed that F1 and F2 are key to measuring vowel distinctiveness. *Relevance to current study*: Clopper et al. discovered some of the aspects of vowel production that affect speech perception and dialect discrimination. This was helpful as the current study sought to identify changes in diphthongal production in patients with SS.

Clopper, C., Levi, S., & Pisoni, D (2004). Some acoustic cues for the perceptual categorization of American English regional dialects. *Journal of Phonetics*, *32*, 111-140. doi: 10.1044/1092-4388(2011/10-0278)

Objective: This study aimed to determine the acoustic characteristics that naïve listeners use to distinguish between different dialects and determine where a speaker is from. This study analyzed both speech production and perception cues. *Method*: A total of 66 speakers were selected with 11 speakers from each regional dialect area in the United States (New England, North, North Midland, South Midland, South, and West). The speakers were selected from TIMIT Acoustic-Phonetic Continuous Speech Corpus and were all males between the ages 20 and 29 at the time of the recordings. Frequency measurements were made for all of the recordings. Twenty-three listeners were chosen from the undergrad program at Indiana University. Listeners were to listen to each of the 66 speakers and place them in a dialect region. *Results*: Means for vowel brightness, /oʊ/ backness, /æ/ diphthongization, /ɑɪ/ diphthongization, and /oɪ/ diphthongization didn't differ significantly across dialects. Listeners were only able to correctly place 33% of the first calibration sentences, 28% of the second calibration sentences, and 33% of the novel sentences. *Discussion*: Overall perception scores were low, but statistically listeners did better than had been anticipated. The results prove that the speakers consistently produced phonologically distinct phrases that could be measured acoustically. *Relevance to current study*: The current study analyzed the acoustical changes in diphthongs of patients with SS before and after nebulized saline treatment. The theories presented in this study by Clopper, Levi and Pisoni helped in understanding the acoustic data received compared to the patient's perceptual data in the current study.

Dromey, C., Nissen, S. L., Roy, N., & Merrill, R. M. (2008). Articulatory changes following treatment of muscle tension dysphonia: Preliminary acoustic evidence. *Journal of Speech, Language, and Hearing Research, 51*, 196. doi:10.1044/1092-4388(2008/015)

Objective: This study aimed to discover if there is acoustic evidence for articulatory changes in the diphthongs /eɪ/ and /ɑɪ/ after successful treatment of Muscle Tension Dysphonia

(MTD). *Method*: One hundred and eleven women with MTD were recorded pre- and post-treatment to analyze any acoustic evidence of supraglottal vocal tract changes that may indicate voice improvement. Perceptual ratings of dysphonia severity were used to confirm acoustic evidence. F1 and F2 frequencies were measured in the diphthongs. To compare these formants to normative data, global measures of speech timing were also acquired from the participants. Younger females with normal voices were also recorded twice as a control group. *Results*: Speech continuity was evident for speakers with MTD through F2 transition increases in slope and timing measures when compared to the controls. *Discussion:* Individuals with MTD may experience changes in articulatory and phonatory behaviors after successful treatment targeting the larynx. *Relevance to current study*: The current study analyzed data in a similar manner as was used in this study by Dromey et al.

Dromey, C., Heaton, E., & Hopkin, J. A. (2011). The acoustic effects of vowel equalization training in singers. *Journal of Voice, 25,* 678-682. doi:10.1016/j.jvoice.2010.09.003

Objective: The purpose of this study was to analyze the effects of one voice lesson on vowel equalization on the formant frequencies of singers. *Method*: Sixteen amateur singers who sing at least one hour a day were recorded individually singing *Somewhere Over the Rainbow*, and then their vowels were recorded in isolation. Singers were trained in the vowel equalization technique for 15 minutes. After training and coaching, singers were asked to re-record the song three times, as well as their vowels in isolation. *Results*: Results were analyzed using *Praat*. In the singing passage, F1 and F2 of /ɑ/ decreased after training. /e/ and /i/ also experienced more neutral placement. The vowels in isolation also tended to neutralize after equalization training. F2 for /e/ and /i/ decreased while for /u/ it increased. *Discussion*: Singers may be able to benefit from training in their attempts to neutralize their vowels and balance between brightness and warmth. Limitations of the study include that tongue height was not analyzed in as great of detail as tongue advancement. *Relevance to current study*: Vowels are affected by oral and pharyngeal space as discussed by this article. The current work analyzed the changes in diphthongs in response to nebulized saline treatment.

Erickson-Levendoski, E., & Sivasankar, M. (2011). Investigating the effects of caffeine on phonation. *Journal of Voice, 25*, e215-e219. doi:10.1016/j.jvoice.2011.02.009

Objective: The aim of this study was to analyze how voice production is affected by caffeine consumption and vocal loading. Specifically, the authors examined if caffeine can affect vocal production adversely, and if caffeine makes the adverse phonatory effects of vocal loading (i.e., speaking for prolonged periods of time with background noise) worse. *Method*: Two groups of 16 healthy participants consumed a caffeine concentrate of 480 mg or 24 mg. Participants' voice measures were taken as participants completed the vocal loading task. *Results*: The authors found that voice production was not adversely affected by caffeine consumption. In addition, vocal loading was not worsened by caffeine. *Discussion*: It was suggested that individuals should be appraised individually as to whether, as part of their vocal hygiene program, they should be recommended to eliminate caffeine. *Relevance to the current study*: Similar to this study, the current work sought to determine if a consumed or nebulized substance can have an effect on the voice production of individuals. The current study however, looked at nebulized saline on the voice and speech production of those with SS.

Finkelhor, B. K., Titze, I. R., & Durham, P. L. (1988). The effect of viscosity changes in the vocal folds on the range of oscillation. Journal of Voice, 1, 320-325. http://www.sciencedirect.com.erl.lib.byu.edu/science/article/pii/S0892199788800055

Objective: This study examined the effects of viscosity changes in four canine larynges by the internal environment of the vocal folds. *Method:* Several osmotic solutions were administered to the larynges and measurements were taken of the fluid transport in and out of each of the canine larynges. *Results:* In each hydration condition, the oscillation threshold pressure shifted. *Discussion:* The threshold of oscillation was raised with an increased viscosity of vocal fold tissue (decreased hydration). Threshold of oscillation was lowered with a decreased viscosity of vocal fold tissue (increased hydration). *Relevance to the current work:* This study demonstrated a step toward understanding functional disorders related to or caused by vocal fold dehydration.

Fox, R. A., & Jacewicz, E. (2009). Cross-dialectal variation in formant dynamics of American English vowels. The *Journal of the Acoustical Society of America, 126,* 2603-2618. Retrieved from http://search.proquest.com/docview/742779841?accountid=4488. doi: 10.1121/1.3212921

Objective: The purpose of this study was to analyze a series of target vowels in three different dialects of American English (Western North Carolina, Central Ohio, and Southern Wisconsin). *Method*: Speakers included 48 women from the ages of 51-56, 16 women from each dialect region. Five vowels were evaluated (/æ, ɪ, ɛ, aɪ, e/) in /bVdz/ and /bVts/ words. The target words were recorded in sentences that included both emphatic and nonemphatic vowels. The first two formants were analyzed, as well as the vowel duration, the vector length (F1 by F2 plane), and the spectral rate of change. Formants were measured at five different times throughout the duration of each vowel. *Results*: The authors found that vowel vowels were longer when followed by voiced consonants (means = 213 and 166 ms, respectively) and that emphasized vowels had longer durations than nonemphatic vowels (means = 217 and 161 ms, respectively). Duration also differed significantly as function of dialect, most notably with speakers from Wisconsin and North Carolina (means = 171 and 211 ms, respectively). Vowels varied greatly in regards to F1 and F2. North Carolina's /ɪ, ɛ, aɪ/ were the most fronted. The effect of emphasis was most evident for North Carolina's /æ/ and the effect of context was greatest on Ohio's /æ/. *Discussion*: This study discovered more about what aspects affect dialectal differences in vowels. It was evident from this research that the speaker's vowel duration, emphasis, and spectral rate of change varied depending on their dialect. *Relevance to current study*: Fox et al. described several acoustic aspects to examine in order to determine the distinctness of vowels in a given population. The current study examined diphthongs in a SS population and used several of these acoustic aspects.

Fridland, V., Bartlett, K., & Kreuz, R. (2004). Do you hear what I hear? Experimental measurement of the perceptual salience of acoustically manipulated vowel variants by Southern speakers in Memphis, TN. *Language Variation and Change, 16,* 1-16. doi: 10.10170S0954394504161012

Objective: This study examined the perceptual awareness and social values of certain vowels as they differ from between Southern and Northern shifts based on manipulated speech samples. *Method*: Two European-American speakers from Memphis, Tennessee were chosen to read a list of monosyllabic words with the vowels /i/, /ɪ/, /oʊ/, /ə/, /u/, /eɪ/, and /ɛ/. The speakers included one male and one female. ASL speech synthesis software from Kay Elemetrics Computer Speech Lab (CSL) was used to manipulate the F1 and F2 of each vowel. Vowels were manipulated to replicate the Southern shift. One hundred and forty-one African-American and European-Americans listened to the words after they were resynthesized and asked to determine which of the words sounded more Southern. All listeners were native to Memphis, Tennessee. *Results*: Listeners had a 58% success rate at identifying the more Southern word, t (140) = 10.02, $p < .01$. Listeners were more accurate with the front vowel subsets compared to the back vowel subsets t (140) = 2.23, $p < .05$. *Discussion*: The authors concluded that mid-front vowels were more influential in socially identifying Southern words. Both the production and perception of vowels were closely interlinked and with only a few phonetic cues listeners seemed to make social judgments on dialect. *Relevance to current study*: Fridland et al. explored the perceptual awareness of vowels in determining dialect. This information was important in the current study as it sought to determine the differences in diphthongs of a SS population compared with and without treatment.

Hemler, R. J., Wieneke, G. H., & Dejonckere, P. H. (1997). The effect of relative humidity of inhaled air on acoustic parameters of voice in normal subjects. *Journal of Voice, 11*, 295-300. doi:10.1007/s004050100321

Objective: The purpose of this study was to determine if the effects of relative humidity (RH) on the voice can be verified. *Method*: Three different substances (dry air, standard room air, and humidified air) were inhaled by eight healthy individuals. Participants produced a sustained /ɑ/ at a controlled pitch and loudness multiple times. Perturbation and noise-to-harmonic parameters were analyzed in the sustained vowel recordings. *Results*: Perturbation increased after the inhalation of dry air. There was no significant difference between standard and humidified air with regards to the noise-to-harmonic ratio. *Discussion*: The researchers concluded that the human voice is sensitive to decreases in RH of inhaled air due to the significant increases that were found in perturbation after a short period of time inhaling dry air. *Relevance to current study*: RH and the effects it has on the voice were discussed in the current study.

Hillenbrand, J., Getty, L. A., Clark, M. J., & Wheeler, K. (1995). Acoustic characteristics of American English vowels. *The Journal of the Acoustical Society of America, 97*, 3099. doi:00001-4966/95/97/3099/13/$6.00

Objective: This study attempted to expand on previous research regarding vowel acoustics measured by Peterson and Barney (1952). *Method*: Forty-five men, 48 women, and 46 adolescent children (27 boys, 19 girls) were recorded saying 12 vowels (i, ɪ, e, ɛ, æ, ɑ, ɔ, o, ʊ, u, v, ɚ). The majority of the speakers originated from Michigan and all underwent a series of screenings, including a dialect assessment. The vowels were produced in h-V-d syllables and both the vowels' duration and the first four formants were calculated. *Results*: Men's vowel durations were significantly shorter compared to both women and children, $F[2,33] = 9.04$, $p < 0.001$. These data suggest that tongue positions tended to be lower and in some cases more anterior than in the Peterson and Barney (1952) study. *Discussion*: This study provides a large normative data set on the fundamental and formant frequency values of these different groups of American English speakers. Minor differences were found between the Hillenbrand et al. and Peterson and Barney studies, possibly attributed to Hillenbrand et al.'s use of LPC. *Relevance to current study*: Hillenbrand et al. indicated that while normative data from the Peterson and Barney study have typically been held as the standard for American English vowels, such standards should be created for specific dialects at certain points in time.

Jacewicz, E., Fox, R. A., & Salmons, J. (2011). Vowel change across three age groups of speakers in three regional varieties of American English. *Journal of Phonetics, 39,* 683-693. doi:10.1016/j.wocn.2011.07.003

Objective: The purpose of this study was to examine vowels (/i, e, æ/) in three regional areas across three generations of female speakers. *Method*: One hundred and twenty-three female speakers from the ages of 20 to 65 years old participated in this study. Speakers were born in either western North Carolina, central Ohio, or southeastern Wisconsin. Emphatic and non-emphatic vowels were tested in sentence pairs. F1 and F2 were measured at multiple points of each target vowel. Vowel duration, trajectory length, and spectral centroid were also measured. *Results:* Mean vowel durations differed significantly (156 ms for/i/, 174 ms for/e/, and 239 ms for/æ/) across the three vowel types. NC vowels were more fronted than OH vowels. All vowels differed in formant frequencies. *Discussion:* The results proved that there is a shift in the way /ɪ, ɛ, æ/ are produced which leans toward more monophthongization. They proved the changes of vowel acoustics throughout time and across regions. *Relevance to current work:* Jacewicz et al. helped us understand that vowel acoustics vary with location and time which was important in the current work as vowels in SS are compared with norms.

Labov, W., Ash, S., & Boberg, C. (2006). *The Atlas of North American English.* Berlin, Germany: Mouton de Gruyter. http://books.google.com/books?hl=en&lr=&id=tsPvynQtlMoC&oi=fnd&pg=PR1&dq=The+Atlas+of+North+American+English&ots=EXU1Aqpjcw&sig=gcm7TnfMLDkNuM0I0Xml2IKTQ00#v=onepage&q=The%20Atlas%20of%20North%20American%20English&f=false

Objective: This book sought to provide a widespread view of phonology and pronunciation throughout North America. It was based on data collected from a series of telephone conversations. *Relevance to current work:* The Atlas of North American English defined and characterized the vowels used by speakers of North America. It discussed the features of phonology and pronunciation. This was important to the current study as it explored the pronunciation of diphthong vowels in individuals with SS.

Neel, A. (2008). Vowel space characteristics and vowel identification accuracy. *Journal of Speech, Language, and Hearing Research, 51,* 574-585. doi:10.1044/1092-4388(2008/041)

Objective: Neel attempts to discover the necessity of various production characteristics in the intelligibility of vowels in adults. *Method*: Ten vowel types from the Hillenbrand et al. study were studied (/ɔ/ and /ɚ/ were eliminated). The vowel space location was measured for each vowel using two methods, Bark units and mean Euclidean distances. *Results*: Women were found to have larger relative vowel space areas, as well as F1 and F2 distances, F0 ranges, and mean distance among vowels than men. *Discussion*: The greatest reason for the differences among vowel identification was failure of talkers to adequately distinguish between the neighboring vowel pairs /æ/–/e/ and /ɑ/-/ʌ/. In that respect, vowel characteristics (formant frequency, mean duration, mean fundamental frequency) had little to do with vowel discrimination. Vowel space had less of an impact in vowel identification than vowel distinctiveness between neighboring vowels. *Relevance to current work*: Neel et al. helped us understand where differences in distinguishing vowels may come in to play. This was helpful as the current study attempted to identify distinctions in diphthongs of SS patients before and after a nebulized saline treatment.

Ogut, F., Midilli, R., Oder, G., Engin, E. Z., Karci, B., & Kabasakal, Y. (2005). *Laryngeal findings and voice quality in Sjögren's syndrome. Auris Nasus Larynx, 32*, 375-380. doi:10.1016/j.anl.2005.05.016

Objective: The purpose of this study was to analyze the effects of SS on perceptual ratings of the laryngeal findings and objective voice quality. *Method*: Two groups (a group of individuals with SS and a control group) were studied using the Reflux Symptom Index, laryngoscopic-based scale, outcomes instrument for symptom assessment, and the Reflux Finding Score for laryngeal findings. They were also studied with the Multi Dimensional Voice Program to analyze the voice samples. A t-test was applied to compare results. *Results*: There was significant differences between those with SS and the control group for The Reflux Symptom Index and the Reflux Finding Score. The voice quality measures were also significantly different for SS individuals and the control group. *Discussion*: Laryngeal pathologies are more common in those with SS than in those without. The cause of increased frequency of reflux is hypothesized as the lack of saliva and esophageal pressure. *Relevance to current study*: The current study aimed to address the vocal fold hydration of those with

SS. Ogut et al. explained the differences in the larynx and voice quality in SS patients compared with those without.

Peterson, G., & Barney, H. (1952). Control methods used in a study of the vowels. *The Journal of the Acoustical Society of America, 24*, 175-184. http://www.ling.ohio-state.edu/~pwong/ling500/Module3-Vowels/Article/Peterson_and_Barney.pdf

Objective: This study analyzed the relationship between the intended vowel phoneme and the perceived vowel phoneme. *Method*: Seventy six individuals (33 men, 28 women, 15 children) were recorded saying a combined total of 1520 words. Seventy listeners were chosen to listen to the words at random to identify the words/vowel phonemes. Ten vowels were analyzed. Frequency and amplitude of formants were recorded. Overall recording performance was measured with a calibration technique. *Results:* /i/, /ɚ/, /æ/, and /u/ are well understood by most people whereas /ɑ/ and /ɔ/ are much more challenging. Substitutions made by listeners can probably be accounted for by differing dialects (they hear what they are used to hearing). There was overlap between vowel formants, particularly between /ɚ/ and /ɛ/, /ɚ/ and /ʊ/, /u/ and /ʊ/, and /ɑ/ and /ɔ/. *Discussion:* Previous language background plays a part in both vowel perception and production. Some vowels are naturally understood better than others. *Relevance to current study*: Peterson et al. proved that previous language experience plays a part in perception and production of vowels. The current study addressed the acoustical changes in diphthongs in a given population.

Roy, N., Tanner, K., Gray, S. D., Blomgren, M., & Fisher, K. V. (2003). An evaluation of the effects of three laryngeal lubricants on phonation threshold pressure (PTP). *Journal of Voice, 17*, 331-342. doi:10.1067/S0892-1997(03)00078-X

Objective: This study aimed to evaluate the effects water, mannitol, and Entertainer's Secret Throat relief (laryngeal lubricants) on phonatory function. *Method*: Eighteen healthy females' phonation threshold pressures (PTP) were measured twice before treatment and four time after 2 mL of each substance were nebulized. Over three weeks, participants were tested once a week and a different nebulized treatment was administered each time. Participants were required to produce both comfortable productions and high pitch productions. PTP was measured using an oral-pressure flow system for both frequencies. *Results*: Results proved that Mannitol (an osmotic agent) immediately lowered PTP after its administration; however, the effects only lasted for 20 minutes after administration. The other substances did not produce statistically significant effects on PTP. *Discussion*: While the Mannitol was statistically effective in lowering the PTP, it cannot be recommended for treatment at this time because the results lasted only 20 minutes. Mannitol's results show potential and it is suggested that more studies be conducted to discover the optimal dose, delivery method, and the mechanism underlying Mannitol's effect. *Relevance to the work*: Roy et al. conducted a study similar to the current study in dealing with vocal fold hydration.

Scharinger, M., Monahan, P. J., & Idsardi, W. J. (2011). You had me at "Hello": Rapid extraction of dialect information from spoken words. *Neuroimage*, 56, 2329-2338. doi:10.1016/j.neuroimage.2011.04.007

Objective: Scharinger, Monahan, and Idsardi sought to determine how long it takes to identify a speaker's dialect and/or identification. *Method*: Standard American English and African American English versions of *hello* were recorded and equalized using Praat. Twenty versions were recorded with an average duration of 500 ms (SD = 34.4). Twelve students from the University of Maryland (native Standard American English speakers) were selected to listen to the samples. The experiment lasted about 90 minutes as the participants watched a silent movie while passively listening to groups of hellos. This was a magnetoencephalographic mismatch negativity experiment for the /ɛ/ and /o/ vowels in *hello*. *Results*: Analysis consisted of fixed effects for hemisphere (left/right), position (standard/deviant), dialect (SAA/AAA) and time (early/late). When within-dialect was tested, no significant effects appeared. There were significant effects across-dialects however. Hemisphere ($F(1,196) = 4.51$, $p = 0.05$), position ($F(1,196) = 6.66$, $p = 0.05$), dialect ($F(1,196) = 4.40$, $p = 0.05$) and time ($F(1,196)=21.22$, $p = 0.001$) prove that amplitudes were larger in the left hemisphere later on for AAE and deviants. There was a significant relationship between time, position and dialect that proved that MMNs were larger for SAA as opposed to AAA earlier on. *Discussion*: MMN effects were only reliable across-dialects.

Listeners rapidly determine dialect in the same way they determine speaker identity. Top-down knowledge and bottom-up information are both used in determining dialect and identification. Auditory discrimination happens rapidly, but it can be controlled. *Relevance to current study*: Scharinger et al. described the processes in the brain that allow speaker identification to be determined by the listener. The current study discussed changes in acoustic characteristics of diphthongs due to nebulized treatment.

Sivasankar, M., Erickson, E., Schneider, S., & Hawes, A. (2008). Phonatory effects of airway dehydration: Preliminary evidence for impaired compensation to oral breathing in individuals with a history of vocal fatigue. *Journal of Speech, Language, and Hearing Research, 51*, 1494-1506. doi: 10.1044/1092-4388

Objective: The purpose of this study was to determine if there are any negative phonatory effects of dehydration for speakers with vocal fatigue. *Method*: Sixteen females participated in a repeated measures design. Two groups consisting of a control group and a test group with a history of vocal fatigue were formed. Assessments of nasal resistance, pitch range determination, voice measurement were performed before and after the oral and nasal breathing challenges. Respiratory frequency was measured during the challenges. *Results*: Increased phonation threshold pressure (PTP) was greater following oral breathing at low and moderate humidity level for individuals reporting a history of vocal fatigue as opposed to the controls. Neither group, however, experienced increased PTP after oral breathing in a humid environment. *Discussion*: At low and moderate ambient humidity levels, desiccation challenges might be result in adverse voice production in individuals with a history of vocal fatigue. No effect was seen at high humidity levels, however. Proof of this was seen in the appearance of between-group differences in PTP. Individuals reporting vocal fatigue may exhibit damaged compensation to airway drying caused by short-term oral breathing. *Relevance to current study*: The current study discussed the effects of desiccation challenge on the voice as discussed in this article by Sivasankar, Erickson, Schneider, and Hawes.

Sivasankar, M., & Fisher, K. V. (2002). Oral breathing increases path and vocal effort by superficial drying of vocal fold mucosa. *Journal of Voice, 16*, 172-181. http://dx.doi.org/10.1016/S0892-1997(02)00087-5

Objective: The purpose of this study was to compare the effects of short-term oral and nasal breathing on phonation threshold and perceived vocal effort. *Method*: Participants included 20 females who received instructions to breathe orally and then breathe nasally for 15 minutes before the phonation threshold was measured. *Results*: Phonation threshold was increased with short-term oral breathing but not with short-term nasal breathing. *Discussion*: It can be surmised that oral breathing puts healthy subjects at-risk for increased vocal effort symptoms. *Relevance to the current study*: This study discussed the effects of different types of breathing on the voice. The current study discussed the effects of desiccation (which can be caused by different types of breathing) on the voice and examines a possible saline solution.

Sivasankar, M., & Fisher, K. V. (2003). Oral breathing challenge in participants with vocal attrition. *Journal of Speech, Language, and Hearing Research, 46*, 1416-1427. doi:10.1044/1092-4388(2003/110)

Objective: This study aimed to determine whether or not healthy participants with a history of temporary vocal attrition experienced more harm from oral breathing. *Method*: Participants consisted of 40 healthy females with normal voices. Twenty were a used as controls and the other twenty had experience vocal attrition in the past. The two groups of women were split randomly into oral breathing or nasal breathing groups. The individuals sustained a 15-minute oral or nasal breathing challenge. Comparisons of phonation threshold pressure (PTP) and perceived expiratory vocal effort were made for those participants reporting symptoms of vocal attrition and normal controls. *Results*: Oral breathing, not nasal breathing, increased PTP at low, comfortable, and high pitch as shown by post- and pre-challenge changes in PTP and effort. Participants with vocal attrition experienced significantly greater PTP than in those in the control group. PTP was reduced after nasal breathing for all controls but not for all participants who reported vocal attrition. *Discussion*:

Delayed or inadequate compensatory response to superficial laryngeal dehydration may be responsible for larger increases in PTP in participants reporting vocal attrition. Obligatory oral breathing may place voice users at risk for exacerbating vocal attrition. Sol layer depletion, due to obligatory breathing, increases PTP and vocal effort which provides support for the function of superficial hydration in preserving ease of phonation. *Relevance to current study*: The current study also discussed the fact that oral breathing can affect phonation by drying the vocal folds.

Sivasankar, M., & Erickson, E. (2009). Short-duration accelerated breathing challenges affect phonation. *The Laryngoscope, 119*, 1658-1663. doi:10.1002/lary.20530

Objective: This study aimed to examine accelerated oral breathing challenges in order to determine if they are detrimental to phonation. The study also aimed to determine if there are greater adverse phonatory effects after an accelerated breathing challenge for individuals at increased risk for developing voice problems (smokers) than for nonsmoking controls. *Method*: Participants included 24 females: 12 smokers and 12 non-smoking controls. Over two days, with differing ambient humidity, phonation threshold pressure (PTP) was measured and collected before and after short-term accelerated and habitual breathing challenges. During the challenge, respiratory measures were collected. *Results*: Short-term accelerated breathing significantly increased PTP. Breathing route, ambient humidity, or smoking status did not significantly influence PTP. *Discussion*: PTP is increased by accelerated breathing for smokers and nonsmoking controls. Phonation in female speakers is detrimentally affected by dehydration. *Relevance to current study*: This study examined the effects of desiccation challenges on the voice. The current study similarly discussed the effects of desiccation challenge on the voice and examines the effects of a saline solution.

Strange, W. (1989). Evolving theories of vowel perception. *The Journal of the Acoustical Society of America, 85*. doi:0001-4966/89/052081/-07$00.80

Objective: The purpose of this study was to discuss the evolving theories on vowels including the Simple Target Model (vowels have a specific vowel tract formation and can be plotted graphically by their F1 and F2) and the Dynamic Specification Model (examines undershooting in continuous speech). *Discussion*: The author indicates that the target model is often too simple to explain the complexities of vowel perception. There is so much overlap and variation in vowel targets during coarticulation that other factors must be considered in determining vowel perception. The dynamic specification approach mainly addresses the challenges of coarticulation. Coarticulated vowels are identified more accurately than isolated vowels. Several sources are hypothesized to carry information which helps listeners identify vowels including the syllable nucleus, the duration of the vowel, and formant transition in and out of the syllable nucleus. The initial and final transitional portions of CVC syllables carry information that is perceptually relevant and dynamic. *Relevance to current work:* The current study relied on multiple theories of vowel perception which are discussed in the Strange et al. publication.

Tanner, K., Roy, N., Merrill, R. M., & Elstad, M. (2007). The effects of three nebulized osmotic agents in the dry larynx. *Journal of Speech, Language, and Hearing Research, 50*, 635-646. doi: 10.1044/1092-4388(2007/045)

Objective: This study was designed to analyze the results of three differing nebulized treatments on voice production after a laryngeal desiccation challenge. *Method*: Participants in this study included 60 women who had no previous history of voice-related problems. The study involved a double-blind, randomized design whereby participants were assigned to one of four groups: a control group, a groups using 3 mL of nebulized hyperosmotic sodium-potassium hypertonic saline (HS), a group using nebulized isotonic saline (IS), and a group using nebulized sterile water (SW). Measurements of PTP and self-perceived phonation effort (PPE) were collected and analyzed. *Results*: There was no statistically significant difference in PTP and PPE among the four groups; however, the control group had considerably lower mean PTP values. All four groups experienced similar significant decreases in PPE from baseline to immediately after desiccation. *Discussion*: There was no statistically significant evidence that showed that the nebulized treatments improved PTP after the desiccation challenge. There was only a poor correlation between PPE and PTP.

Relevance to the current study: Similar to this study, the current work examined the effects of nebulized treatments on patients.

Tanner, K., Roy, N., Merrill, R. M., Kendall, K., Miller, K. L., Clegg, D. O., ... & Elstad, M. (2013). Comparing nebulized water versus saline after laryngeal desiccation challenge in Sjögren's Syndrome. *The Laryngoscope, 123*, 2787-2792. 10.1002/lary.24148

Objective: The study attempted to analyze the effects of a laryngeal desiccation challenge and two nebulized hydration treatments on phonation threshold pressure, throat dryness, and vocal effort in patients with Sjögren’s Syndrome. *Method*: Participants included 11 individuals with Primary Sjögren’s Syndrome who participated in a 15-minute laryngeal desiccation challenge. The desiccation challenge consisted of breathing dry air (< 1% relative humidity-transorally). Participants also had a treatment of nebulized isotonic saline or nebulized water (3 mL) for two consecutive weeks. Before and after the desiccation challenge the phonation threshold pressure, self-perceived vocal effort, mouth and throat dryness were assessed. These were also assessed at 5, 35, and 65 minutes after the nebulized treatments. *Results*: The laryngeal desiccation challenge produced statistically significant increases in phonation threshold pressure, vocal effort, and dryness of mouth and throat ($p < .05$). While the nebulized saline had greater treatment effects than water, it was not statistically significant. It was noted that phonation threshold pressure had more of a correlation than vocal effort to throat dryness. *Discussion*: Those with chronic dryness may be at risk for voice problems, and being exposed to dry air for a short period of time increases phonation threshold pressure, vocal effort, and perceived dryness for these individuals. Indivduals with chronic dryness may see some benefits from nebulized treatments, however future research should be done to examine the dose-response relationships for dry air exposure and nebulized treatments. *Relevance to current work*: The participants in the current study had Primary Sjögren’s Syndrome and were treated with nebulizer. The current study was largely based off of this study.

Verdolini, K., Min, Y., Titze, I. R., Lemke, J., Brown, K., Jiang, J., & Fisher, K. (2002). Biological mechanisms underlying voice changes due to dehydration. *Journal of Speech, Language, and Hearing Research*, 45, 268-281. doi:10.1044/1092-4388(2002/021)

Objective: The aim of the study was to determine whether the following are able to mediate increases in phonation threshold pressure (PTP): systemic dehydration, secretory dehydration, or both. *Method*: Participants included four healthy college student (two female, two male). A double-blind placebo-controlled approach was used to examine the impact of three treatments (60-mg dose of a diuretic, Lasix (LA) on one day; 50-mg dose of an oral antihistamine, diphenhydramine hydrochloride (DH) on another day; and a placebo on the third day). The treatments were administered on separate days to each participant. Systemic dehydration was estimated through weight, and secretion dehydration and PTP were estimated through saliva viscosity. Weight and saliva viscosity measures were taken post-treatment. *Results*: A decrease in total body mass of about 1% indicated that LA induced systemic hydration. PTPs also increased several hours after drug administration, evidence of whole-body dehydration. There was no indication that DH caused either secretory dehydration or PTP shifts. *Discussion*: PTP increases can be mediated through systemic dehydration. It is unclear as to whether or not secretory dehydration has any impact on PTP. *Relevance to current study*: The current study examined the effect of systemic and surface hydration on voice and speech in patients with SS. This article also analyzed systemic and surface hydration.

Vorperian, H. K., & Kent, R. D. (2007). Vowel acoustic space development in children: A synthesis of acoustic and anatomic data. *Journal of Speech, Language, and Hearing Research, 50*, 1510-1545. doi: 10.1044/1092-4388(2007/ 104)

Objective: This study consolidated acoustic and anatomic data on English vowels for male and female speakers from infancy to adulthood. It considered the maturation of vowel acoustic space for English in regards to anatomic-acoustic descriptions. *Method*: Fourteen related studies on vowel formant frequencies were examined and summarized as a function of age and sex of the speaker. *Discussion:* The authors found that vowel development can be represented acoustically using F1 and F2, however an F1 to F3 pattern may be more sensitive to age and sex differences. It was also found that as age increases, formant frequencies decrease. By four years of age, differences in formant frequencies can be seen between male and female speakers, with those differences becoming most distinguishable by 16 years of age. *Relevance to current study:* The current work analyzed data on vowel formants (F1 and F2) in diphthongs in females with SS. This article describes the maturation of vowel development and determined that it can be represented acoustically using F1 and F2.

Appendix B: Select Medical History Factors

Factor	Participant							
	1	2	3	4	5	6	7	8
Sex								
Male								
Female	x	x	x	x	x	x	x	x
Age								
36 to 45		x		x		x		
46 to 55								
56 to 65	x							
66 to 75			x		x		x	x
Sicca Symptoms (years since onset)								
0 to 5		x						
6 to 10	x			x		x		
11 to 20			x		x			x
21+							x	
SS (years diagnosed)								
0 to 5		x		x				
6 to 10	x					x		
11 to 20			x		x			x
21+							x	
SS related medications								
Hydroxychloroquine	x	x	x	x	x	x		
Pilocarpine	x	x	x	x	x		x	
Evoxac		x				x		
Retuxan		x						
Anucort				x				
Prednisone					x			
Imuran					x			
Other Sicca treatments								
Restatis				x			x	
Nasal spray				x				
Humidifier				x				
Preservative-free eye drops				x				
Biotene products						x		
Gum						x	x	x
Refresh eye drops							x	
Sugar-free lemon drops							x	

Mouth spray								x
Water								x
Other Health Care conditions								
Hypothyroidism	x				x	x		
Peripheral neuropathy	x							
Juvenile rheumatoid arthritis		x						
Dry eyes/mouth			x					
Arthritis			x					
Osteoporosis			x					
Raynaud's				x				
Rheumatoid arthritis			x				x	x
Heart stent							x	
Lymphoma							x	
Interstitial lung disease								x
Sleep apnea								x
Asthma/Pulmonary Disease	x				x			x
Wears O2							x	x
Smokes					x			
Acid Reflux/heartburn	x	x			x		x	x
Seasonal Allergies	x	x	x	x	x		x	
Voice Training		x						

Appendix C: Recording Instructions

Recordings will be performed twice daily, at similar times of day, for 8 weeks. You will read a paragraph, sentences, a list of words (3 times) and sustain "ah" (3 times for 5 seconds each), during each recording. It is very important that recordings are made under similar conditions, with the same mouth-to-microphone distance, and in quiet environments. Recordings are made with you speaking at comfortable pitch and loudness.

Please read the Zoom H1 instruction manual prior to performing recordings. Recording steps have been summarized here:

1. Put on the headset microphone with the pads over the temples. The silver microphone should be facing your lips, approximately 3 inches away, like the photos enclosed. The microphone puff should be covering the mic (see photo 2).
2. Be sure the mic is plugged into the mic/line in slot on the recorder (see diagram #1).
3. Turn on the recorder by holding the power lever to the left for 2 seconds (see diagram #2). The LCD screen will say "Hi" (see diagram #3).
4. Check the battery level on the upper right of the LCD screen. If the battery is low, replace with another AA battery (enclosed).
5. Test the record level by reading the first sentence of the reading passage (below), watching the moving bars on the left side of the LCD screen (see diagram #4). They should range between 50-75% of the scale. If you are "too loud", a red light will flash (see diagram #5). If this happens, adjust the mic slightly away from your lips (don't just get softer; keep the comfortable pitch and loudness and adjust the mic instead).
6. When you are ready, press the "record" button (see diagram #6).

At the beginning of each recording, say your participant number, day of the week, date and time.

Then read: "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."

"The blue spot is on the key again." (pause briefly)
We were away a year ago. (pause briefly)
We eat eggs every Easter." (pause briefly)

Read the 3 lists of words at normal rate:

List 1	**List 2**	**List 3**
"Bye"	**"Boy"**	**"Bay"**
"Heat"	**"Hoot"**	**"Hat"**
"Bow" (like "go")	**"Bay"**	**"Bow"** (go)
"Hat"	**"Hot"**	**"Hot"**
"Bough" (like "cow")	**"Bough"** (cow)	**"Bye"**
"Hot"	**"Hat"**	**"Hoot"**
"Bay"	**"Bow"** (go)	**"Bough"** (cow)
"Hoot"	**"Heat"**	**"Heat"**
"Boy"	**"Bye"**	**"Boy"**
"Hut"	**"Hut"**	**"Hut"**

Say and hold "ah" for at least 5 seconds at a comfortable pitch and loudness. Do this 3 times, pausing in between.

7. Press the "record" button again to stop recording. Remaining record time available will be indicated on the LCD screen.
8. Turn off the recorder by holding the power lever to the left for 2 seconds. The LCD screen will say "bye".

Appendix D: Patient-based Rating (Weeks 3, 4, 7, and 8)

RATINGS

Participant #: ____
WEEK 3 (Treatment)

Instructions: Please rate your level of vocal effort, mouth dryness, and throat dryness **every morning and evening** using the rating scales below. You may refer to previous ratings.

For vocal effort, please rate the amount required during the recorded reading task by placing a vertical line on the scale. The extreme left of the scale represents "no effort" and the extreme right represents "extreme effort".

For mouth and throat dryness, please rate your current level of dryness by placing a vertical line on the scale below. The extreme left of the scale represents "no dryness" and the extreme right represents "extreme dryness".
(*note: lines not to scale)

Please complete all ratings BEFORE nebulizing.

Date: ___ AM

No Vocal Effort ________________________________ Extreme Vocal Effort

No Mouth Dryness ________________________________ Extreme Mouth Dryness

No Throat Dryness________________________________ Extreme Throat Dryness

PM

No Vocal Effort ________________________________ Extreme Vocal Effort

No Mouth Dryness________________________________ Extreme Mouth Dryness

No Throat Dryness________________________________ Extreme Throat Dryness

Date: ____ AM

No Vocal Effort ______________________________ Extreme Vocal Effort

No Mouth Dryness ______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

PM

No Vocal Effort______________________________ Extreme Vocal Effort

No Mouth Dryness______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

Date: ____ AM

No Vocal Effort ______________________________ Extreme Vocal Effort

No Mouth Dryness ______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

PM

No Vocal Effort______________________________ Extreme Vocal Effort

No Mouth Dryness______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

Date: ____ AM

No Vocal Effort ______________________________ Extreme Vocal Effort

No Mouth Dryness ______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

PM

No Vocal Effort______________________________ Extreme Vocal Effort

No Mouth Dryness______________________________ Extreme Mouth Dryness

No Throat Dryness______________________________ Extreme Throat Dryness

Appendix E: Consent and Authorization Document

BACKGROUND

You are being asked to take part in a research study. People with Sjögren's Syndrome may be more likely to experience voice problems and throat dryness. The University of Utah Health Care Voice Disorders Center is studying the effects of throat dryness and hydration in individuals with Sjögren's.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

STUDY PROCEDURES

This research study will examine the effects of a hydration treatment on the voice and throat dryness. All participants will be individuals with Sjögren's. If you agree to participate in this study, you will participate in an 8-week home program including the hydration treatment, research paperwork, and audio recordings. You will do all research tasks in your own home, and will not need to travel to participate. The hydration treatment is inhaled saline mist. The mist is similar to fluid in the cells in your body.

The study is divided into 4, 2-week phases. The first 2 weeks will be the baseline phase. You will complete daily ratings of your voice and dryness, and recordings of your voice using the portable recorder we send you. The next 2 weeks will be the first treatment phase. You will continue all the ratings you did during the first phase, but will add the daily hydration treatment in the morning and evening. The treatment involves breathing saline using a personal nebulizer. The treatment is 9 mL, and takes approximately 15 minutes to administer.

The next phase of the research study involves withdrawing the nebulized treatment. During this 2-week phase, you will not receive the hydration treatment, but will continue completing daily ratings and audio recordings. The final phase includes 2-weeks of the hydration treatment, ratings, and recordings. You will mail ratings in a prepaid envelope at the end of each 2-week phase. When the study is completed, you will return the audio equipment in a prepaid envelope.

Your participation is outlined in the table below:

Study Phase	Participation
Phase 1 = Baseline 2 weeks	Daily ratings of voice and dryness; Daily recording of voice
Phase 2 = Treatment 2 weeks	Daily ratings of voice and dryness; Daily recordings of voice; Twice-daily nebulized treatment
Phase 3 = Baseline 2 weeks	Daily ratings of voice and dryness; Daily recording of voice
Phase 4 = Treatment 2 weeks	Daily ratings of voice and dryness; Daily recordings of voice; Twice-daily nebulized treatment

You will receive detailed instructions on how to perform the ratings and recordings. The study coordinator will call you before you begin the study to review the instructions with you and answer questions. Also, the study coordinator will be available by telephone to answer any questions you might have.

RISKS
It is possible that you may experience occasional coughing associated with the inhaled mist. This coughing should be infrequent, and should not continue after the treatment is completed. The nebulizers used in this study have been used to treat asthma and have not been reported to be uncomfortable.

REPRODUCTIVE RISKS
If you are pregnant or think you might be pregnant, you should not participate in the study. The inhaled mist is not believed to have adverse effects in pregnancy. However, changes to the voice during pregnancy could influence the research study outcomes. Therefore pregnant women are not being included in this study.

BENEFITS
There are no direct benefits to you from your taking part in this study. The information we get from this study may help us provide better recommendations to address throat dryness in people with Sjögren's.

ALTERNATIVE PROCEDURES
There are no similar alternative treatments to the inhaled treatments being studied in this research.

CONFIDENTIALITY
The results of this study will be stored on a password-protected computer on a University of Utah network drive with restricted access. Only the investigators and research assistants will have access to the results and confidentiality and privacy will be maintained. You will be assigned a code number and your name will not appear on any written or computer documents. All identifying information will be stored separately, preventing any link between you and the results. The results of this study may be published for scientific purposes. By Federal Law, the information gathered in this study may be reviewed by the United States Food and Drug Administration. We will do everything we can to keep your records private, but cannot guarantee this.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact Dr. Kristine Tanner at (801) 633-7471. If you think you may have been injured from being in this study, please call Dr. Mark Elstad, MD or Dr. Kathy Kendall, MD at (801) 587-8368. The doctors can be reached at this number during the hours of 8:30 am to 4:30 pm.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY
If you are injured from being in this study, medical care is available to you at the University of Utah, as it is to all sick or injured people. The University of has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION
It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

COSTS AND COMPENSATION TO PARTICIPANTS
There is no cost associated with your participation in this study. You will be compensated in the amount of $160 after completing the study. A check will be mailed after you have completed the 8-week program and have returned the ratings and recording equipment. Compensation is not available to participants who do not complete the study. Brigham Young University, Provo, Utah is funding this study, and will retain your name and citizenship status for accounting purposes. If you prefer not to have your information retained by Brigham Young University, you may still participate in the study and can choose not to receive compensation.

NUMBER OF PARTICIPANTS

We expect to enroll 15 individuals with Sjögren's in this study at The University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.
This is the information we will use:

- Name
- Address
- Telephone number
- Participant's prior medical history (self-report)
- Sjögren's Syndrome diagnosis medical records
- Vocal measures and throat dryness ratings that will be performed in the study

Others who will have access to your information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of The University of Utah Health Sciences Center who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

If we share your information with anyone outside The University of Utah Health Sciences Center you will not be identified by name, social security number, address, telephone number, or any other information that would directly identify you, unless required by law.

You may revoke this authorization. This must be done in writing. You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to Kristine Tanner, Ph.D., Voice Disorders Center, 729 Arapeen Dr., Salt Lake City, UT, 84108. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

This authorization does not have an expiration date.

CONSENT
I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

____
Participant's Name

_________________________ ____________
Participant's Signature Date

____
Name of Person Obtaining Authorization and Consent

_________________________ ____________
Signature of Person Obtaining Authorization and Consent Date

Would you like to receive information on future studies involving Sjögren's Syndrome?

Yes ______ (we will retain your name, telephone number, and mailing address to provide information)

No ______

Appendix F: Participant Tracking Sheet

Participant # ____ **PARTICIPANT LOG**

On the day before beginning the study, complete:

___ Voice Handicap Index
___ Sjogren's Symptom Severity Scales
___ Medical History

Week 1 (Baseline)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording
__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings
__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording
__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings

Week 2 (Baseline)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording
__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings
__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording
__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings

On the last day of week 2, complete:

___ Voice Handicap Index
___ Sjogren's Symptom Severity Scales

Week 3 (Treatment)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording	__AM Recording
__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings	__AM Ratings
__AM Treatment	__AM Treatment	__AM Treatment	__AM Treatment	__AM Treatment	__AM Treatment	__AM Treatment
__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording	__PM Recording
__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings	__PM Ratings
__PM Treatment	__PM Treatment	__PM Treatment	__PM Treatment	__PM Treatment	__PM Treatment	__PM Treatment

Week 4 (Treatment)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment

On the last day of week 4, complete:
___ Voice Handicap Index
___ Sjogren's Symptom Severity Scales

Week 5 (Baseline)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings

Week 6 (Baseline)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings	__AM Recording __AM Ratings __PM Recording __PM Ratings

On the last day of week 6, complete:
___ Voice Handicap Index
___ Sjogren's Symptom Severity Scales

Week 7 (Treatment)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment

Week 8 (Treatment)

Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______	Date:_______
__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment	__AM Recording __AM Ratings __AM Treatment __PM Recording __PM Ratings __PM Treatment

On the last day of week 8, complete:
___ Voice Handicap Index
___ Sjogren's Symptom Severity Scales