Published in final edited form as:

Ann Otol Rhinol Laryngol. 2010 February ; 119(2): 125–132.

Multi-parameter analysis of titanium vocal fold medializing implant in an excised larynx model

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Abstract

Objective—Evaluate the efficacy of the titanium vocal fold medializing implant (TVFMI) for the treatment of unilateral vocal fold paralysis (UVFP) based on acoustic, aerodynamic, and mucosal wave measurements in an excised larynx setup.

Methods—Measurements were recorded on eight excised canine larynges with simulated UVFP before and after medialization with the TVFMI.

Results—Phonation threshold flow (PTF) and phonation threshold power (PTW) decreased significantly after medialization ($p < 0.001$; $p = 0.008$). Phonation threshold pressure (PTP) also decreased, but this difference was not significant ($p = 0.081$). Percent jitter and percent shimmer decreased significantly after medialization ($p = 0.005$; $p = 0.034$). Signal to noise ratio (SNR) increased significantly ($p = 0.05$). Differences in mucosal wave characteristics were discernable, but not significant. Phase difference between the normal and paralyzed vocal fold and amplitude of the paralyzed vocal fold decreased ($p = 0.15$; $p = 0.78$). Glottal gap decreased significantly ($p = 0.004$).

Conclusions—The TVFMI was effective in achieving vocal fold medialization, improving vocal aerodynamic and acoustic characteristics of phonation significantly and mucosal wave characteristics discernibly. This study provides objective, quantitative support for the use of the TVFMI in improving vocal function in patients with unilateral vocal fold paralysis.

Keywords

titanium vocal fold medializing implant; unilateral vocal fold paralysis; laryngeal framework surgery

INTRODUCTION

Unilateral vocal fold paralysis (UVFP) is typically caused by injury to the recurrent laryngeal nerve, which controls the intrinsic laryngeal muscles necessary for vocal fold adduction. The inability to adduct the paralyzed vocal fold impairs voice, swallowing, and breathing function (1). Current treatment of glottic insufficiency due to unilateral VFP is primarily surgical, with the goal of medializing the paralyzed vocal fold to improve

laryngeal function. Various autogenous and alloplastic materials have been utilized to adduct the paralyzed vocal fold and improve associated dysphonia (2,3). Vocal fold injections can be used to achieve vocal fold medialization by increasing volume and stiffness. Although this treatment can be effective in the partial restoration of vocal fold function, the resultant vocal fold stiffness decreases or eliminates the mucosal wave (2,4). Overcorrection of the vocal fold is difficult to reverse and negatively alters vocal fold configuration at the anterior commissure, leading to abnormal acoustic and aerodynamic parameters of phonation (5). Additionally, injected materials are reabsorbed by the surrounding tissue over time, which may decrease or negate the initial improvements in laryngeal function following surgery (6).

Since its introduction by Isshiki *et al.*, thyroplasty has become an increasingly popular method for correcting unilateral VFP. This method entails medializing the vocal fold with an implant, commonly a silicone wedge, inserted through a window in the thyroid cartilage (3,7). The Isshiki thyroplasty has been found to improve vocal quality (8,9). Insertion of the implant is performed under local anesthesia which provides the ability to adjust the degree of medialization based on intraoperative phonation (10). Thyroplasty also offers advantages over injection laryngoplasty. By inserting an implant, the membranous vocal fold structure is preserved and the procedure is reversible (11). Injected material also tends to migrate through the laryngeal tissue over time, whereas solid implants maintain a stable shape and size (12).

Despite its benefits, thyroplasty with a silicone implant presents several disadvantages in both technique and implant material. The silicone implant must be carved during surgery, prolonging operation time and decreasing standardization. Suboptimal shaping can hinder success in improving breathing, swallowing, and voicing function (10,13,14). Following the procedure, allergic reactions to silicone have also been observed (15). Submucosal hemorrhage and extrusion of the implant, causing obstruction of the laryngeal system, are also possible complications (16).

In response to the complications encountered in thyroplasty using a silicone implant, alternative implants have been proposed. These alternatives have included implants made of ceramic (17), Gore-tex (18), and hydroxylapatite (13). The concept of an adjustable implant has received attention recently because endolaryngeal swelling and hematoma can affect intraoperative evaluation of phonation when determining the degree of medialization. Adjustable implant systems, such as that developed by Montgomery *et al.*, have attempted to standardize the shape and size of laryngeal implants to reduce trauma and time required for surgery. These implants also allow for postoperative adjustment without replacing the implant (14,19). However, these adjustable implants had the disadvantage of complicated designs and discrete degrees of medialization. Previous adjustable implants were composed of multiple parts and variation of medialization required manipulation of a monometric screw or the insertion of different sized preformed implants.

The titanium vocal fold medializing implant (TVFMI) was developed by Friedrich to address concerns regarding current thyroplasty techniques. The results of initial clinical trials indicated that the implant succeeded in significantly reducing the width of the glottal gap and had several advantages over previous methods of vocal fold medialization (20). Using a preformed implant decreased operation time, which resulted in reduced intralaryngeal swelling and hematoma during and following surgery. The TVFMI is also unlikely to migrate through laryngeal tissue because it is compressed during insertion but expands to its original conformation in the laryngeal tissue, creating a secure fit with the thyroid window. Anchoring the implant with sutures to the thyroid lamina provides fixation and stabilization, further reducing the risk for extrusion. In a clinical study of 20 patients, no

extrusion was observed 2, 6 or 12 months after the procedure. This system standardized implant shape and size, and the use of titanium provided the malleability necessary to adapt the implant to individual patients. In contrast to earlier adjustable implant models, the TVFMI provides adjustability in medialization along a continuous scale by pressing the posterior part of the implant inward and securing its dorsal flange to the thyroid cartilage to maintain that depth. The simplicity of the TVFMI allows for its adaptability by using standard otolaryngology equipment, similar to earlier thyroplasty methods, without the complication of forming an implant during surgery.

Additional studies have evaluated the effect of medialization thyroplasty using the TVFMI in patients with unilateral VFP. Videostroboscopy indicated almost complete glottal closure following thyroplasty in most patients (21). Subjective evaluations of laryngeal function by patients indicated significant improvements in voice quality and vocal efficiency, as well as reduced hoarseness. There were also significant improvements in non-phonatory activities such as increased breathing control, reduced dyspnea during phonation, and recovered laughing and coughing capabilities. Acoustic analysis indicated significant decreases in percent jitter, percent shimmer, irregularity, and noise in the voice signal as well as significant increases in its period correlation and glottal-to-noise excitation ratio (21,22). Additionally, the TVFMI achieved vocal fold medialization without compromising respiratory performance. This was determined by observing the effect of medialization using the implant on pulmonary function during physical exertion (23). Although previous studies have examined the effects of TVFMI on pulmonary function, its effects on aerodynamic parameters of phonation have not been examined.

The effect of TVFMI insertion on the mucosal wave has not been analyzed in patients or excised models. Although thyroplasty has been used as a technique for over twenty years, post-medialization mucosal wave has only been analyzed with stroboscopy and glottography (19,24-27). Videostroboscopy is unable to accurately image irregular patterns of vibration characterized by aperiodicity or changes in fundamental frequency because it creates a composite image of the mucosal wave averaged over several cycles (28). High-speed video is an improved method of mucosal wave analysis because it allows for real-time visualization of the mucosal wave (29). In comparing the accuracy of the two methods in characterizing the mucosal wave in pathological larynges, high-speed video was found to be significantly more accurate and interpretable than stroboscopy (29-31). These attributes allow for quantification of the impact of TVFMI on vibration.

In this study, an excised larynx model was used to examine the effects of the TVFMI on the aerodynamic parameters of phonation threshold flow (PTF), phonation threshold pressure (PTP), and phonation threshold power (PTW), acoustic parameters of jitter, shimmer, and signal-to-noise ratio (SNR), and mucosal wave parameters of amplitude and phase difference. Previous studies have used excised canine larynges as a model for unilateral vocal fold paralysis. Noordzij *et al.* performed a series of studies evaluating arytenoid adduction and type I thyroplasty in a canine model (32-34). Additionally, the canine model has recently been used to model unilateral vocal fold paralysis by Czerwinka *et al.* (35). By taking measurements of these parameters in a controlled environment, the potential human variability that may be present in clinical studies was eliminated.

MATERIALS AND METHODS

Larynges

Eight larynges were harvested postmortem from canines sacrificed for non-research purposes. The larynges were excised according to the protocol described by Jiang and Titze

(24). After excision, the larynges were examined for evidence of trauma or disorders and frozen in 0.9% saline solution.

Apparatus

Immediately prior to the experiment, the epiglottis, corniculate cartilages, cuneiform cartilages, and ventricular folds of each larynx were dissected away to expose the true vocal folds. The superior cornu and posterosuperior part of the thyroid cartilage ipsilateral to the normal vocal fold were also dissected away to facilitate insertion of lateral micrometers into the arytenoid cartilage. The larynx was mounted on the apparatus (Figure 1) as specified by Jiang and Titze (36). The trachea was fastened by a metal pull clamp to a tube connected to the pseudolung of the apparatus. Through the insertion of one 3-pronged micrometer in the arytenoid cartilage ipsilateral to the dissected thyroid cartilage (Figure 2A), only one vocal fold was adducted, simulating unilateral VFP with the unadducted vocal fold, as in Czerwonka *et al.* (35). The level of the adducted vocal fold was adjusted before the first trial by moving the micrometer in the superior and inferior directions until it was in the same plane as the unadducted vocal fold. The superior portion of the thyroid cartilage midline was sutured to a third micrometer, allowing for precise control of vocal fold elongation. The vocal fold adduction, height, and elongation remained constant by maintaining the same micrometer positions throughout trials.

The apparatus used to initiate and sustain phonation in these trials was designed to simulate the human respiratory system. Pressurized airflow was passed through two Concha Therm III humidifiers (Fisher & Paykel Healthcare Inc., Laguna Hills, California) in series to humidify and warm the air. The occurrence of dehydration was further diminished by frequent application of 0.9% saline solution between trials. Airflow was controlled manually throughout the experiment and was measured by an Omega airflow meter (model FMA-1601A, Omega Engineering Inc., Stamford, Connecticut). Pressure measurements were taken immediately before the air passed into the larynx using a Heise digital pressure meter (901 series, Ashcroft Inc., Stratford, Connecticut).

Acoustic data were collected using a Sony microphone (model ECM-88, Sony Electronics Inc., New York, New York). The microphone was positioned at a 45° angle to the vertical axis of the vocal tract and approximately 10 cm from the glottis to minimize acoustic noise produced by turbulent airflow. The acoustic signal was subsequently amplified by a Symetrix preamplifier (model 302, Symetrix Inc., Mountlake Terrace, Washington). A National Instruments data acquisition board (model AT-MIO-16; National Instruments Corp, Austin, Texas) and customized LabVIEW 8.5 software were used to simultaneously record airflow, pressure, and acoustic data on a personal computer. Aerodynamic data were recorded at a sampling rate of 200 Hz and acoustic data were recorded at a sampling rate of 40,000 Hz. Experimental trials were conducted in a triple-walled, sound-proof room to reduce background noise and stabilize humidity levels and temperature.

The vocal fold mucosal wave was recorded for approximately 200 milliseconds during phonation by a high-speed digital camera (model Fastcam-ultima APX; Photron, San Diego, CA). High-speed videos of the movement were recorded with a resolution of 512×256 pixels at a rate of 4000 Hz.

Experimental Methods

Trials were conducted as a sequence of 5 second periods of phonation, followed by 5 second periods of rest. The sequence of phonating and resting periods was repeated on the same larynx in succession for a total of ten cycles. During each period of phonation, airflow

passing through the laryngeal system was manually increased gradually and consistently until the onset of phonation.

The TVFMI (Heinz Kurz Company, Dusslingen, Germany) was inserted into the larynx through a thyroplasty window in the thyroid cartilage ipsilateral to the paralyzed vocal fold according to the protocol described by Friedrich (20). Optimal medialization was determined empirically by minimizing the aerodynamic power necessary to initiate phonation. This position was stabilized with sutures to the thyroid cartilage. The implant is available in three sizes, and different dimension thyroplasty windows are required for the insertion of each. In this study, the 13-mm implant was used in all larynges, requiring a 6×11 mm window.

Data Analysis

Phonation was evaluated before and after insertion of the implant. The measured values of airflow and pressure that coincided with the initiation of phonation were recorded as the onset phonation threshold flow (PTF) and onset phonation threshold pressure (PTP), respectively. Phonation threshold power (PTW) was calculated as the product of these values.

PTF, PTP, and PTW were determined manually with a custom LabVIEW 8.5 program. The program graphically displayed the spectrogram, airflow, and pressure signals as functions of time for each trial; airflow and pressure values corresponding to the initiation of phonation were recorded as PTF and PTP, respectively.

Acoustic analysis was done by measuring the signal-to-noise ratio (SNR) and the perturbation parameters of percent jitter and percent shimmer. The voice signal was trimmed using the GoldWave 5.1.2600.0 program (GoldWave Inc., St. John's, Canada), and acoustic analysis was conducted using Computerized Speech Lab (CSpeech) software (Madison, WI).

High speed video recordings of the mucosal wave were analyzed using a customized MATLAB program (The MathWorks, Natick, MA). The vibratory properties of each of the four vocal fold lips (right-upper, right-lower, left-upper, left-lower) were quantified via digital videokymography (VKG), a line-scan imaging technique. Threshold-based edge detection, manual wave segment extraction, and non-linear least squares curve fitting using the Fourier Series equation were applied to the VKG to determine the most closely fitting sinusoidal curve. The coefficients of the wave function for this curve were used to derive the frequency, amplitude, and phase of the mucosal wave of each vocal fold lip, both before and after implant insertion. Inter-vocal fold phase difference was calculated as the absolute value of the divergence between the sinusoidal phase measurements for the right and left upper folds. Mucosal wave amplitude was calculated as the average of the amplitudes of the upper and lower paralyzed vocal fold lips. Using the available technology, only relative values rather than absolute values could be obtained. This was sufficient for pre-/post-treatment comparisons. Changes in glottal gap were evaluated by measuring the relative change after medialization.

Paired *t*-tests were used to determine if inserting the implant had a significant effect on the measured parameters. If data were not normal, a Mann-Whitney Rank Sum Test was performed. Tests were two-tailed and a significance level of $\alpha=0.05$ was used.

RESULTS

Paired *t*-tests demonstrated that there were significant decreases in PTF and PTW after medialization. PTF decreased from 127 mL/s to 46 mL/s ($p<0.001$) and PTW decreased from 2301 mL/s*cmH₂O to 649 mL/s*cmH₂O ($p=0.008$) (Figure 3). PTP decreased from 16.41 cmH₂O to 12.48 cmH₂O after medialization, but this difference was not significant ($p=0.081$).

SNR, percent jitter, and percent shimmer data before and after TVFMI insertion are provided in Figures 4, 5, and 6, respectively. There were significant changes in each of these parameters after medialization. Mean SNR increased from 2.43 to 6.65 ($p=0.05$). Percent jitter decreased from 7.15% to 3.58% and percent shimmer decreased from 27.80% to 13.69% ($p=0.005$; $p=0.034$).

There was also a significant decrease in glottal gap. Glottal gap decreased from 68.98 to 30.75 ($p=0.004$) (Figure 7). Although differences in phase difference and amplitude of the mucosal wave were discernible, they were not significant. Mean phase difference between the normal and paralyzed vocal folds decreased from 1.03 to 0.008 ($p=0.15$). Mean amplitude of the paralyzed vocal fold decreased from 1.71 to 1.64 ($p=0.78$).

DISCUSSION

This study provides an objective evaluation of the effect of TVFMI insertion on the aerodynamic, acoustic, and mucosal wave characteristics of phonation. By simulating UVFP in an excised larynx model, these measurements were taken in a controlled and repeatable environment. The results supplement those of previous studies that have examined the effect of the implant on pulmonary aerodynamic and acoustic characteristics of phonation and provide support for its therapeutic use in the treatment of UVFP.

Inserting the TVFMI decreased the aerodynamic power necessary to produce phonation. This was caused by medialization of the paralyzed vocal fold as demonstrated by a significant reduction in glottal gap. The decrease in PTF was significant, whereas the decrease PTP was not. This may be because PTF is more sensitive than PTP to changes in glottal abduction as demonstrated in an excised larynx experiment by Hottinger *et al.* (37).

This decrease in the airflow required to initiate phonation also increases the acoustic quality of the voice signal. SNR increased because signal power in the form of phonation increased while noise power in the form of airflow decreased. Additionally, decreases in the perturbation measures of percent jitter and percent shimmer were also observed and can be attributed to vocal fold medialization restoring vocal fold contact and vibrational periodicity.

There were discernable changes in the mucosal wave characteristics following TVFMI insertion, though these differences were not significant. Thyroplasty type I increases the closed phase over one cycle, improving glottic vibration which has been correlated with more efficient phonation (38). In addition, the phase difference between the right and left vocal folds decreased from 1.03 to 0.008, reflective of improved vocal fold symmetry. Phase difference is typically an intra-vocal fold parameter equal to the difference between the phases of the upper and lower regions of the same vocal fold. The upper and lower regions are part of the two-mass mode of vibration. Because the excised model has a one-mass mode of vibration, we did not examine phase differences between the upper and lower folds; rather, we evaluated inter-vocal fold phase difference. Therefore, a one-mass mode of vibration was sufficient for our calculations. The study of hemilaryngeal phonation performed by Jiang and Titze indicated that a surface is required for proper vibration and phonation (36). Simulated paralysis causes abnormal vibration because neither fold has a

surface against which it can vibrate; adducting the paralyzed fold restores vibrational harmony. The decrease in inter-vocal fold phase difference after medialization suggests that medialization increased synchronization of the mucosal waves.

The lack of significance in this decrease may have resulted from an insufficient sample size. It could also be due to inadequate color contrast in some of the video recordings. Analysis is dependent on threshold-based edge detection and the subsequent fitting of a sinusoidal curve to the mucosal wave. Threshold-based edge detection requires color contrast between the vocal fold tissue and the glottal gap. Although mucosal wave movement was still discernible on the paralyzed vocal fold following TVFMI insertion, the adduction of the vocal fold by the implant made this contrast difficult to distinguish.

Hyper-adduction of the vocal fold would result in increased jitter and shimmer; the results of this study indicate that hyper-adduction did not occur, as jitter and shimmer were both significantly decreased. Hyper-adduction would also lead to pressed phonation due to complete closure of the glottic gap; however, the glottic gap was significantly decreased but not eliminated.

Although the TVFMI is a patented implant for clinical use, the measurement of acoustic, aerodynamic, and mucosal wave parameters in a controlled setting provides additional support for its use. Physicians in different regions have personal preferences for the numerous materials used in thyroplasty; standardized measurements of the effects of different implants provide a quantitative basis for their comparison. The TVFMI is not yet widely used in the United States, so additional information on its effectiveness in treating unilateral vocal fold paralysis may benefit clinicians. This study further contributes to the body of scientific research because it examined the effects of medialization using TVFMI on physiological parameters, including the novel parameters of phonatory aerodynamics and high-speed video analysis of mucosal wave.

The results of this study provide objective support for the TVFMI that supplements previous human subject studies (21-23). By examining the effect of the procedure on a comprehensive range of phonatory parameters in a controlled experimental setting, variation in these parameters unrelated to TVFMI insertion was reduced. Although Schneider *et al.* determined that TVFMI insertion did not affect aerodynamic parameters relating to pulmonary function during physical exertion, the effect of this procedure on vocal aerodynamics has not been previously studied (22,23).

Future research could use the excised larynx model to compare TVFMI insertion to injection or thyroplasty using other materials such as Silastic or hydroxylapatite. This would allow for objective assessment and direct quantitative comparisons between different treatments for UVFP.

This is the first study evaluating the effect of TVFMI insertion on vocal aerodynamics and mucosal wave characteristics. Future studies could measure these parameters in human subjects with the aim of quantitatively determining optimal implant position.

CONCLUSION

The TVFMI was effective in achieving vocal fold medialization, significantly improving vocal aerodynamic and acoustic characteristics of phonation and discernibly improving mucosal wave characteristics. This study provides objective, quantitative support for the use of the TVFMI in improving vocal function in patients with unilateral vocal fold paralysis.

Acknowledgments

This study was funded by NIH grant number R01 DC008153 from the National Institute on Deafness and Other Communicative Disorders.

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Figure 1.
Schematic diagram of excised larynx experimental apparatus.

Figure 2. Excised canine larynx with simulated right vocal fold paralysis before (A) and after (B) TVFMI insertion.

Figure 3. Phonation threshold power measurements before and after TVFMI insertion. PTW significantly decreased from 1987 cmH₂O*mL/s to 503 cmH₂O*mL/s after medialization (p=0.008).

Figure 4. Signal-to-noise ratio measurements before and after TVFMI insertion. SNR significantly increased from 1.96 to 6.36 after medialization ($p=0.05$).

Figure 5. Percent jitter measurements before and after TVFMI insertion. Percent jitter significantly decreased from 7.15% to 3.58% after medialization ($p=0.005$).

Figure 6. Percent shimmer measurements before and after TVFMI insertion. Percent shimmer significantly decreased from 27.80% to 13.69% after medialization ($p=0.034$).

Figure 7. Glottal gap measurements before and after TVFMI insertion. Glottal gap significantly decreased from 68.98 to 30.75 after medialization ($p=0.004$).

Table 1

Summary statistics before and after titanium vocal fold medializing implant (TVFMI) insertion.

Parameter	Pre-TVFMI	Post-TVFMI	Percent change	p-value
PTF	127 ± 43	46 ± 27	−63	<0.001*
PTP	16.41 ± 7.13	12.48 ± 6.47	−24	0.081
PTW	2301 ± 1698	649 ± 644	−72	0.008*
SNR	2.43 ± 1.19	6.65 ± 4.55	174	0.05*
Percent jitter	7.15 ± 1.78	3.58 ± 1.96	−50	0.005*
Percent shimmer	27.80 ± 9.00	13.69 ± 11.07	−51	0.034*
Phase difference	1.03 ± 0.70	0.008 ± 1.49	−99	0.15
Glottal gap	68.98 ± 27.21	30.75 ± 6.04	−55	0.004*
Amplitude	1.71 ± 1.05	1.64 ± 0.73	−4	0.78

PTF=phonation threshold flow; PTP=phonation threshold pressure; PTW=phonation threshold power; SNR=signal-to-noise ratio.

Asterisk denotes significant p-value.