Medialization Laryngoplasty After Injection Augmentation

*Valeria Silva Merea, †Solomon Husain, and ‡Lucian Sulica, *†‡*New York, New York*

Summary: Objectives. This study aims to assess the effect of vocal fold injection augmentation (IA) on subsequent medialization laryngoplasty (ML).

Study Design. A retrospective cohort study with follow-up telephone survey was carried out.

Methods. Clinical records of patients with unilateral vocal fold paralysis or paresis (VFP) who underwent ML between April 2006 and March 2015 were reviewed. Patients who underwent IA before ML were compared with patients who did not, with respect to demographic information, symptoms, Voice Handicap Index-10 (VHI-10), etiology of VFP, and revision rate. Among patients undergoing IA, the effects of injection material and of interval from IA to ML on revision rate were assessed. Follow-up telephone surveys were conducted to evaluate long-term outcomes using VHI-10 and a condition-specific questionnaire.

Results. One hundred thirty-five patients (70 male:65 female) with vocal fold paralysis (125) or paresis (10) underwent ML (96 left:39 right). Sixty-six (48.9%) patients underwent concurrent arytenoid adduction. Fourteen (10.4%) patients required revision. Fifty-six (41.5%) patients had prior IA; five (8.9%) patients underwent revision. Seventy-nine (58.5%) patients did not have IA; nine (11.4%) patients required revision ($P = 0.78$). Neither augmentation material nor length of interval between last IA and ML affected the revision rate ($P = 1.00$; $P \geq 0.11$ for all tested intervals, respectively). No difference in follow-up VHI-10 score was found between patients who had IA before ML and patients who had not ($P = 0.73$).

Conclusions. IA does not appear to affect the revision rate or long-term outcome of subsequent ML.

Key Words: Vocal fold paresis–Vocal fold paralysis–Injection augmentation–Medialization laryngoplasty–Outcome.

INTRODUCTION

Medialization laryngoplasty (ML) is the operation of choice for long-term rehabilitation of voice and swallowing symptoms from glottic insufficiency resulting from vocal fold paralysis or paresis (VFP). Injection augmentation (IA) is a widely used temporary treatment for symptoms of glottic insufficiency, which has enjoyed an expanding role since it has once again proved practical and efficacious in the office setting, as it was historically conceived.[1]

A substantial number of patients treated with IA go on to have ML, yet there are no data on the effect of IA on subsequent framework surgery. As injectable agents affect vocal fold position and may cause residual mass effects or fibrosis, there is reason to believe that IA may adversely affect the outcome of ML. This is particularly true when ML is undertaken soon after IA, within the period that injectable mass effect persists. No studies have investigated the appropriate timing of ML after a prior IA procedure.

We hypothesized that patients with IA before ML, and especially those with a short interval between IA and ML, would be more likely to have suboptimal results, as demonstrated by increased revision rate and low patient satisfaction. This study aims

(1) to determine the effect of IA on the rate of revision of ML for unilateral VFP; and
(2) to define the impact of IA material and timing of laryngeal framework surgery after IA with respect to revision rates and patient satisfaction.

MATERIALS AND METHODS

The study was approved by the institutional review board. All ML procedures performed between April 2006 and March 2015 were identified from the senior author's surgical log. Medical records of patients who underwent this procedure were reviewed for demographic information, comorbidities, surgical history, medications, smoking history, presence of dysphagia or aspiration, dyspnea, Voice Handicap Index-10 (VHI-10), date of onset of voice complaint, diagnosis, and etiology, as well as information regarding IA, ML, and revision procedures.

Patients who present to our center with symptomatic VFP and in whom the potential for spontaneous recovery exists are offered IA. When swallowing symptoms predominate, and clinically significant aspiration is thought to be a risk, IA is recommended. We consider potential for spontaneous recovery to exist when (1) the recurrent laryngeal nerve is believed to be intact, and (2) the VFP is of less than 12 months' duration. If the vagus or recurrent laryngeal nerve has been transected, or the VFP is secondary to neoplastic invasion, or has been present for 12 or more months, patients are offered ML. Both treatment options, IA and ML, are discussed at the initial assessment; treatment chosen may differ from that recommended because of patient preference.

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From the *New York-Presbyterian Hospital, Department of Otolaryngology—Head and Neck Surgery, Weill Cornell Medical College, New York, New York; †Weill Cornell Medical College, New York, New York; and the ‡Sean Parker Institute for the Voice, Department of Otolaryngology—Head & Neck Surgery, Weill Cornell Medical College, New York, New York.

Address correspondence and reprint requests to Lucian Sulica, Sean Parker Institute for the Voice, 240 East 59th Street, New York, NY 10022. E-mail: lus2005@med.cornell.edu

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TABLE 1.
Materials Used for Injection Augmentation

Material	Injection Procedure First	Second	Third	Fourth	Total
CaHA	22	13	3	1	39 (47.0%)
CMC	26	4	3	1	34 (41.0%)
Micronized dermis (Cymetra, LifeCell, Branchburg, NJ)	1	1	—	—	2 (2.4%)
Hyaluronic acid (Restylane, Galderma Laboratories, Fort Worth, TX)	1	—	—	—	1 (1.2%)
Hyaluronic acid (Juvéderm, Allergan, Irvine, CA)	1	—	—	—	1 (1.2%)
Absorbable gelatin (Gelfoam, Pfizer, New York, NY)	1	—	—	—	1 (1.2%)
Collagen	1	—	—	—	1 (1.2%)
Fat	1	—	—	—	1 (1.2%)
Polytetrafluoroethylene	—	1	—	—	1 (1.2%)
Unknown	2	—	—	—	2 (2.4%)
TOTAL	56	19	6	2	83

Abbreviation: CaHA, calcium hydroxylapatite; CMC, carboxylmethylcellulose.

All patients 18 years or older at the time of follow-up survey (see below), who were treated for vocal fold paralysis or paresis, were included in the study. Younger patients were excluded, as were patients who had initial ML performed at an outside institution. In addition, patients who had ML as part of more complex reconstructions such as those involving muscle flaps, who had laryngoplasties other than those to medialize the vocal fold or for other diagnoses besides VFP (atrophy, scar, sulcus, soft tissue defects after cancer surgery), and those who had bilateral ML were also excluded from this study.

Patients were contacted by phone to complete a survey that included general questions on events since their last office visit, a Likert scale questionnaire on vocal function, and the VHI-10 (Appendix). A validated Spanish version of the VHI-10 questionnaire was used for Spanish-speaking patients.[2]

Patients with IA before ML were compared with patients without a history of IA with respect to surgical revision rate and long-term satisfaction with their voice. The interval between last IA and framework surgery was evaluated as an independent variable. Statistical analysis was performed using GraphPad Prism 7 (GraphPad Software, San Diego, CA) software and Microsoft Excel for Mac 2015 (Microsoft Corporation, Redmond, WA). Two-tailed *P* values were calculated for all statistical analyses.

RESULTS

One hundred sixty-six patients who underwent ML were identified, and 31 of those were excluded per exclusion criteria outlined above. Of the 135 patients included, 70 (52%) were male. The mean age at the time of framework surgery was 57.5 years (SD = 14.3; range = 15–87 years). Only eight (5.9%) patients were smokers at the time of surgery. All were dysphonic; 74 (54.8%) patients presented with swallowing symptoms (not necessarily aspiration), and 29 (21.5%) patients complained of dyspnea. Initial VHI-10 mean score, available for 82 (60.7%) patients, was 26.7 (SD = 9.6) and ranged from 0 to 40, the full range of the questionnaire itself. Paralysis was present in 125 (92.6%) patients, and paresis in 10 (7.4%) patients. The left vocal fold was the most commonly affected (96 patients; 71.1%). The most common etiology of vocal fold palsy was iatrogenic (86 patients; 63.7%), followed by idiopathic (26 patients; 19.2%) and neoplastic (21 patients; 15.6%).

Injection augmentation

Fifty-six (41.5%) patients underwent 83 IA procedures before framework surgery. Nineteen (34%) patients underwent at least two injections (Table 1). Twenty-two (39.3%) out of the 56 patients who underwent IA before ML had already had injections before presentation to our center; these accounted for 42.2% of the total number of injections done before ML. The injection materials used at our center were carboxylmethylcellulose (CMC) (Radiesse Voice Gel or Prolaryn, Merz Aesthetics, San Mateo, CA) and calcium hydroxylapatite (CaHA) (Radiesse Voice or Prolaryn Plus; Merz Aesthetics). Other injection materials used in patients injected elsewhere are shown in Table 1.

The mean interval between onset of VFP and the first IA was 293 days (median = 106) or just less than 10 months. The intervals ranged from 1 day to 15 years (SD = 754 days). Excluding a single outlier who underwent IA after 15 years, the mean was 200 days (median = 100, SD = 296 days). In contrast, the mean interval between the last IA and the ML was 430 days or 14 months (median = 207 days; range = 15 days to 17 years; SD = 909 days). When the outliers at both ends were removed, the mean was 233 days (median = 200; SD = 125). There was no statistical difference in intervals from onset of VFP to first IA, and from last IA to framework surgery between patients who had IA by other otolaryngologists and patients who underwent IA by the senior author ($P = 0.36$ and 0.44, respectively).

Framework surgery

Of the 135 patients who underwent unilateral ML, 66 (48.9%) underwent arytenoid adduction at the time of the medialization. In all cases, the procedure consisted of implant medialization using a Gore-Tex implant (W.L. Gore and Associates, Flagstaff, AZ). In one patient, cricothyroid approximation was also performed at the time of the medialization. The mean interval between onset of VFP and ML was 34 months (range = 1 month to 31.5 years; SD = 64 months). The mean interval from onset

TABLE 2.
Details of Revision Surgery

Revision Framework Surgery	
Removal of old implant, new implant placed, AA	6
Removal of old implant, new implant placed	3
Old implant left in place, new implant added	1
Removal of old implant, new implant placed; contralateral medialization	1
Removal of old implant, new implant placed, AA; pharyngoplasty	1
Old implant left in place, AA; pharyngoplasty	1
Partial removal of implant, AA	1
TOTAL	**14**

Abbreviation: AA, arytenoid adduction.

of palsy to framework surgery did not differ for patients with IA (28 months, SD = 41 months) compared with patients without (39 months, SD = 76 months; unpaired, two-tailed *t* test, $P = 0.27$).

Revision framework surgery

Fourteen (10.4%) patients underwent revision surgery; details are shown in Table 2. The mean interval between the initial framework surgery and the revision was 12.5 months (range = 4–27 months). Five (8.9%) of the 56 patients who had had IA before their framework surgery underwent revision surgery, versus 9 (11.4%) of 79 who did not have prior injection. This difference did not reach statistical significance (Fisher exact test, $P = 0.78$). In three of these cases, the material used for the last injection was CaHA, whereas CMC was the filler for the other two. Figure 1 depicts the distribution of the sample groups, with the prior IA group subdivided into short-acting (eg, CMC, collagen, and micronized dermis), long-acting (eg, CaHA and Teflon), and unknown injectables. When comparing the two most commonly used materials in our study when used before framework surgery, 11.5% of the CaHA injections required revision surgery, whereas revision was needed in 8% of patients who had a CMC IA (Fisher exact test, $P = 1.00$).

There was no difference in revision between patients who had arytenoid adduction at the original surgery (6 of 66 patients or 9.1%) and those who did not (8 of 69 patients or 11.6%) in the rate of revision (Fisher exact test, $P = 0.42$).

Patients whose ML was within 5 months of their last IA procedure had the highest cumulative revision rate at 20%, with a *P* value that approached statistical significance (Fisher exact test, $P = 0.11$). Figure 2 illustrates the relationship between interval from last IA to ML, and revision framework surgery, whereas Table 3 shows the cumulative revision rates and *P* values on Fisher exact test for intervals from 1 to 12 months.

Follow-up survey

Sixty-three (56.8%) patients participated in the survey. Twenty-four deceased patients were excluded, 32 patients could not be reached, 11 patients refused to complete the survey, and 5 patients were unable to participate (eg, patients with severe dementia, or non-English or non-Spanish speakers). No patient had had any additional procedure to address their VFP since their last visit to our center. Mean postop VHI-10 score among patients who completed the survey was 13.7 (SD = 9.6; range 0–40). In patients who had both initial and postoperative VHI-10 scores, there was a statistically significant decrease in VHI-10 score for both groups studied ($P < 0.0001$ for both). When comparing postop VHI scores of patients who underwent IA before ML with patients who did not, there was no significant difference between their scores ($P = 0.73$). Of note, initial visit VHI scores were also compared and no difference was detected (Wilcoxon, $P = 0.11$). The results of the questionnaire on vocal fold function were compared for the two groups (IA before ML, vs. no IA before ML),

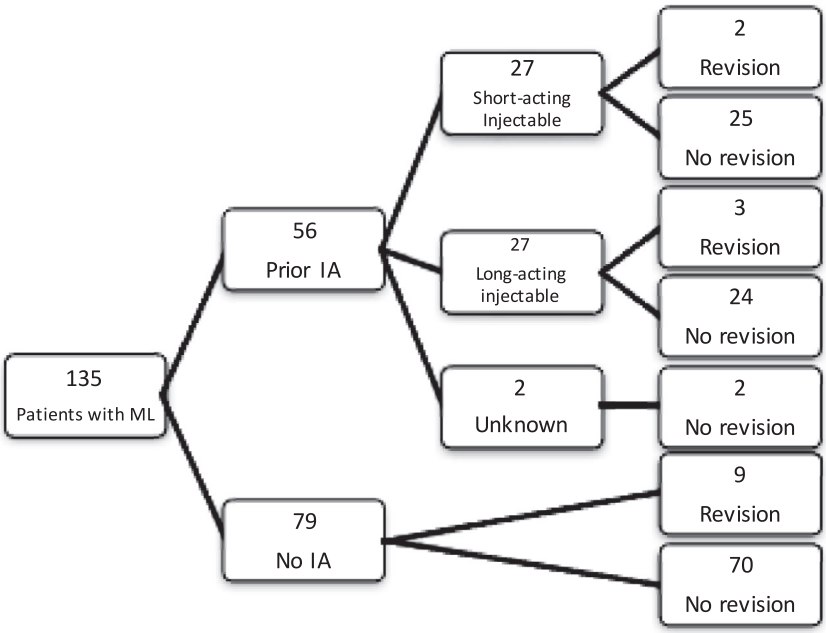

FIGURE 1. Distribution of sample groups resulting in revision framework surgery. IA, injection augmentation; ML, medialization laryngoplasty.

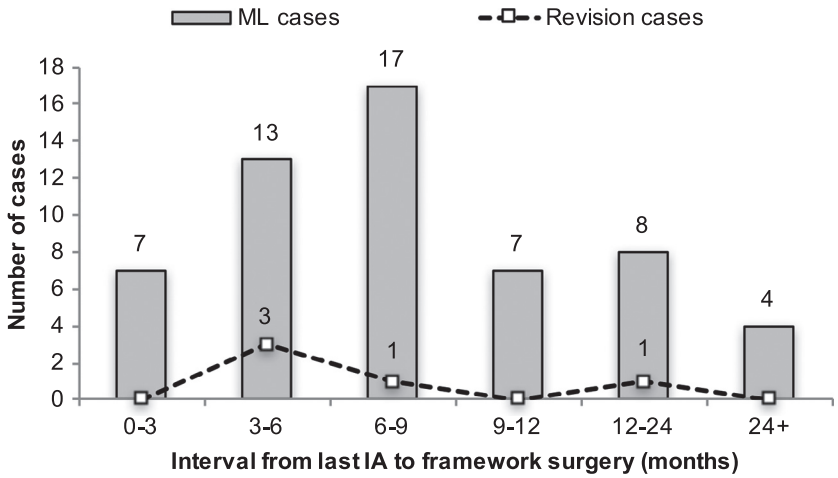

FIGURE 2. Distribution of cases according to interval from last injection augmentation to medialization laryngoplasty. IA, injection augmentation; ML, medialization laryngoplasty.

and no statistically significant difference was found in any of the categories. Table 4 shows phone survey results for these two groups. Within patients with IA, there was no statistical difference in VHI-10 score between patients whose last IA was within 6 months of ML and patients with a longer interval. Similarly, this interval did not affect voice quality, vocal endurance, vocal projection, or anxiety about future problems.

DISCUSSION

IA procedures relieve the symptoms of glottic insufficiency by medial displacement of the free edge of the compromised vocal fold as a result of the expansion of the muscle compartment.[3] ML, in contrast, shifts the muscle compartment medially by means of an inert, space-occupying implant inserted into the paraglottic space. Thus, even though IA and ML share indications and appear to achieve similar results,[4–9] their mechanisms are not exactly equivalent. Any residual mass effect from injectable has the potential to affect the outcome of subsequent ML by misleading the surgeon regarding the amount of medialization achieved, and result in postoperative deterioration of results.

TABLE 3.
Results of Fisher Exact Test (Two-tailed *P* value) for Intervals from Last Injection to Framework Surgery

Effect of Interval Between Last IA and ML on Revisions				
Interval (mo)	Cumulative Number of Patients	Cumulative Number of Revisions	Cumulative Revision Rate (%)	*P* Value
1	2	0	0.0	1.00
2	3	0	0.0	1.00
3	7	0	0.0	1.00
4	11	1	9.1	1.00
5	15	3	20.0	0.11
6	18	3	16.7	0.34
7	29	4	13.8	0.35
8	34	4	11.8	0.64
9	37	4	10.8	0.65
10	39	4	10.3	1.00
11	41	4	9.8	1.00
12	44	4	9.1	1.00

Abbreviation: IA, injection augmentation; ML, medialization laryngoplasty.

Different materials have different mechanisms and durations of action. The two major injection materials used in our study were CaHA and CMC. CaHA is a stable, biocompatible compound of calcium and phosphate, naturally found in human bones and teeth. As an injectable, it is composed of smooth microspheres 25–45 μm in size suspended in a gel carrier consisting primarily of water, glycerin, and CMC. The initial augmentation is caused in part by the carrier gel, but as this gel is resorbed, the remaining CaHA microspheres stimulate collagen production in addition to their own mass effect.[10] In his *in vivo* canine model, Chhetri et al found that CaHA particles remained stable over 12 months, although reductions in medialization took place over that period.[11] Moon et al reported stability of augmentation in a rabbit model at 6-month follow-up.[12] In humans, CaHA's therapeutic duration remains variable. The vocal fold's intrinsic tendency to reinnervate—but not necessarily regain motion[13]—confounds simple assessment of results by yielding a substantial number cases of long-term symptom relief, which are probably not due to injectable. Multiple studies showed excellent clinical results in the short term, with benefits at the 5- to 12-month follow-up,[14–17] and a well-conceived retrospective study that took measures to account for confounders reported an average of 18.6 months of benefit.[18] Our own experience is that in VFP, which results from nerve transection (and is thus unlikely to appreciably reinnervate), clinical benefit very rarely extends up to a year. In the context of altering ML results, however, relevant persistence may extend beyond clinical benefit. In a large retrospective study, CaHA, easily seen radiographically and fluorodeoxyglucose avid, was seen up to about 18 months on computed tomography.[19] Similarly, injected sites with such amount did not show fluorodeoxyglucose uptake 18 months after injection.[19]

Radiesse Voice Gel (now Prolaryn Gel, Merz Aesthetics) is an organic polymer that is composed of CMC, glycerin, and water, and serves as the carrier substance in CaHA. CMC is thought to be a viable, safe, and efficacious shorter term injection material

TABLE 4.
Analysis of Phone Survey Results

	No IA	Prior IA	*P* Value	Test
Same field, N (%)			0.531	Fisher exact
No	7 (25.9%)	8 (38.1%)		
Yes	20 (74.1%)	13 (61.9%)		
Days of work missed, N (%)			0.501	Chi-square
0	22 (91.7%)	18 (90.0%)		
1	0 (0.0%)	0 (0.0%)		
2–4	1 (4.2%)	0 (0.0%)		
5–7	0 (0.0%)	0 (0.0%)		
More than 7	1 (4.2%)	2 (10.0%)		
Visited another otolaryngologist, N (%)			1.000	Fisher exact
No	32 (94.1%)	28 (96.6%)		
Yes	2 (5.9%)	1 (3.4%)		
Likert scale questions: 0 ("Strongly disagree") to 4 ("Strongly agree")	Median			
1. I can participate in my profession without vocal limitation.	3	3	0.383	Mann-Whitney
2. My current voice quality is good.	3	3	0.243	Mann-Whitney
3. My vocal endurance or stamina is strong.	3	2	0.143	Mann-Whitney
4. My ability to project my voice is good.	2	2	0.405	Mann-Whitney
5. Since my last visit to WCMC I have experienced voice problems.	1	2	0.553	Mann-Whitney
6. My vocal fold problem and subsequent surgery has had a significant adverse effect on my current voice quality and function.	0	1	0.224	Mann-Whitney
7. I suffer from anxiety about vocal fold problems in the future.	1	1	0.562	Mann-Whitney
8. I have knowledge and resources to manage any future voice problems, should they arise.	3	3	0.894	Mann-Whitney
VHI-10, Mean (SD)	13.3 (10.0)	14.1 (9.3)	0.732	Unpaired *t* test

Abbreviation: IA, injection augmentation; WCMC, Weill Cornell Medical College.

for the treatment of glottic insufficiency.[20] A small study in 11 patients showed excellent postoperative videostroboscopic results and a duration of clinical effect of 2–3 months after injection.[21]

Contrary to our hypothesis, there was no difference in the rate of revision surgery between patients who had a prior IA and those who did not. We had expected residual mass effects and fibrosis after IA to lead to a potential undermedialization at ML, which, in turn, would lead to revision. A higher rate of revision was expected for longer lasting material, that is, CaHA, but no effect for injection material was found. This hypothesis is clearly dependent on the timing of ML following IA, as a long enough interval would allow for any implant material to be degraded. In our study, there was no statistically significant difference in revision rate with regard to interval from last IA to ML. However, patients who underwent framework surgery within 5 months of an IA had the highest rate of revision. These "short interval" MLs are most likely related to poor injection results, and suggest that it may be the quality of the injection that determines the need for ML in such cases. This may explain the lack of a stronger observed effect of interval from IA to ML.

The retrospective nature of the chart review, with inherent confounding variables and bias, is a limitation of this study. In addition, even though we had a reasonably robust sample of patients who underwent ML, our power for subanalysis was limited given the small number of revision events within subgroups. Thus, true differences may exist, which we are unable to detect. Furthermore, our 56.8% telephone-survey response rate was limited and may have also introduced bias. This response rate, however, is comparable with that of other survey studies.[22,23] Finally, the decision to undergo revision surgery may be influenced by multiple factors beyond voice outcome from the original surgery, which are not examined here. Patient or surgeon preference, patients' age and overall health status, and professional and social obligations may determine whether further surgery is pursued.

Based on our results, IA does not appear to adversely affect the outcome of subsequent ML. In addition, there appears to be no set or minimum time interval one should wait between IA and subsequent ML for optimal results. Overall, the IA-to-ML interval may be self-regulating. In other words, patients do not undergo ML unless their voice is poor, which, in turn, may result from a technically poor IA ("short interval" ML), which does not prejudice the outcome of the framework surgery, or from the expected voice deterioration as appropriately placed injectable resorbs.

CONCLUSIONS

IA does not appear to influence the outcome of subsequent laryngeal framework surgery, as reflected in the rate of revision and patient perception of voice quality and function. Similarly, the interval between last IA and ML does not appear to affect

revision rates. However, given that this interval may have been influenced by technically poor injections, one should still consider waiting for the injectable to resorb as evidenced by videostroboscopic examination, or as long as the injectable's purported life span, before proceeding with framework surgery.

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APPENDIX

Phone survey

Medialization Laryngoplasty: Long-Term Outcomes Patient Code: _____

To begin, I'd like to ask a few questions about your current voice use and how it relates to your profession:

Registration Questions	Do you continue to work in the same profession as you did prior to undergoing medialization laryngoplasty?	N	Y		
	If not, was your VF problem the main reason?	N	Y		
	If not, but not because of VF problem please explain:				
	How many days of work have you missed in the past year because of a voice problem?	0	1	2–4	5–7 > 7
	Have you been treated by a non-WCMC ENT for a voice problem since your last visit?	N	Y	Date(s):	
	If yes, Were you diagnosed with vocal fold paralysis/paresis?	N	Y	Date:	
	Were you treated with any (or all) of the following?	Voice rest Surgery		Medication Voice therapy	
	Other notes:				

For the following 8 statements, please answer on a scale of 0–4, 0 representing "strongly disagree," 2 representing "neutral," and 4 representing "strongly agree."

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Likert Scale—Vocal Function	I can participate in my profession without vocal limitation.	0	1	2	3	4
	My current voice quality is good.	0	1	2	3	4
	My vocal endurance or stamina is strong.	0	1	2	3	4
	My ability to project my voice is good.	0	1	2	3	4
	Since my last visit to WCMC I have experienced voice problems.	0	1	2	3	4
	My vocal fold problem and subsequent surgery has had a significant adverse effect on my current voice quality and function.	0	1	2	3	4
	I suffer from anxiety about VF problems in the future.	0	1	2	3	4
	I have knowledge and resources to manage any future voice problems, should they arise.	0	1	2	3	4

The last questions are part of a standardized questionnaire you completed on your first visit to our office. Please answer on a scale of 0–4, 0 representing "never," 2 representing "sometimes," and 4 representing "always."

		Never	Almost Never	Sometimes	Almost Always	Always
Voice Handicap Index-10	My voice makes it difficult for people to hear me.	0	1	2	3	4
	People have difficulty understanding me in a noisy room.	0	1	2	3	4
	My voice difficulties restrict my personal and social life.	0	1	2	3	4
	I feel left out of conversations because of my voice.	0	1	2	3	4
	My voice problem causes me to lose income.	0	1	2	3	4
	I feel as though I have to strain to produce voice.	0	1	2	3	4
	The clarity of my voice is unpredictable.	0	1	2	3	4
	My voice problems upset me.	0	1	2	3	4
	My voice makes me feel handicapped.	0	1	2	3	4
	People ask, "What's wrong with your voice?"	0	1	2	3	4

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