Vocal Hygiene Education, Voice Production Therapy, and the Role of Patient Adherence: A Treatment Effectiveness Study in Women With Phonotrauma

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Purpose: To assess the effectiveness of vocal hygiene education (VHE) and voice production therapy (VP) in altering patient perception of vocal handicap in adult women with benign, bilateral phonotraumatic vocal fold lesions and the role of adherence in that perception.

Method: Sixty-two women were randomly assigned to 6 weeks of VP (n = 31) or VHE (n = 31), followed by 4 weeks of self-study. The primary outcome measure was the Voice Handicap Index (VHI) score, assessed at baseline, post-therapy, and post-self-study. Patient adherence was assessed as a cofactor.

Results: Both groups achieved a decrease in VHI scores from baseline to completion of the study, although the improvement was significantly greater for the VP group. The treatment effect size was large for the VP group and small for the VHE group. More participants adhered to VP than to VHE. Only adherent participants achieved significant improvement. Only adherent participants in the VP group improved with self-study. More than two thirds of the VP group achieved final VHI scores within normal limits, compared with approximately one third of those in the VHE group. Conclusions: VP therapy may be more effective than VHE in addressing patient perception of vocal handicap in adult women with phonotrauma, and self-study may be an important component of therapy. However, adherence is a critical mediator of outcome.

KEY WORDS: vocal hygiene, voice therapy, phonotrauma, nodules, voice disorders, compliance, adherence

ost leading voice experts consider vocal hygiene education an essential component of voice therapy for patients with phonotraumatic lesions of the vocal folds (Boone, McFarlane, & Von Berg, 2005; Colton & Casper, 1996; Stemple, 2005). Sparse data are available, however, to support its effectiveness. In this article, we present a study in which the relative outcomes of vocal hygiene education and voice production therapy were assessed from the perspective of patient self-assessment of vocal handicap, with examination of the influence of patient adherence on treatment outcome. A review of the mechanisms of phonotraumatic lesions is presented, followed by the conceptual framework for vocal hygiene education and voice production therapy and, finally, patient adherence. Throughout, the relevant research literature is

reviewed and the gaps in current knowledge are highlighted, thereby building the rationale for this study and emphasizing its potential relevance to clinical practice.

Phonotraumatic Lesions of the Vocal Folds

The nomenclature and differential diagnosis of benign lesions of the mid-membranous vocal folds are controversial. Traditional nomenclature has included primarily nodules, polyps, and cysts. More recently, fibrous masses and reactive lesions have been added (Verdolini, Rosen, & Branski, 2006). In clinical practice, these benign lesions are often grouped together because of some commonalities of etiology, presentation, treatment, and challenges to their differential diagnosis (Rosen, Murry, Zinn, Zullo, & Sonbolian, 2000).

Phonotrauma is considered a major common factor contributing to the formation of many mid-fold, benign lesions (Rosen, 2004; Verdolini et al., 2006). Phonotrauma, a term first used by Verdolini (1998), is the inflammatory response of the vocal fold mucosa to the biomechanical loads and deformations that can occur during high-effort vibration. The tissues of the vocal folds typically can withstand the normal biomechanical forces without harm, or with only minor and transient effects. Under conditions of phonotraumatic voice use, however, the forces exerted upon and within the vibrating tissues are substantial, particularly shear and collision stresses (Titze, 1994). Over a prolonged time, and without sufficient rest periods (Titze, Svec, & Popolo, 2003), a localized response—a lesion—is formed, most commonly at the midpoint of the vibratory margin of one or both of the membranous vocal folds (Johns, 2003; Rosen, 2004; Verdolini et al., 2006). Other important factors that may contribute to lesion formation include health problems, such as laryngopharyngeal reflux (Koufman, 1991); psychosocial or personality characteristics (Roy, Bless, & Heisey, 2000); and perhaps even a genetic predisposition to mucosal anomalies (Gray, Hammond, & Hanson, 1995). The phonotraumatic vocal style as well as the lesions themselves may result in impaired voice quality, limited vocal stamina, physical discomfort, and other symptoms of a voice disorder. Voice therapy, including both vocal hygiene education and voice production skill building, together with medical management, is an important part of treatment for phonotraumatic voice disorders (Bouchayer & Cornut, 1992; Garrett & Ossoff, 2000; Johns, 2003; Sulica & Behrman, 2003).

Vocal Hygiene Education

Conceptual approach. The goal of vocal hygiene education is to reduce nonspeech- and speech-related factors that may contribute to the inflammatory response of the vocal fold mucosa. In what is sometimes referred to as

indirect therapy (Carding, Horsley, & Docherty, 1999), the patient is educated regarding the behavioral and lifestyle choices consonant with good vocal hygiene. Speech-related factors that are frequently addressed in vocal hygiene education include reduction in loud voice use and the overall amount of talking. Nonspeech factors commonly addressed include laryngopharyngeal reflux (LPR), throat-clearing, hydration, dehydrating medications, and inhaled irritants (Bouchayer & Cornut, 1992; Johns, 2003).

Supporting literature. With the single exception of smoking, empirical evidence supporting the contribution of each of the separate components of vocal hygiene education to the treatment of phonotraumatic voice disorders is limited. No data are available that describe the outcome of reduction in voice use or throat-clearing, for example. In contrast, data are available on LPR in general, although findings are still limited in regard to the effectiveness of its management. LPR is considered an inflammatory agent of vocal fold mucosa (Ylitalo, Baugh, Li, & Thibeault, 2004) and a factor contributing to dysphonia (Hanson & Jiang, 2000; Koufman, 1991), but no direct evidence links LPR with benign lesion formation (Vaezi, Hicks, Abelson, & Richter, 2003). Similarly, hydration is considered a critical factor in vocal fold health and prevention of dysphonia in general, a finding that is supported by some evidence in canine models (Jiang, Verdolini, Ng, & Hanson, 2000). However, the amount of vocal improvement that can be achieved by increased systemic hydration (drinking water) is unclear (Verdolini et al., 2002; Verdolini, Titze, & Fennell, 1994; Verdolini-Marston, Sandage, & Titze, 1994). The benefits of reduction in caffeine consumption, considered a potentially dehydrating agent, to vocal health has limited empirical support (Maughan & Griffin, 2003).

The overall effectiveness of a comprehensive vocal hygiene education program has received some research attention. A thorough literature review yielded eight studies (Broaddus-Lawrence, Treole, McCabe, Allen, & Toppin, 2000; Carding et al., 1999; Chan, 1994; Duffy & Hazlett, 2004; Holmberg, Hillman, Hammarberg, Södersten, & Doyle, 2001; Roy et al., 2001, 2002; Timmermans, De Bodt, Wuyts, & Van de Heyning, 2003). The data, summarized in Table 1, show that some of the studies focused on individuals with healthy voices, and those that did assess individuals with voice disorders yielded mixed results. Given the popularity of vocal hygiene education as a component of voice therapy for phonotraumatic voice disorders and the lack of data describing its effectiveness, additional research is warranted.

Voice Production Therapy

Conceptual approach. Whereas vocal hygiene education is an information-only approach, voice production

Table 1. Literature review of research assessing outcomes of vocal hygiene education.

Study	N	Treatment groups/ approaches	Duration of vocal hygiene	Outcome measures	Findings
Broaddus-Lawrence et al. (2000)	11 adult untrained singers (students) with no history of voice disorders	Vocal hygiene	Four 1-hr sessions	Surveys (self-report)	"No significant decrease in the number of vocally abusive behaviors by the subjects." "No significant changes in the subjects' practice of vocal hygiene behaviors."
Carding et al. (1999)	45 patients with voice disorders seeking treatment (hyperfunction and phonotraumatic lesions not requiring surgery)	 No treatment control (n = 15) Indirect therapy (n = 15) Direct and indirect therapy combined (n = 15) 	8 weekly (40–45 min) sessions (follow-up 1 month later)	Patient questionnaire of vocal performance Voice quality ratings by doctoral students in speech-language pathology Indirect/fiberoptic laryngoscopy Electroglottography Acoustic analysis	 Controls: 86% showed no significant change on any measures. Indirect: 46% showed significant change in voice quality. Direct: 93% showed significant changes in voice quality.
Chan (1994)	25 kindergarten teachers without voice disorders	 Vocal hygiene (n = 12) No treatment control (n = 13) 	2 months (1 workshop session followed by daily self-practice)	Acoustic analysis Electroglottography	Significant voice improvement in treatment group.
Duffy & Hazlett (2004)	55 student teachers with no self-reported voice or speech problems	 Control (n = 23) Direct therapy (n = 12) Indirect therapy (n = 20) 	1 year (2-semester training course)	Acoustic measures Self-perception	 Control: deterioration. Direct: improvement. Indirect: no change. The self-rating scores varied in agreement with the acoustic results.
Holmberg et al. (2001)	11 women with vocal nodules seeking treatment	5 phases included for all participants: vocal hygiene, direct facilitation, respiration, relaxation, carryover	4–6 months, 1 session/week, 3 sessions for each approach	 Auditory perceptual rating of vocal quality by SLPs Acoustic analysis (FO and SPL) Videostroboscopy 	 Nodules did not disappear but did decrease in size for 9 clients. No change in SPL (loudness), increase in F0. Some improvement in voice quality (decrease in vocal fry, scrape, instability, aphonic periods). "No significant parameter changes between the baseline and vocal hygiene for the group, and individual data showed cases of increased values for some parameters (e.g. press) at the end of vocal hygiene the whole therapy protocol was needed for significant changes and improvement in voice quality."

(Continued on the following page)

Table 1 Continued. Literature review of research assessing outcomes of vocal hygiene education.

Study	N	Treatment groups/ approaches	Duration of vocal hygiene	Outcome measures	Findings
Roy et al. (2002)	50 elementary and secondary school teachers with history of voice problems but not currently seeking treatment	 Vocal hygiene (n = 17) Voice amplification (n = 17) No treatment control (n = 16) 	6 weeks (4 sessions)	Voice Handicap Index (VHI) Voice Severity Rating Scale Posttreatment questionnaire Acoustic analysis	 Only the amplification group demonstrated significantly decreased VHI scores (no change for hygiene and increased scores for control participants). Teacher self-ratings (voice severity ratings) changed significantly in amplification group only (no significant change for hygiene or control participants). The voice amplification group reported greater "ease of voice production" than the hygiene group. Only the amplification group demonstrated significant reductions of jitter and shimmer, and NHR approached significance (hygiene also experienced reductions but were nonsignificant). Amplification group reported higher compliance than hygiene group.
Roy et al. (2001)	58 teachers with voice disorders (not diagnosed by an otolaryngologist nor currently seeking treatment)	 Vocal hygiene (n = 20) Vocal function exercises (n = 19) No treatment control (n = 19) 	6 weeks (4 sessions)	VHI Questionnaire on compliance and self-reported voice improvement	Only the vocal function exercise group had reduced VHI scores, overall voice improvement, and greater ease and clarity (compliance was reported as similar for both groups).
Timmermans et al. (2003)	23 theater and radio students (vocal status not reported)	 Direct therapy (all participants) Indirect therapy (all participants) 	 Voice training for 2 years (30 hr/year) Vocal hygiene education for 1 year (30 hr) 	European Laryngological Society protocol (including Dysphonia Severity Index [DSI]) VHI Perceptual evaluation (GRBAS) Acoustic analysis	 More DSI improvement after 9 months than 18 months. Perceptual evaluation unchanged after 9 months and improved after 18 months. Jitter and MPT significantly improved after 18 months. "Low effectiveness of the vocal hygiene program."

Note. The terms indirect therapy and direct therapy, as used by the authors, correspond to vocal hygiene education and voice production therapy, respectively. NHR = noise to harmonic ratio; GRBAS = grade, roughness, breathiness, asthenia, severity; MPT = maximum phonation time.

therapy focuses on changing the manner of voice production. Sometimes called direct therapy (Carding et al., 1999), it involves vocal exercises that may target one or more subsystems of voice production: speech-breathing, mode of phonation, resonation, and articulation. Although the specific techniques frequently vary among clinicians, the goal of voice production therapy is to help the patient use a manner of voice production that is not phonotraumatic yet meets the daily communicative needs of the patient.

Supporting literature. Many studies have documented positive outcomes of voice therapy for patients with a variety of benign lesions (Blood, 1994; Gordon, Pearson, Paton, & Montgomery, 1997; Gullivan-Murphy, Drinnan, O'Dwyer, Ridha, & Carding, 2006; Lancer, Syder, Jones, & Le Boutillier, 1988; MacKenzie, Millar, Wilson, Sellars, & Deary, 2001; McCrory, 2001; Murry & Woodson, 1992; Sellars, Carding, Deary, MacKenzie, & Wilson, 2002; S. Smith & Thyme, 1976; Speyer et al., 2002; Verdolini-Marston, Burke, Lessac, Glaze, & Caldwell, 1995). However, in these studies vocal hygiene education was either included in the overall therapy protocol or it was not specifically identified as being included or excluded. Although a growing body of evidence suggests that voice therapy as a whole is generally effective in minimizing the symptoms of a phonotraumatic voice disorder, the role of vocal hygiene education is an important question that bears further examination.

Patient Adherence

Both vocal hygiene education and voice production therapy are predicated on patient adherence. Adherence may be defined as the extent to which a patient follows through with agreed-on or prescribed actions and does what the clinician expects him or her to do (Zweben & Li, 1981). Adherence has been acknowledged as a potentially significant variable in voice therapy outcome in overviews of treatment practices (Mueller & Larson, 1992; Pannbacker, 1998) and therapy outcomes research (Murry & Woodson, 1992; Roy et al., 2003; Verdolini-Marston et al., 1995). Vocal hygiene education and voice production therapy demand different types of behavioral and lifestyle changes, and it is possible that patient adherence is different, on average, for each intervention. Roy et al. (2002) found that teachers who participated in a vocal hygiene education group were significantly less adherent with the therapy than teachers who were advised to use amplification in the classroom. Given that a treatment approach is only as good as the patient's ability to comply with it, further exploration of potential differences in patient adherence between vocal hygiene and voice production therapy is warranted. Therefore, the purpose of this study was to compare the outcomes of vocal hygiene education and voice production therapy relative to the patient's perception of vocal handicap and to examine the role of patient adherence in the treatment of voice disorders in adult women with benign mid-vocal fold phonotraumatic lesions. This study was approved by the New York University Committee on Activities Involving Human Subjects.

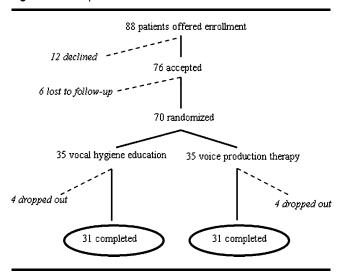
Method Participants

Women ages 18 years and older were offered participation in this study if they had a recent (within 3 months) diagnosis by an otolaryngologist of bilateral, fairly symmetric, mid-membranous, benign, free-edge vocal fold lesions. Most commonly, these lesions are diagnosed as nodules, but descriptors used by otolaryngologists also include pre-nodules and mid-fold swelling, among other labels. Some otolaryngologists identify a unilateral benign lesion as a "nodule," but those patients were not included in this study. All participants had to be recommended for voice therapy as the definitive treatment—that is, patients were not included who were recommended for preoperative or diagnostic voice therapy. Further inclusion criteria specified that participants must have experienced symptoms of their voice disorder for a minimum of 3 months prior to enrollment, had not smoked within the prior 3 years, and were able to read and fully participate in therapy conducted in English. Participants were otherwise generally in good health with no history of neurologic or systemic disease that might contribute to the voice disorder other than LPR. No participant had a diagnosis of chronic rhinosinusitis or asthma that required frequent medication. No participant had a history of laryngeal surgery or any procedures of the lower or upper airway or head and neck that could reasonably be expected to currently affect voice production. Participants were recruited from the clinical practices of otolaryngologists in New York City, from advertisements placed in neighborhood newspapers, and from flyers posted on the main campus of New York University. Sixty-two women participated in the study, 31 per group. Details of the enrollment and dropouts are provided in Figure 1. The racial and ethnic diversity of the participants was reflective of the geographic region, with 20% (13/62) Hispanic or Latino, 24% (15/62) African American, and 13% (8/62) Asian. Almost every participant was being treated for LPR.

Design

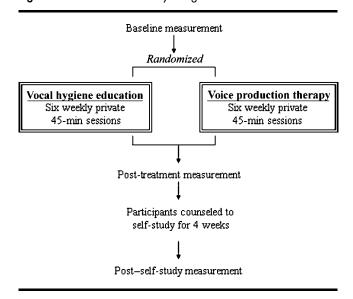
After providing informed consent, participants were assigned to voice production therapy or vocal hygiene education through a computer-generated random number list. Both groups underwent six consecutive weekly 45-min private sessions (hereafter referred to as the

Figure 1. Participant enrollment.



therapy period). Participants then were instructed that, during the subsequent 4 weeks, they each should adhere to the guidelines provided by the voice therapist (in the case of the vocal hygiene education group) or to continue to practice the voice production exercises and adhere to the techniques learned (in the case of the voice production therapy group). These 4 weeks are referred to hereafter as the self-study period. Outcome measures were obtained at baseline, within 1 week after completion of the 6 weeks of treatment, and again within 1 week after completion of the self-study period. All sessions were conducted at no cost to the participants. The study design is summarized in Figure 2. After completing their participation, all women were offered six weekly sessions of voice production therapy at no charge if they had been

Figure 2. Overview of the study design.



in the vocal hygiene education group, or vocal hygiene therapy if they had been in the voice production group.

The rationale for 6 weeks of therapy and 4 weeks of self-study was as follows. Six sessions is often cited as an average (Dunnet, MacKenzie, Robinson, Sellars, & Wilson, 1997; Mueller & Larson, 1992) and has been used in other studies (Roy et al., 2001, 2002, 2003; Sellars et al., 2002), although the duration of voice therapy in research studies varies greatly, from 2 weeks (Verdolini-Marston et al., 1995) to more than 3 months (Speyer, Wieneke, & Dejonckere, 2004a). However, as the duration of a research study increases, the complexity of maintaining patient enrollment and managing data increases, and both of these can be threats to successful completion of a clinical study. In clinical practice, the duration of voice therapy also varies widely. Often, otolaryngologists recommend that their patients return for medical reevaluation after 2 to 3 months of voice therapy. Six weeks was considered sufficient to achieve competence in the target voice production goals, which the participants could then practice on their own. The 4 weeks of self-study were reasoned to be an adequate period for assessing the potential for further change in outcome measures by using self-guided practice.

Voice therapy was conducted by the first author and the third author. When possible, assignment of therapist was made on an alternating basis. In some cases, assignment was based on geographical and scheduling preferences of the participants and availability of the therapists. No participant was permitted to change therapists during the study. Both the first author and the third author are speech-language pathologists who are experienced voice therapists. They both have attended the Lessac-Madsen Resonant Voice Therapy (LMRVT) training course as well as other seminars and training courses that have addressed a variety of techniques and issues related to the rapeutic intervention for individuals with voice disorders. Cross-training between the two therapists and frequent meetings throughout the study were conducted to promote adherence to the protocols and similarity of care.

Treatment Protocols

Vocal hygiene education. Participants in the vocal hygiene education group received no direct work on their voices. They were not provided with vocal exercises. Their sessions were informational only, focusing on the following broad concepts, introduced in the first session: avoid throat-clearing, increase water intake, limit loud talking, balance extra vocal demands with voice rest, humidify the environment, discuss potentially drying medications with their physician, limit voice use during illness, and manage diet to control laryngopharyngeal reflux disease. These concepts were reviewed during

each subsequent therapy session. Discussion emphasized ways to adapt each participant's lifestyle to incorporate improved vocal hygiene habits. For each participant, the successes in achieving improved vocal hygiene over the prior week were reviewed and positively reinforced. Lack of success was discussed matter-of-factly, without punitive implication, and a problem-solving approach was used to help each participant find ways to achieve greater success in the upcoming week.

In typical clinical practice, vocal hygiene education does not occupy multiple therapy sessions as a sole focus of the therapy; however, the vocal hygiene education and voice production interventions had to be equivalent in duration to prevent confounding data interpretation with an additional variable (treatment duration). We hypothesized that regular attendance at weekly sessions for the vocal hygiene group might actually improve adherence, although boredom or fatigue on the part of the participant was an acknowledged risk. Therefore, two additional activities were incorporated into the vocal hygiene education program to fill time.

One time-filling activity was a 5- to 10-min review of archival stroboscopic examinations showing a variety of larvngeal pathologies, with discussion of the ways in which voice production can be altered. The second activity was a 10-min steam treatment, during which each participant breathed warm, moist air using a facial steamer. These filler activities were designed to help prevent participant boredom (and possible increased nonadherence) due to the repetitive nature of the 6 weeks of vocal hygiene education. Steaming is advised by many therapists as a means of hydrating the vocal fold mucosa, and some therapists include steaming in their therapy sessions. Participants were provided with general advice to maintain excellent hydration outside of the sessions, by drinking water; by using a humidifier at night; and, if they desired, by using a facial steamer. However, a specific recommendation to use a facial steamer was not made. Extraclinical monitoring of vocal hygiene habits, including steaming, was not conducted separately from the weekly session discussions of the prior week's habits.

Voice production therapy. Participants in the voice production therapy group received LMRVT. LMRVT targets a phonation strategy referred to as resonant voice production (Verdolini-Marston et al., 1995) or flow phonation (a term attributed to Sundberg, 1987). The target is acoustic output containing strong harmonic structure achieved without hyperadduction of the vocal folds (Berry et al., 2001; Verdolini, Druker, Palmer, & Samawi, 1998). Although the physiology is incompletely understood, it may involve narrowing of the epilaryngeal space along the antero-posterior axis, without medial ventricular fold compression, to increase vocal tract inertance (C. G. Smith, Finnegan, & Karnell, 2005; Titze, 2001).

Inertance is an acoustic property of the accelerating or decelerating supraglottal air mass that facilitates vocal fold vibration by causing the oscillating supraglottal pressures to be in phase with vocal fold velocity. Thus, the subglottal pressure necessary to vibrate the folds can be reduced (Titze, 2001). It is hypothesized that the physical manifestations of this laryngeal maneuver perceived by the speaker are a buzz sensation in the front of the mouth and face and a sense of ease of production at the level of the larynx (Rulnick, Heuer, Perez, Emerich, & Sataloff, 1997; Sundberg, 1987; Titze, 2001, 2006; Verdolini et al., 1998).

The LMRVT treatment protocol adhered closely to the protocol as described by Verdolini (2000) and as provided in the LMRVT training sessions conducted by Dr. Verdolini, except that no information on vocal hygiene education was provided. If a participant raised a question regarding vocal hygiene (e.g., management of LPR), she was directed to contact her otolaryngologist for advice. Participants progressed through the resonant voice components (core basic training gesture, chant, vocal communicator, resonant voice mini, messa di voce, and conversation) according to the standard LMRVT protocol as taught by Dr. Verdolini. Mastery of a task was judged by the clinician. Home practice sheets were provided, again consistent with the published protocol and course; these practice sheets addressed tasks completed during each session, and carryover activities were designed as appropriate for each individual participant. Extraclinical monitoring of adherence was not conducted. Although both clinicians attempted to adhere as closely as possible to the protocol, the progress and relative success in achieving the resonant voice targets varied across participants. The self-study implementation of LMRVT was tailored to each individual participant but adhered to the general format of deactivation stretches, activation resonant voice exercises, incorporation of resonant voice into daily speaking activities, and problem-solving techniques (returning to the basic training gesture, using extreme resonant voice on softly produced words and phrases from earlier sessions).

Outcome Measures

Voice Handicap Index. The primary outcome measure was patient self-assessment, captured with the Voice Handicap Index (VHI; Jacobson et al., 1997). Phonotraumatic vocal fold lesions are not life threatening; they are significant for their potential to cause social, emotional, and occupational handicaps. Therefore, the patient's self-assessment of the voice disorder is paramount in treatment planning. The VHI is a 30-item self-report inventory that evaluates the individual's perception of the degree to which the voice is a handicap in daily life. Each statement is rated on a 5-point Likert scale that ranges from

0 (no problem) to 4 (always a problem). Total scores range from 0 (no handicap) to 120 (maximal handicap). Jacobson et al. (1997) calculated good internal consistency (Cronbach's alpha coefficient r=.95), and test—retest reliability (Pearson product—moment correlation coefficient =.92). The authors calculated the 95% confidence interval (critical difference score) such that a minimum change of 18 points across treatment was required to achieve clinical significance.

Despite the widespread popularity of the VHI, no normative data exist that describe expected scores from adults with healthy voices. We reasoned that, in addition to assessing participants' change scores after treatment, it might also be informative to compare their scores with the scores of adults who had no history of voice problems. Therefore, VHI scores were obtained from 100 adults (50 male and 50 female) who accompanied a friend or relative to the general Ear, Nose, and Throat Clinic of a hospital in New York City. None of the participants had smoked cigars or cigarettes within the prior 3 years, and none had experienced a voice problem in the past other than the transient voice changes that accompany a cold. The appointment process for the general Ear, Nose, and Throat Clinic typically screens patient complaints, and patients reporting voice problems would have been routed to the laryngology clinic instead of the general clinic. Despite that screening process, however, it is possible that some portion of the participants were accompanying a patient with a voice disorder, which could have influenced their responses on the VHI.

Analysis of the VHI scores by gender revealed no significant differences (p=.36), so the data were collapsed and analyzed as a single sample. The mean score from the sample was 9.3 (SD=11.2, range: 0–19). The 95% confidence interval was 2.2. This finding means that if repeated samples of participants without a voice disorder completed the VHI, then 95% of the samples would have a mean between 7.1 and 11.5 (9.3 + 2.2). Therefore, the upper limit of 11.5 was considered the cutoff for a VHI score expected from an individual without a voice disorder.

Patient-determined treatment following study participation. After each woman with phonotrauma had completed her participation in the study, the first author met with the participant and asked about her satisfaction with her voice and her preference for continued treatment, if any. All participants were directed to return to their otolaryngologist for a follow-up examination, regardless of their level of satisfaction or desire for further treatment.

Patient adherence as a cofactor of outcome. Each participant's self-assessment of adherence was measured using a 10-cm visual analogue scale with end anchors of completely adherent and completely nonadherent. After the therapy period, each participant was asked to assess how much she had adhered to the guidelines provided

by the voice therapist (in the case of the vocal hygiene education group) or had practiced the voice production exercises and adhered to the techniques learned (in the case of the voice production therapy group). After the self-study period, each participant was asked to rate her continued adherence in a similar fashion.

Two hypotheses were tested with regard to adherence. The first hypothesis was that therapeutic outcome was linearly related to adherence—that is, outcome is proportionately related to adherence level across all levels of adherence. To test this hypothesis, adherence was treated as a continuous variable and correlated with VHI score. The second hypothesis was that the degree of adherence may not be linearly related to outcome; instead, it might be that a level of adherence needed to be achieved to realize therapeutic gain. This hypothesis was tested by converting adherence into a dichotomous variable. Participants who gave themselves a score of 7.5 or greater were identified as adherent. Those who scored themselves below 7.5 were identified as nonadherent. The rationale for the 7.5 criterion is as follows: First, use of 75% is consistent with other criterion levels in speech-language therapies, in which session goals are often written such that the patient should be able to perform a task successfully 75% or 80% of the time (Roth & Paul, 2002). Second, after completing the visual analogue scale, each participant was asked whether she considered herself to have been adherent. Responses of "no," "not really," "sort of," and so on, were categorized as negative. Responses of "yes," "pretty much," "I think so," "most of the time," and so on, were categorized as positive. (These categorizations were made before the clinician looked at the response on the adherence visual analogue scale.) One hundred percent of the participants who gave a positive response scored themselves at or above 7.5 on the visual analogue scale. Ninety-seven percent (30/31) of the participants who gave a negative response scored themselves below 7.5. Finally, in an earlier planning meeting for this project in which the first author met with an interdisciplinary group (see the Acknowledgments section), it was reasoned that a patient who adhered to therapy less than 75% of the time could not be judged overall to be adherent.

Results Participants

Five participants (2 from the vocal hygiene condition and 3 from the voice production condition) missed the data collection session immediately after completion of the 6 weeks of therapy because of illness or travel. All 5 of the participants did communicate with the principal investigator by telephone, however, and received

instructions on the 4 weeks of self-study. All 62 participants did attend the final data collection session. Incomplete data from participants (those who dropped out after enrollment but before completion of the study or who missed a post-therapy evaluation session) were not excluded from the study. Those missing data were analyzed using the intention-to-treat statistical model, in which the conservative approach was used such that scores were imputed from the earlier visit. Therefore, for cases in which the first post-therapy visit was missed, the baseline scores for those participants were used. For participants who dropped out after three or four sessions, the baseline scores were used for both follow-up evaluations, and they were considered nonadherent. The results were compared with the as-treated statistical analysis, in which only those participants who completed all evaluations and therapy sessions were included in the data analyses. No statistically significant differences were obtained, and therefore as-treated analyses are reported.

Equivalence of groups at baseline was assessed for age and VHI score. The mean age of the participants in the vocal hygiene education group was 30.2 (SD=8.2, range: 18-49), which was virtually the same as the ages of participants in the voice production therapy group (M=29.0, SD=8.1, range: 19-40). Baseline scores for the VHI were equivalent between the two groups, as reported in the next section and in Tables 2 and 3.

VHI Scores

A linear mixed effect statistical model was fit to the data. VHI score, age of the participant, and therapist were included in the model. The two-way interaction term between treatment group and time point was also included in the model because a plot of VHI score against time revealed that patterns of change in VHI score appeared to be group dependent. Age and therapist did not have a significant effect on VHI score (ps = .74 and .66, respectively) and were removed from the model. The subsequent model included treatment group, adherence, time point, and the Group × Time Point interaction. Treatment group was not significant, F(1, 115) = 3.49, p = .064. Time point at which the measures were taken had a significant effect on VHI score, F(2, 115) = 52.6, p < .0001. Adherence level was also significant, F(1, 115) = 9.29, p = .003; however, the Group × Time Point interaction was significant, F(2, 115) = 14.31, p < .0001, making it incorrect to interpret the significance of the main effects of treatment group and time separately. Therefore, the effect of treatment group on VHI score was analyzed within the context of time.

The VHI scores for both treatment groups are presented in Table 2. Because of the simultaneous multiple comparisons, degrees of freedom were calculated using the containment method, and all p values were adjusted using the Tukey-Kramer adjustment and compared with .05. VHI scores are also presented in a box-andwhisker plot in Figure 3 to help the reader visualize change in scores within and across groups. Note that both groups achieved a statistically significant decrease in VHI scores from baseline to completion of the study, although the improvement was significantly greater for the voice production group. Note also that, for the vocal hygiene education group, only the VHI change score from baseline to post-self-study achieved statistical significance. In contrast, for the voice production group the VHI change scores from baseline to post-therapy and from baseline to post–self-study were statistically significant.

In addition to statistical significance, the clinical significance of differences in VHI scores was assessed.

Table 2. Voice Handicap Index (VHI) mean scores.

Group	Baseline VHI score	VHI score after 6 weeks of therapy	VHI score after 4 weeks of self-study	Change in score: Baseline to post-therapy and significance	Change in score: Post-therapy to post-self-study and significance	Change in score: Baseline to post–self-study and significance
Vocal hygiene	39.7 (SD = 18.0; range: 8-80)	32.8 (SD = 18.7; range: 0-72)	31.7 (SD = 18.2; range: 0-75)	-6.9 p = .074 (t = -2.75)	-1.1 p = .998 (t =43)	-8.0 $p = .018$ $(t = -3.26)$
Voice production	42.5 (SD = 17.7; range: 10-74)	23.9 (SD = 14.8; range: 0-50)	16.5 (SD = 13.8; range: 0-48)	-18.6 $p < .0001$ $(t = -7.42)$	-7.4 $p = .049$ $(t = -2.91)$	- 26.0 p < .0001 (t = -10.71)
Difference between group means and significance	-2.8 $p = .984$ $(t = 0.68)$	-8.9 p = .315 (t = 2.06)	-15.2 $p < .007$ $(t = 3.56)$			

Note. Change scores in boldface are statistically significant. Degree of freedom for t statistics is 77.

Table 3. VHI mean scores by adherence (df = 77).

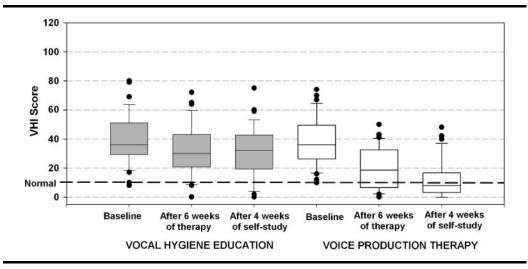
Group	Baseline VHI score	VHI score after 6 weeks of therapy	VHI score after 4 weeks of self-study	Change in score: Baseline to post-therapy and significance	Change in score: Post-therapy to post-self-study and significance	Change in score: Baseline to post-self-study and significance
Vocal hygiene, adherent	36.8 (SD = 16.6; range: 8–69)	27.1 (SD = 15.9; range: 0-53)	23.3 (SD = 16.2; range: 0-49)	-9.7 $p = .03$ $(t = -3.12)$	-3.8 $p = .813$ $(t = -1.25)$	- 13.5 p = .0006 (t = -4.36)
Voice production, adherent	38.7 (<i>SD</i> = 18.2; range: 10–74)	16.3 (<i>SD</i> = 12.9; range: 0–39)	8.3 (<i>SD</i> = 10.0; range: 0-40)	-22.4 $p < .0001$ $(t = -8.78)$	-8.0 $p = .03$ $(t = -3.11)$	-30.4 $p < .0001$ $(t = -12.42)$
Difference between group means and significance	-1.9 $p = .999$ $(t = -0.39)$	-10.8 $p = .223$ $(t = -2.26)$	-15 $p = .028$ $(t = -3.14)$			
Vocal hygiene, nonadherent	40.3 (<i>SD</i> = 19.5; range: 17–80)	39.2 (<i>SD</i> = 20.3; range: 10–72)	40.4 (SD = 16.2; range: 17–75)	-2.1	1.8	-0.1
Voice production, nonadherent	38.8 (<i>SD</i> = 16.5; range: 16–61)	36.4 (SD = 12.5; range: 18–50)	33.2 (<i>SD</i> = 12.5; range: 16–48)	-0.4	-3.2	-3.6
Difference between group means	-1.5	-2.8	-7.2			

Note. Significant findings are in boldface. Statistical results are presented for adherent participants only, because no significant main effects were obtained for the nonadherent participants. Descriptive statistics for nonadherent participants are included for consideration of clinical significance only. Blank cells indicate data not applicable.

The standardized effect size (the mean change score from baseline to post–self-study divided by the pooled standard deviation of the scores at baseline) was 1.01 for the voice production group and 0.44 for the vocal hygiene education group. Interpreting these change scores

according to Cohen's (1988) widely used convention of effect size, where 0.2 is small, 0.5 is medium, and 0.8 is large, a large treatment effect was obtained for the voice production therapy group, and a small effect was obtained for the vocal hygiene education group.

Figure 3. Voice Handicap Index (VHI) Score x Treatment Group. In a box-and-whisker plot, such as the one shown here, the boundary of the box closest to zero indicates the 25th percentile, and the boundary of the box farthest from zero indicates the 75th percentile. Whiskers above and below the box indicate the 10th and 90th percentiles. The horizontal line within the box marks the median. Symbols lying outside the box represent outlying data points.



Clinical significance may also be assessed using the method of Jacobson et al. (1997), whereby within-group comparisons between pre- and post-treatment VHI scores are relevant to clinical practice when the scores decrease by at least 18 points. From the vocal hygiene group, 8 participants achieved a decrease of at least 18 points; 6 of them achieved the drop in scores from baseline to post-therapy, with the other 2 achieving the decrease from baseline to post-self-study. From the voice production group, 21 participants achieved a similar decrease in VHI scores; 17 of them achieved the decrease from baseline to post-therapy, and the other 4 achieved the decrease from baseline to post-self-study. The overall difference between the groups (8 from vocal hygiene and 21 from voice production) was statistically significant, $\chi^2(1, N =$ 28) = 3.84, p = .016.

The VHI scores were also assessed relative to the scores obtained from the group of 100 control participants who completed the VHI and who did not have voice disorders. Two participants in the vocal hygiene education group had VHI scores within normal limits at baseline, and an additional 2 achieved normal VHI scores on completion of the self-study period. In the voice production group, 1 participant had a normal VHI score at baseline, and an additional 21 achieved VHI scores within normal limits after the self-study period.

VHI Scores by Adherence

Pearson product—moment correlation coefficients were calculated to assess the linear relationship between post-therapy VHI and adherence scores (r=-.47, p=.16) and post—self-study VHI and adherence scores (r=-.49, p=.13). The respective R^2 values of .22 and .24 indicate that patient perception of adherence bears little relationship to patient perception of vocal handicap after treatment using a linear model.

Adherence was assessed as a dichotomous variable to test the hypothesis that a participant needed to be adherent (using self-judgment) at least 75% of the time for gains to be achieved. For the vocal hygiene education group, 48% (15/31) of the participants rated themselves as nonadherent for the therapy and self-study periods. For the voice production group, approximately 16% (5/31) rated themselves as nonadherent for the therapy period, compared with 23% (7/31) for the self-study period. The VHI scores were analyzed by adherence level (see Figure 4). For the nonadherent participants, treatment group, time point, and the Group × Time Point interaction did not have statistically significant effects (ps = .56, .64, and .69,respectively); therefore, within-group statistical testing was not conducted. For the adherent participants, however, treatment group had a marginally significant effect, F(1,77) = 3.66, p = .059. Time point was significant, F(2, 77) = 65.77, p < .0001, and the Group × Time Point interaction was significant, F(2,77) = 9.73, p = .0002. Because of the significance of the Group × Time Point interaction, the effect of adherence level on VHI score for the voice production group was analyzed within the context of time. Results of the within-group statistical assessments are presented in Table 3. All p values were adjusted using the Tukey–Kramer adjustment due to the simultaneous multiple comparisons. All t tests have 77 degrees of freedom (calculated using the containment method).

The clinical significance of the VHI scores by adherence also was assessed. The standard effect size for the nonadherent participants in the voice production group was small (0.2) and for the vocal hygiene group was nonexistent. For the adherent participants, the effect size was large for both the voice production (1.7) and vocal hygiene education (0.8) groups. Of note is that the final mean VHI score of 8.3 for the adherent voice production participants was within normal limits, whereas the final scores for all vocal hygiene education participants and the nonadherent participants of the voice production group remained well above normal.

The relationship between the baseline VHI scores and adherence scores was assessed to determine whether adherence could be predicted from the degree of self-perceived vocal handicap. The Pearson product—moment correlation coefficient between the baseline VHI score and the post-therapy adherence score was .434 (p=.12). The R^2 value of .189 indicates no correlation between the two scores.

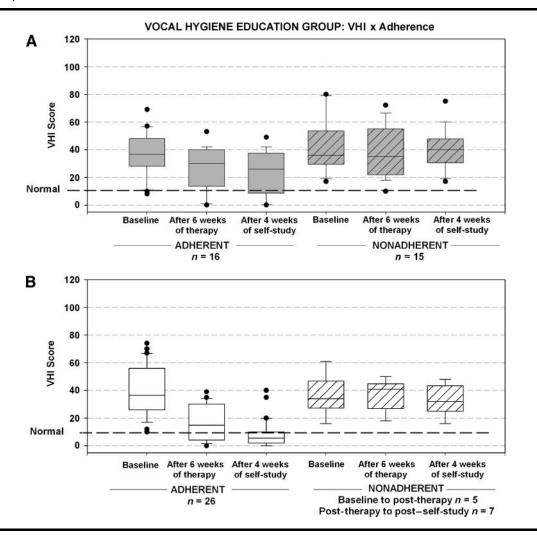
Patient-Determined Follow-Up Treatment

On completion of the study, each of the 62 participants was asked about her satisfaction with her voice and her preferences for continued treatment, if any (see Table 4). Twenty-five percent of the participants in the vocal hygiene group were satisfied with their voices at the end of the study and declined additional treatment, as compared with a 75% satisfaction rate in the voice production group. The overall difference in satisfaction was significant, $\chi^2(3, N=30)=13.6, p=.004$. To further assess group differences, all three of the "not satisfied" categories for each treatment group were grouped together for comparison with the "satisfied with voice" category. Chi-squared test reveals that nearly all of the difference between groups was attributable to the higher satisfaction of the voice production group, $\chi^2(1, N=61)=13.1, p=.0003$.

Discussion Summary of Main Effects

In this section, we discuss the three main effects of this study and their clinical relevance. First, the data

Figure 4. VHI Score × Adherence for the vocal hygiene education group (Panel A) and the voice production therapy group (Panel B).



show that 6 weeks of voice production therapy is more effective than a similar amount of vocal hygiene education as judged by patient perception of vocal handicap. Second, participants in both groups who considered themselves adherent with the treatment protocol obtained better outcomes than nonadherent participants. Third, adherent participants continued to benefit from a

period of self-study, but only in the voice production group.

Treatment × Time Effect

On average, participants in the voice production therapy group achieved superior outcomes in regard to

Table 4. Treatment decision after completion of the clinical trial.

Group	Satisfied with voice, further treatment declined Not satisfied with voice, further treatment deferred to later date		Not satisfied with voice, additional voice therapy elected	Not satisfied with voice, surgery elected	Total	
VH	7	12	11	1	31	
VP	21	6	3	1	31	
Total	28	18	14	2	62	

Note. VH = vocal hygiene group; VP = voice production therapy group.

their voice disorder, as measured by self-perception, than did participants in vocal hygiene education. The data to support this statement may be summarized as follows. When compared with the vocal hygiene education group, voice production participants had, on average, greater improvement in VHI scores; this difference was statistically significant, and the effect size was large. Despite the statistically significant decrease in VHI scores from baseline to final assessment for the vocal hygiene education group, only 8 participants achieved a decrease in VHI score of 18 points or greater, whereas 21 participants in the voice production group achieved a similar improvement in VHI score. Furthermore, more than two thirds of the voice production group achieved final VHI scores within normal limits, compared with approximately one third of those in the vocal hygiene group. Finally, three quarters of the voice production group was satisfied with their voice on completion of the study, compared with one quarter of the vocal hygiene education group.

Some evidence documents that vocal hygiene alone can be beneficial in adults who may be at risk for voice disorders, such as teachers (Chan, 1994), singers (Broaddus-Lawrence et al., 2000), and radio professionals (Timmermans et al., 2003). However, the data from studies of individuals with voice disorders are generally consistent with the findings of this research. Roy et al. (2001) assessed 58 dysphonic teachers randomized to vocal hygiene, vocal function exercises, or a no-treatment control group. The vocal hygiene and vocal function groups had four sessions over 6 weeks. Only the vocal function exercise group demonstrated statistically significant improvement in VHI scores. Roy et al. (2002) assessed a different group of 44 teachers randomized to voice amplification, vocal hygiene, or a nontreatment control group. Again, the vocal hygiene group did not demonstrate statistically significant improvement. In both studies, however, changes in VHI scores were in the correct direction (improving) for participants in the vocal hygiene groups. None of the teachers in either study were currently seeking treatment for a voice disorder, and the health status of their vocal folds was unknown. It is difficult to generalize findings from these participants to women with known vocal fold pathology who are specifically seeking treatment for their voice problems. Furthermore, the inclusion of a 10-min steam once per week in the vocal hygiene group could have influenced the extraclinical behavior of the participants and therefore affected the outcome of that treatment arm.

Holmberg et al. (2001) assessed 10 women with nodules who took part in a course of voice therapy of 4 to 6 months' duration consisting of five sequential elements of 3 weeks each: (a) vocal hygiene, (b) direct facilitation, (c) respiration, (d) relaxation, and (e) carryover. No significant improvement was found after the vocal hygiene phase on measures of voice quality, acoustic data, or

stroboscopic features. In contrast, Carding et al. (1999) found different results. They assessed 45 voice disordered individuals assigned to no treatment, indirect therapy, or a combination of indirect and direct therapies. Slightly fewer than half of the patients in the vocal hygiene education group achieved significant improvement in voice quality, compared with more than 90% of patients in the combined vocal hygiene and voice production group.

Few studies have developed normative data for the VHI, and those that have are based on non-Englishspeaking populations. The criterion of 11.5 as the cutoff for a normal VHI score used in this study is consistent with the limited amount of published normative data, however. Using a Portuguese translation of the VHI, Guimarães and Abberton (2003) found a mean score of 10.5 (SD = 1.8) in 56 control participants. Peeters et al. (2004) used a Dutch translation of the VHI to assess 38 healthy volunteers and found a mean score of 2.3 (SD = 2.7, range: 0-9), with a confidence interval of 7.7(yielding a normal criterion of 10). Speyer, Wieneke, and Dejonckere (2004b) used Jacobson et al.'s (1997) 18-point critical difference score and established the normal cutoff as 18 points. AVHI score within normal limits does not necessarily identify the absence of a voice disorder and likely has little relevance for treatment planning for the individual voice patient. The normal score does, however, provide additional relevant information to assist in interpretation of the mean data describing therapy effectiveness for a group of individuals.

Adherence Effect

A second relevant finding from this study is that adherent participants received greater benefit from voice production therapy, during both the therapy and the selfstudy periods, than did the nonadherent patients, as judged by patient perception of vocal handicap. This finding is also consistent with the common clinical belief that voice therapy "works" when patients adhere to the program. Furthermore, the relationship of adherence to treatment outcome does not appear to be linear. The data suggest that a critical level of adherence must be achieved to result in perception of treatment gains. Unsurprising as this finding may be, the data do add substantially to the corpus of empirical evidence that demonstrates the adherence effect. The only other data exploring the relationship of adherence to treatment outcome known to us are from Verdolini-Marston et al. (1995). In their study of 13 women with nodules randomized to 2 weeks of confidential or resonant voice therapy or to a no-treatment control condition, the authors found that adherence had a greater effect on outcome than did type of therapy. Although Roy et al. (2001, 2002) did measure self-report of adherence in their clinical trials of therapy efficacy, they reported only the percentage of nonadherent participants in each treatment group. The relationship of adherence and treatment outcome was not explored directly, and their scale is not readily comparable with the scale used in this study.

It is notable that participants in this study appeared to find it easier to adhere to the voice production therapy than to the vocal hygiene education. Furthermore, on average, participants in the voice production group maintained their adherence during the self-study period, whereas those in vocal hygiene education did not. In debriefing conversations with each participant at the conclusion of the study, we noted that two components of the vocal hygiene regimen proved the most problematic: (a) reducing the overall amount of voice use and (b) reducing loudness level. Perhaps this finding is a function of geography: New York City is a noisy and aggressive environment that does not lend itself easily to soft speech. However, the lesser group adherence to vocal hygiene education may also be a function of the treatment itself. Reduction in overall voice use and loudness level may be unrealistic for many individuals. In a survey of 305 teachers asking how likely they would be to incorporate vocal hygiene techniques into the classroom, only 4 of 23 techniques listed were rated as "very likely" to be performed (Williams & Deem, 2000). Clearly, our hypothesis that regular attendance in weekly sessions for the vocal hygiene education group might improve adherence was not supported.

The 12% dropout rate in this study is consistent with the 12% dropout rate reported by Roy et al. (2002) but low when compared with dropout rates of some other studies. Roy et al. (2003) reported a 17% dropout rate. Sellars et al. (2002) found that 18% of 100 participants dropped out of therapy prior to completion of a preestablished six-session regimen. MacKenzie et al. (2001) reported a 25% dropout rate of 204 therapy participants after 6 weeks, and an additional 10% dropped out at 12 to 14 weeks. Perhaps the relatively low dropout rate in this study was due to the fact that all therapy was provided at no cost to the participants.

Self-Study Effect

A third finding of note is that adherent patients continued to perceive benefit during the self-study period, more so in the voice production group than in the vocal hygiene education group. The absolute value of the VHI change score during the self-study period was not clinically significant for either group; however, it is notable that in the voice production group, 25% of the decrease in VHI score from baseline to completion of the study was achieved during the self-study period. The extent of the average improvement during this period was surprising and, to our knowledge, this finding is novel: The effectiveness of self-practice as a follow-up to

in-session voice therapy has not been studied. Effective self-practice does have implications for potential changes in delivery of treatment, particularly in cases where therapy is not easily accessible for the voice patient or when insurance coverage is limited. Certainly the concept of self-study warrants further research.

Limitations of the Study

One limitation of this study was the use of two therapists, one of whom was the PI of the study. Interim data analyses could have biased the principal investigator relative to delivery of treatment. However, the other therapist (the third author) was not privy to results of interim data analyses, and no therapist effect was found, which suggests that bias was not a factor. Nevertheless, this design decision, made for reasons of economics (clinical studies are expensive) does weaken this study's internal validity. In contrast, however, the use of two therapists strengthens external validity. Another factor relevant to internal validity is the clinician's assumption of therapy equipoise. Most experienced clinicians do favor certain treatment techniques or approaches. In this study, both clinicians were biased in favor of the voice production therapy as a long-term, permanent solution. It is important to note, however, that both clinicians also expected that after 6 weeks of therapy, vocal hygiene education would yield an outcome equivalent to voice production therapy provided that the participants adhered to the treatments. It was expected that only during the self-study period would differences in adherence and treatment outcome become evidence. The findings from this study did not support those beliefs completely.

Another shortcoming of this study was that assessment of outcome was limited to patient perception using the VHI and patient selection of follow-up treatment on completion of study participation. The status of the vocal fold mucosa after therapy would have been valuable data to obtain. In fact, as part of the informed consent process, all participants agreed to follow-up stroboscopic examination after completion of the self-study period. However, postintervention data were not obtained on 34% (21/62) of all participants (12 from the vocal hygiene education group and 9 from the voice production therapy group) because those participants did not return for a follow-up medical evaluation. (The participants who did not follow up with a medical evaluation were still offered six sessions of additional therapy at no charge.) Unfortunately, participant attrition is one of the challenges of clinical research. Missing data from 34% of the participants is unacceptably high and prohibits report of the data on vocal fold examination from the remaining participants.

A third limitation of the study was that adherence was measured only by participant self-report. Although

no single ideal measure of adherence exists, the use of additional, more objective measures (e.g., recordings of daily practice and practice diaries) would have strengthened this study.

Finally, data regarding treatment progress would have been an important contribution to this study, such as the level in the LMRVT treatment hierarchy at which each participant ended treatment, the extent to which each participant successfully attained resonant voice, the type and frequency of tasks actually practiced by the participants during the self-study period, an independent assessment of the participants' abilities to use resonant voice in communicative activities of daily living, and the contribution of specific components of the vocal hygiene and voice production protocols to the overall outcome. Those additional data would have greatly enhanced the clinical application of the findings of this study, and so the issues they raise remain for future studies to answer.

Further Research

This research provokes many questions. Despite the greater effectiveness of the voice production therapy, one third of the VHI scores from that group were above normal limits. The ability of voice production therapy to completely address the symptoms of phonotrauma should be examined with longer term therapy and follow-up. The factors that regulate adherence with vocal hygiene education and voice production therapy are also uncertain, and further research on this topic is warranted, as are methods that could increase adherence. Another area of further research might be exploration of methods for using self-study to increase the overall effectiveness of voice therapy. Finally, the relative effectiveness of a combined program of vocal hygiene education and voice production exercises compared with voice production exercises alone may further elucidate the extent to which the voice therapist should devote precious therapy time to vocal hygiene education and perhaps help identify which patients might benefit from vocal hygiene education.

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