Evaluation of a Shorter Follow-up Time to Capture Benefit of a Trial Vocal Fold Augmentation

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Summary: Objective. Trial vocal fold injection (TVFI) is employed diagnostically for patients with subtle glottic insufficiency to explore potential for improvement. Clinical experience demonstrates the time to and length of peak benefit of the TVFI is variable. Previous studies collected data 4 weeks or more after TVFI. The aim of this study was to compare subjectively successful and unsuccessful TVFI patient groups. It is hypothesized that patients with subjectively reported success will also have significant improvements in Voice Handicap Index-10 (VHI-10), phase closure percentage, and aerodynamic measures 2 weeks after trial augmentation.

Methods/Design. Subjects with glottic insufficiency were included in this retrospective review if they underwent office-based, per-oral vocal fold injection augmentation specifically for trial purposes. Patients were divided into "successful" and "unsuccessful" groups based on their subjective experience during the 2-week post-TVFI period. VHI-10, subjective report, phase closure evaluation using frame-by-frame analysis, and aerodynamic data were collected pre- and 2 weeks post-TVFI.

Results. Of the subjects, 15 of 23 (65%) reported a successful subjective improvement of their symptom, whereas 8 (35%) were unsuccessful (only partial improvement or no improvement). The number of subjects with an improvement in VHI-10 by 5 or more points was not significantly different between groups. The number of subjects that demonstrated complete, long phase closure was significantly higher in the successful group ($P = 0.021$).

Conclusions. The understanding of how to more precisely determine the success of TVFI remains incomplete. Subjective improvement of successful TVFI was captured with basic clinical questioning, yet the VHI-10 was unable to confidently demonstrate this reported success 2 weeks after TVFI.

Key Words: Trial vocal fold injection–Injection augmentation–Glottic insufficiency–Vocal fold atrophy– Muscle tension dysphonia.

INTRODUCTION

Trial vocal fold injection augmentation (TVFI) is defined as the use of a temporary injectable substance to augment the vocal folds when the benefits of permanent augmentation are uncertain. The concept of TVFI was initially described on a cohort of patients with nonparalytic glottic insufficiency (GI) with the exception of vocal fold scar.[1] After the initial paper, others have worked to demonstrate the effectiveness and usefulness of TVFI for predicting long-term outcomes of more durable augmentation with some degree of certainty. The ability to predict the outcome after permanent augmentation via fat augmentation or thyroplasty in those who experience a successful TVFI seems variable based on when the post-TVFI patient data are collected and if a validated survey and/or objective acoustic and aerodynamic measurements can reliably capture the true outcomes. A study by Young et al saw only a 42% positive response to TVFI using carboxymethylcellulose (CMC) in a vocal fold atrophy population; this anecdotally seems low. However, of those 42% of patients who had a positive TVFI, 75% had a positive response to long-term augmentation, suggesting that outcomes of TVFI are predictive of long-term augmentation outcomes; overall 65% of their subjects had a significant improvement after long-term augmentation whether or not TVFI was successful.[2] A study by Dumberger et al demonstrated an "excellent" correlation with change in subjective rating of the post-TVFI and post-Gore-Tex medialization laryngoplasty voices (via GRBAS (grade, roughness, breathiness, asthenia, strain) scale) and "good" correlation with pre- and post-TVFI glottal function index. Interestingly, they only demonstrated "moderate" correlation using the voice-related quality of life (VRQOL) patient-reported outcome measure.[3] Although not trying to evaluate the predictability of a permanent augmentation based on a TVFI outcome, a third study of limited sample size by Sachs et al suggests that injection augmentation is less successful than thyroplasty for patients with vocal fold atrophy. Although Sachs et al used longer acting injectable materials than CMC, duration to collection of data was variable, and patients' subjective outcomes were better than what their objective and validated survey data reported.[4] This suggests that objective measurements and validated questionnaires may not be able to reliably capture subjective improvement.

What makes a TVFI successful or not remains debatable. In the aforementioned studies, postinjection Voice Handicap Index-10 (VHI-10) score or VRQOL score, widely used, validated, and accepted self-reported instruments, were used to demonstrate improvement. Although these scored measures assign a numerical data point to a patient's "status," they are only useful in demonstrating the benefit, or lack thereof, if the patient reports their outcome when the injectable is in an ideal conformation in the vocal fold(s). The data points in the first two studies were taken between 4 and 12 weeks (Young et al) and 3-9 weeks (Dumberger et al) after the TVFI and thus may have already missed the benefit

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"window" during which a self-reported improvement on a validated patient-reported outcome measure would have been captured.

The benefit of TVFI goes beyond a quality change in the voice. Symptoms such as vocal fatigue, vocal effort, voice quality, shortness of breath with speech, reliability, predictability, chronic cough/throat clearing, and mucus sensation have been shown to improve with vocal fold augmentation.[1,5,6] Although VHI-10 and VRQOL are proven to capture the subjective impact of the patient's voice problem, these instruments may not accurately demonstrate change or ask the best questions based on the patient's primary throat symptom. In addition, other throat-related outcome measures, for example, the Reflux Symptom Index (RSI), have been shown to decrease in patients with vocal fold atrophy when they undergo TVFI.[5] Anecdotally, success may better be determined through a more open-ended question regarding the patient's global opinion on whether or not the TVFI works for them. Looking at the usefulness of objective acoustic and aerodynamic data in the diagnosis of vocal fold atrophy patients, Vaca et al prospectively demonstrated that electroglottographic and aerodynamic data were not able to diagnose atrophy, unlike laryngovideostroboscopy (LVS).[7] A recent presentation of magnetic resonance imaging studies demonstrated lack of focal CMC in the thyroarytenoid muscle soon after augmentation, as compared with other fillers that maintained a location in the vocal fold; this suggests the material itself may dissipate quickly and the effect is from residual inflammation or another cause.[8]

Thus, based on multiple factors, including time from injection, material properties, and the inabilities of our best patient-reported outcome measures and objective acoustic and aerodynamic measures to capture all necessary information from a patient, it appears we remain uncertain on how or when to determine success after TVFI.

The aim of this study was to compare subjectively self-reported "successful" to "unsuccessful" TVFI patient groups in their pre- and postinjection measures at the 2-week time point after TVFI. It is hypothesized that patients with subjectively reported success will have significant improvements in VHI-10, phase closure, subglottic pressure, and glottic airflow 2 weeks after trial augmentation, whereas the subjectively "unsuccessful" group will not demonstrate significant improvements in the aforementioned measures. Like VHI-10 and VRQOL that are subjective by nature, does the subjective categorization of "successful" or "unsuccessful" by the patient afford enough information to determine whether or not global vocal fold augmentation is beneficial, or are other, more conventional voice measures, both subjective and objective, helpful in determining success 2 weeks after TVFI?

METHODS

This is a retrospective study using data from a prospectively maintained electronic medical record that was conducted at a tertiary academic medical center between November 2014 and March 2016. Institutional Review Board approval was obtained for the review. Patients were identified if they had undergone an office-based injection with CMC. Subjects were included if they were given the CMC injection specifically for purposes of TVFI and had been given diagnosis on their initial visit of paresis (presumed longer than 6 months based on their history), atrophy, or unilateral vocal fold paralysis (immobile vocal fold >12 months duration). Patients with known vocal fold scar or neurologic diagnosis (tremor, Parkinson's disease, spasmodic dysphonia, etc) were excluded.

All but one subject had been given the diagnosis of vocal fold paresis, and/or vocal fold atrophy demonstrated on transnasal flexible LVS after using a routine set of neurolaryngeal tasks and stroboscopic findings of glottal closure/mucosal wave findings. The LVS examinations were not reviewed before inclusion criteria were met in an effort to not exclude any subject who may have been offered TVFI based on the entire clinical picture. Laryngeal electromyography is admittedly not used in the senior author's routine clinical practice for patients with subtle glottic insufficiency from nonparalytic glottic insufficiency.

One patient with true vocal fold paralysis was included as the paralysis was long-standing (years), and the patient had symptoms of subtle glottic insufficiency (vocal fatigue and effort), which led the patient to choose TVFI over immediate permanent options as highly the patient was functional and was not comfortable risking changing the voice quality. Of note, and as described in the original paper on the subject of TVFI, it is not typical to perform TVFI in the setting of long-standing complete vocal fold paralysis (rather durable/permanent medialization is typically offered up front), with the exception of patients who themselves are unsure if they would gain anything from improving their glottic insufficiency, as was the case here.[1]

All patients had undergone per-oral, office-based TVFI with CMC by the first author and had at least one VHI-10 score recorded before and 2 weeks after TVFI. Volumes of injection material per side of TVFI were variable and are not as relevant as the final vocal fold appearance (needle location within the thyroarytenoid muscle or paraglottic space, despite a routine per-oral approach is inherently variable); TVFIs are deemed complete when a conformational, convex change is seen in the vocal fold with an approximately 20% overcorrection). The volumes are reported to determine if there was a difference in volume placed between groups based on eventual success or unsuccessful designation. All post-TVFI data were collected at the 2-week time point.

Patients were divided into one of three categories based on their subjective response to the TVFI as documented in their medical record from their 2-week follow-up visit: success, partial success, or failure. This was often a response to the basic questions posed to the patient: "Do you feel the TVFI made a difference for you? What do you feel improved? What did not improve at any point?" Success is defined as a clearly subjective positive response to one or more of their presenting complaints. This was never presumed to be just a quality of voice complaint although it was often included. Vocal fatigue, vocal effort, voice quality, shortness of breath with speech, reliability, chronic cough/throat clearing, and mucus sensation are among the most common complaints that change in patients with subtle after TVFI. Partial success is defined as some improvement in one or all of their presenting complaints without a clear

complete response of any complaint. Failure is defined as no obvious subjective improvement of any presenting complaint. The three groups were narrowed to two groups for the purpose of data evaluation and to be conservative in who was determined a success. Only those with a clearly successful TVFI were placed into the final "successful" group, and those with partial success or failure were grouped together as "unsuccessful."

Aerodynamic measures including subglottic pressure (in cm H_2O) and airflow (in mL/second) as well as maximum phonation time were obtained from the medical record on the dates of their initial visit and 2-week follow-up visit after their TVFI. Aerodynamic measures were collected using the Phonatory Aerodynamic System (PAS, Model 6600, Pentax Medical, Montvale, NJ, USA). Patients were instructed to hold the device with the mask placed against their face to prevent air leakage and the straw resting on top of their tongue. Airflow and subglottic pressure were collected from repetitions of the syllable /pa/ at comfortable pitch and loudness, excluding the initial and final syllables. Maximum phonation time was not included due to missing data points. Frame-by-frame analysis (FBFA; as previously described) was used to determine the percentage of closed frames in at least 1, but for most subjects, 3 glottic cycles (an average percentage was obtained).[9]

FBFA was performed using video review by a laryngologist and a speech-language pathologist independently after both reviewed and agreed upon the technique. Of note, some included male subjects (subjects 3, 5, and 12) had what can be defined as a preinjection complete, long-phase closure (defined here as more than 40% closed frames per glottic cycle).[8,10] Although this numerical definition remains somewhat loose, the entire clinical picture of an exaggerated mucosal wave bilaterally in atrophy or unilaterally in paresis (due to decreased muscle tone) with significant supraglottic hyperfunction led to these patients being offered a TVFI; thus percent closed frames was calculated to add an objective measure of pre- and post-TVFI change, but it is not always universally able to determine those who would benefit from a TVFI. FBFA was not always possible due to severe supraglottic hyperfunction in the setting of glottic insufficiency and the inability to reliably report the percentage of closed versus open frames in the cycle. All subjects with at least one good cycle at most comfortable pitch and loudness were included in the analysis.

Unpaired *t* tests were conducted to compare successful versus unsuccessful group measures. Paired *t* tests were used to compare pre- to post-TVFI measures within each group. To compare the proportion of patients with an improvement in VHI-10 by 5 or more points, the chi-squared test was used. The significance threshold was set at 0.05.

RESULTS

Sixty-six patients underwent office-based per-oral CMC injection between November 2014 and December 2016. Of these, 23 patients met criteria for TVFI. The average total injected volumes of CMC (unilateral or combined bilateral volumes) was statistically similar between the successful and unsuccessful group subjects ($P = 0.55$). The exact amounts and sides injected are in Table 1A,B. There were 15 (65%) subjectively reported successful TVFIs and 8 (35%) unsuccessful. The ages between the two groups were similar; however, the successful TVFI group had a statistically significant higher proportion of females ($P = 0.012$). Of the eight unsuccessful subjects, four were complete failures, and all those failures carried the diagnosis of true vocal fold atrophy. Of the other four unsuccessful subjects who had a partial success, two had been diagnosed with bilateral atrophy, one with both atrophy and unilateral paresis, and one with right long-standing vocal fold paralysis with short but complete phase closure. From the success group, 11 of 15 had been diagnosed with paresis (10 with unilateral and 1 with bilateral), and 4 with bilateral vocal fold atrophy. One patient (subject 8) was found to have TVF scar during the TVFI on one of his vocal folds (seen on surface as the injectable inflated his vocal fold) in addition to his vocal fold atrophy and was included because his scar was not realized as a pre-procedure diagnosis (hence the reason TVFI can be helpful) (Figure 1, Table 1A,B).

The average preinjection VHI-10 score for the successful group was 24.93 and 17.25 for the unsuccessful group. These scores were not significantly different between the two groups ($P = 0.077$). The average postinjection VHI-10 scores for the groups were also statistically similar ($P = 0.38$). The unsuccessful group's VHI-10 scores before and after TVFI revealed no significant difference ($P = 0.812$). The successful group's average pre- and post-VHI-10 scores were statistically different ($P = 0.019$); However, to keep with the previous convention of using an improvement by 5 or more points in VHI-10 to determine true improvement as seen in Young et al, the proportion of subjects with this finding in the two groups were also compared in this fashion. The successful group approached significant improvement in VHI-10, but ultimately no significant difference was found between the number of subjects who improved their VHI-10 score by 5 or more points after TVFI between the successful and unsuccessful groups ($P = 0.0531$)[2] (Table 2).

FBFA of glottic closure during vibration was possible in 17 subjects (7 unsuccessful and 10 successful). The groups were statistically similar regarding percentage of closed phase frames pre-TVFI ($P = 0.23$) and post-TVFI ($P = 0.41$). The groups were then compared to see if number of subjects with complete, long-phase closure differed before and after TVFI. The two groups were no different from one another in this regard when compared pre- to post-TVFI. Each group was also compared in this regard internally. Of the subjectively unsuccessful group, 3 of 7 (43%) had complete, long-phase closure before TVFI and remained the only three (43%) with the same finding after TVFI ($P = 1.00$). Of the successful group, only 1 of 13 (7.6%) subjects had complete, long-phase closure pre-TVFI but 5 of 10 (50%) achieved this post-TVFI, which reached statistical significance ($P = 0.021$) (Table 3). Average subglottic pressure and average glottic airflow was not significantly different between or within the groups (Table 4).

DISCUSSION

As recent studies intend to learn more about the usefulness of TVFI in predicting who will benefit from long-term vocal fold augmentation, it may be more appropriate to first determine what truly makes a TVFI successful. A study by Gillespie et al sought

TABLE 1.
Unsuccessful and Successful Subjects

A

Unsuccessful Group

Subject	Age (y)	Gender	Volume CMC Left (mL)	Volume CMC Right (mL)	Trial Result	Diagnosis
1	84	M	0	0.3	Failure	Atrophy B, cough
2	88	M	0.5	0.6	Failure	Atrophy B
3	82	M	0.3	0.3	Failure	Atrophy B
4	82	M	0.3	0.3	Partial success	Atrophy B
5	72	M	0.3	0.1	Partial Success	Paresis R, Atrophy B
6	63	F	0	0.5	Partial Success	Paralysis R Long-standing
7	31	M	0.2	0.45	Failure	Paresis R
8	73	M	0.3	0.3	Partial Success	Atrophy B, scar R

B

Successful Group

Subject	Age (y)	Gender	Volume CMC Left (mL)	Volume CMC Right (mL)	Trial Result	Diagnosis
9	32	F	0.5	0.1	Success	Adductor Paresis L
10	65	F	0.3	0.3	Success	Atrophy B
11	66	M	0.3	0.3	Success	Atrophy B
12	69	M	0	0.4	Success	Paresis R
13	72	F	0.3	0.3	Success	Atrophy B, Hypomobility R
14	57	F	0	0.3	Success	Paresis R
15	44	F	0.2	0.2	Success	Atrophy B
16	48	M	0	0.5	Success	Paresis R
17	83	F	0.65	0	Success	Paresis L
18	61	F	0.25	0.25	Success	Atrophy B, Paresis L
19	61	M	0	0.5	Success	Paresis R
20	63	F	0.4	0	Success	Paresis L
21	54	F	0.5	0	Success	Paresis L
22	66	F	0.3	0.3	Success	Paresis B
23	81	M	0.6	0.4	Success	Atrophy B

Abbreviations: B, bilateral; CMC, carboxymethylcellulose; L, Left; R, right.

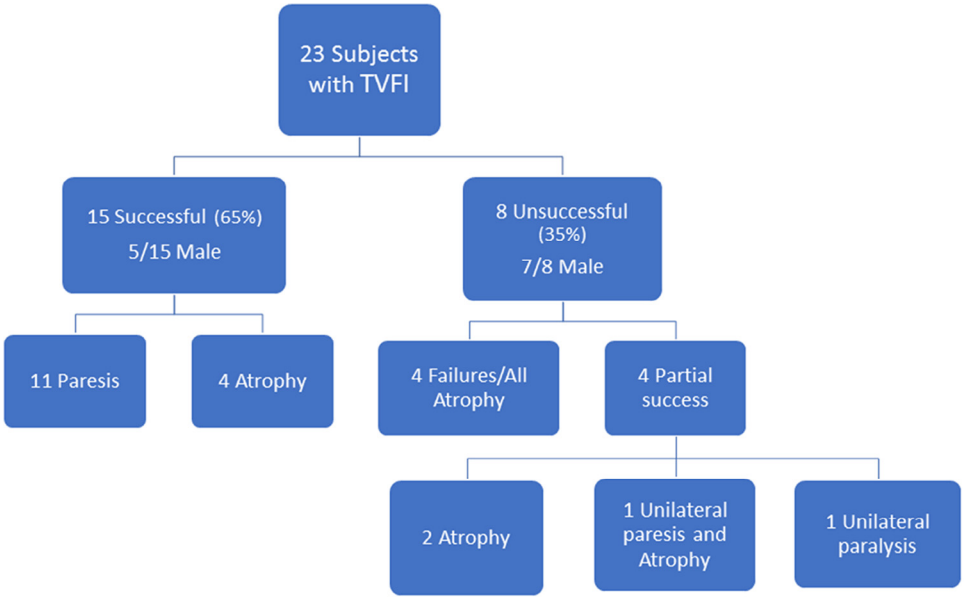

FIGURE 1. Subjects.

TABLE 2.
Voice Handicap Index-10 (VHI) Scores and Change (Delta)

Unsuccessful Group VHI-10			
Subject	VHI-10 Pre	VHI-10 Post	Delta VHI-10
1	0	0	0
2	18	31	−13
3	21	11	10*
4	2	4	−2
5	22	19	3
6	21	31	−10
7	19	18	1
8	35	17	18*
Average	17.25	16.375	
Successful Group VHI-10			
Subject	VHI-10 Pre	VHI-10 Post	Delta VHI-10
9	26	11	15*
10	14	9	5*
11	21	21	0
12	33	32	1
13	33	16	17*
14	20	15	5*
15	32	33	−1
16	30	29	1
17	22	20	2
18	24	21	3
19	35	32	3
20	4	3	1
21	25	9	16*
22	23	21	2
23	32	36	−4
Average	24.93	20.53†	

* Subject improved VHI-10 by 5 or more. The number of subjects that improved in this fashion was not significant between groups when compared ($P = 0.7$).
† Average VHI-10 scores did reach significance pre- to post-TVFI in the successful group ($P = 0.019$); however, individual improvement and then comparison of the number of subjects with this effect as above (*) seems a better analysis of TVFI success and was not significant between groups (ie, both groups had similar number of subjects who improved VHI-10 by 5 or more points).

TABLE 3.
Frame-by-Frame Analysis (FBFA) of Phase Closure Percentage

Unsuccessful Group FBFA		
Subject	% Closed Pre	% Closed Post
1	23	48*
2	N/A	N/A
3	48*	49*
4	0	0
5	44*	60
6	35	38
7	0.00	0.00
8	0.5*	0.61*
Successful Group FBFA		
Subject	% Closed Pre	% Closed Post
9	5	38
10	26	18
11	28	73*
12	44*	43*
13	N/A	N/A
14	24	N/A
15	23	41*
16	27	68*
17	N/A	N/A
18	20	N/A
19	13	17
20	35	42*
21	23	21
22	25	N/A
23	31	15

Abbreviation: N/A, not available.
* Subjects with complete, long-phase closure. In the successful group, the number of subjects post-TVFI with complete, long-phase closure was significantly higher than pre-TVFI ($P = 0.021$). In the unsuccessful group, three male subjects with atrophy started with complete, long-phase closure.

to determine if VHI-10 scores correlated to acoustic and aerodynamic measurements. Except for average phonatory airflow in speech measurements in patients with unilateral vocal fold paralysis, VHI-10 scores did not correlate with objective measures, suggesting the patient's perceived handicap is unable to be captured in objective acoustic and aerodynamic measures.[11] This study intended to examine if collecting subjective and objective data after TVFI at an earlier time point than previously reported would capture more subjects who subjectively reported a successful change at some point during the post-TVFI period. At 2 weeks post-TVFI, 65% of subjects reported a complete subjective benefit of at least one of their complaints at some point during the early augmentation period. The two groups did not differ from each other in their preinjection measures, including VHI-10, and only the successful patients demonstrated a significant increase in the number of subjects with a complete, long-phase closure after injection. Other self-reported outcomes may be needed to capture TVFI success, especially in future studies that intend to determine if TVFI predicts permanent augmentation.

The unsuccessful group demonstrated no change in closure pre- to postinjection. Of the seven patients in this group, three had complete, long closure, while two others had complete, short closure, and two had no mid-membranous closure. In the three older, male patients with atrophy and complete, long-phase closure, closure may have been achieved with supraglottic hyperfunction as compensation for GI. TVFI in these subjects was offered due to clinical signs of GI, such as prominent vocal processes with scalloped membranous vocal fold, increased mucosal wave amplitude and hyperfunction despite a long-phase closure pattern. The finding suggests that pretreatment evidence of long-phase closure may predict a poor response to TVFI despite other signs of atrophy (which is more common in males); in other words, and mostly inspiration for further study, if a patient can achieve long-phase closure by any means, they may be less likely to benefit from trial vocal fold injection augmentation. There are

TABLE 4.
Aerodynamic Measures

Unsuccessful Group Aerodynamic Measures				
Subject	SGP Pre (cm H_2O)	SGP Post (cm H_2O)	Airflow Pre (mL/s)	Airflow Post (mL/s)
1	N/A	N/A	N/A	N/A
2	16.27	N/A	490	N/A
3	6.36	4.22	80	150
4	13.51	8.51	360	280
5	6.95	5.92	30	290
6	7.47	4.51	60	40
7	4.57	5.7	220	200
8	N/A	7.8	N/A	10
Averages	9.19	6.11	206.67	161.67
Successful Group Aerodynamic Measures				
Subject	SGP Pre (cm H_2O)	SGP Post (cm H_2O)	Airflow Pre (mL/s)	Airflow Post (mL/s)
9	4.89	8.01	190	25
10	7.78	7.32	120	130
11	7.18	8.22	450	510
12	6.49	8.69	110	160
13	6.38	4.75	140	150
14	7.75	4.6	30	60
15	5.49	7.4	70	800
16	8.3	6.68	500	50
17	8.18	8.37	210	160
18	6.1	5.9	140	800
19	8.6	N/A	430	N/A
20	7.31	8.01	130	210
21	4.42	6.7	10	100
22	9.58	10.02	320	280
23	5.7	3.71	100	5.3
Averages	6.94	7.03	196.67	245.74

Abbreviations: N/A, not available; SGP, subglottic pressure.
Note: There was no significant improvement in aerodynamic measures between or within groups.

other physiological reasons that should be entertained in the consideration of why those males with long-phase closure did not respond as readily as those without, including changes in vocal fold contact, the cranio-caudal direction that may not be appreciated on stroboscopy, and inefficient conversion of aerodynamic to acoustic energy. Additionally, decreased pulmonary function with reduced respiratory support is always a possibility in older patients with atrophy.

This observation does not account for the poor response in the other four patients in the unsuccessful group who did not have complete, long-phase closure preinjection. The two patients in this group who had no mid-membranous closure pretreatment demonstrated overall improved closure, although they maintained either very short closure (1 closed frame) or no mid-membranous closure postinjection (possibly this represented underaugmentation with resultant findings at the 2-week follow-up). Similarly, of the two patients who demonstrated short, complete closure preinjection, only one achieved complete, long closure postinjection. It is unclear why these patients demonstrated a poor response to treatment although underaugmentation could be blamed.

Unlike the unsuccessful group, patients in the successful group had significantly increased number of subjects with complete, long-phase closure after TVFI. Together, the findings indicate that improvement in phase closure, examined by FBFA, can be used to help corroborate the subjective success of TVFI in most patients. That being the case, especially with a small number of subjects, this finding is not conclusive but provides some guidance for an end point in further studies trying to determine TVFI outcomes that may help predict permanent vocal fold augmentation success. Regardless, a visualized improvement in phase closure did not translate to meaningful VHI-10 improvement at their 2-week follow-up.

Contrary to what was hypothesized, the successful group did not demonstrate a significant change in any other measure apart from the aforementioned phase closure at 2 weeks post-TVFI, nor was the successful group significantly different from the unsuccessful group on any post-treatment measure. Interestingly, while the successful group's reported benefit from the injection and increased number of subjects with complete, long-phase closure seemed to correlate, they demonstrated no clinically significant change in VHI-10 score. It is possible that patients

were not seen when the injection was in its optimal configuration (window of benefit was missed), thereby leading to scores that were not representative of their experience over the course of the injection. There must exist a "sweet spot" at which the volume of augmentation material is ideal, and this period of time may be days and not weeks. Unlike gross paralytic glottic incompetence where weeks to months of benefit can be seen with common short-acting augmentation materials used for TVFI, vocal folds with subtler glottic insufficiency may lose their benefit sooner. One reason for this may be that TVFI for subtle glottic insufficiency requires smaller CMC volumes to produce an effect as opposed to what is used for paralytic glottic insufficiency and therefore would not last as long.

The subjective success rate of TVFI in this study was nearly 55% higher than in the Young et al study, likely due to the strict use of VHI-10 criteria in determining success.[2] This finding suggests that change in VHI-10 cannot always be considered when determining success of TVFI. This may be due to the inherent nature of the VHI-10 being collected after the period of benefit (ie, it occurs before the 2-week point after TVFI), or that VHI-10 may incompletely capture all the complaints and improvements that accompany subtle glottic insufficiency. This has been posited in the study by Young et al, that subjective improvement may already be passed by the time the patient returns for follow-up and that only objective aerodynamic measures and stroboscopic evidence of improvement in glottal competence, if any at all, remains.[2]

This study's limitations included a small sample size, its retrospective nature, and included outcomes that are subjective. One can also argue that FBFA is inherently variable as patient effort can influence the closure pattern despite a clinician's best coaching. While aerodynamic data were believed to be more valuable in the study of glottic insufficiency, acoustic data may have proved helpful. This study lacked acoustic data. This was intentional on the part of the authors due to lack of confidence in the sound attenuation of our voice laboratories to afford use of these data for research purposes. Prior studies have demonstrated good test-retest reliability in acoustic and aerodynamic measures taken 1 week apart.[12] It is likely that subjects given the same tests 2 weeks apart using the same protocol in the voice laboratory would perform the tasks similarly and allow any laryngeal changes to be noted; however, patient and test administrator differences day to day can also be argued as variable. Finally, placebo effect is always considered when expected objective data do not match up. Patients may just want to feel better. However, an increased number of successful TVFI patients demonstrating an improvement in phase closure speaks against this.

CONCLUSION

The understanding of how to more precisely determine the success of TVFI remains incomplete. The number of subjects with complete, long-phase closure was the only objective change that was statistically higher 2 weeks after the TVFI. Subjective improvement of successful TVFI was captured with basic questions yet the VHI-10 was unable to confidently demonstrate this reported success. Further studies to definitively capture objective and subjective data during the small period of benefit of the TVFI and to compare this to long-term augmentation outcomes are necessary.

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