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Excised Larynx Evaluation of Wedge-Shaped Adjustable Balloon Implant for Minimally Invasive Type I Thyroplasty

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Abstract

Objectives/Hypothesis—To describe the method of inserting a wedge-shaped adjustable balloon implant (wABI) via a minithyrotomy for medialization thyroplasty and evaluate its effect on a range of phonatory parameters using the excised larynx bench apparatus.

Study Design—Repeated measures with each larynx serving as its own control.

Methods—A prototype wABI was deployed in six excised canine larynges of various sizes through a minithyrotomy and then filled with saline. Mucosal wave, aerodynamic, and acoustic parameters were measured for three conditions: normal, vocal fold paralysis, and paralysis with the wABI.

Results—Phonation threshold pressure ($P < .001$), flow ($P < .001$), and power ($P = .002$) were significantly lower for wABI compared to paralysis trials; values did not differ significantly from normal trials. Percent jitter ($P = .002$) and percent shimmer ($P = .007$) were also significantly decreased compared to the paralysis condition, and values were not significantly different compared to normal. The mucosal wave was preserved after insertion of the wABI.

Conclusions—Effective vocal fold medialization with preservation of the mucosal wave was observed with the wABI in this preliminary excised larynx experiment. The wABI offers the potential for a minimally invasive insertion in addition to postoperative adjustability. Further studies in living animals and humans are warranted to evaluate clinical utility.

Keywords

Adjustable balloon implant; medialization thyroplasty; vocal fold paralysis; glottic insufficiency

INTRODUCTION

Glottic insufficiency prevents efficient transduction of aerodynamic energy into acoustic energy and leads to a breathy, hoarse voice.¹ Numerous studies have addressed the surgical management of this problem, beginning with the use of a pedicled thyroid cartilage flap by Payr² and continuing with the descriptions of medialization thyroplasty (MT) by Isshiki et al.³ and Koufman.⁴ Since these foundational studies, a variety of implants have been proposed, each capable of significantly improving patient voice if used correctly. Although currently used implants such as the titanium vocal fold medializing implant⁵ and expanded polytetrafluoroethylene⁶ represent valuable advances in the management of glottic insufficiency, both are inserted via the standard thyroplasty operation and require a revision thyroplasty for any postoperative modifications other than supplementary vocal fold injection.

Reported revision rates vary across studies. Rosen reported a relatively low rate of 5.5% based on a national survey.⁷ Koufman and Isaacson reported a rate of 12.5% in a series of 56 patients,⁸ and Anderson et al. reported a rate of 33% in a series of 96 patients.⁹ The higher rate reported by Anderson may be attributed to a high portion of patients being professional voice users, including professional singers in whom secondary procedures were performed more frequently. Although MT has traditionally been performed for unilateral vocal fold paralysis, it can also be performed for other causes of glottic insufficiency, such as paresis, atrophy, bowing, scarring, and presbylaryngis. If performed in a patient with a progressive disorder such as presbylaryngis, future revisions can be anticipated as the previous degree of medialization is no longer adequate.¹⁰

In a previous study, we presented the adjustable balloon implant.¹¹ A spherical silicone balloon was introduced into excised larynges, stabilized with a metal frame, and filled with saline until the desired degree of medialization was achieved. This implant had the key potential advantage of allowing for minimally invasive revisions. Though promising, insertion was still performed via a traditional thyroplasty window. Additionally, the spherical shape required placement of a stabilizing frame and resulted in a small residual posterior glottic gap.

To address these issues, we considered modifying the shape of the implant to allow for a less invasive insertion as well as alleviate concerns regarding balloon shape once fully inflated. Here, we present a wedge-shaped adjustable balloon implant (wABI) that can be inserted via a minithyrotomy and does not require a supporting frame. Additionally, the wedge shape may allow for closure of a posterior glottal chink, which was not possible with a spherical implant. The purposes of this preliminary excised larynx study were to determine if the wABI could be used effectively for vocal fold medialization, determine if insertion of the wABI could restore normal phonation, and to verify that insertion of the wABI did not eliminate the mucosal wave.

MATERIALS AND METHODS

Larynges

Six larynges were excised postmortem from canines sacrificed for unrelated purposes according to the protocol described by Jiang and Titze.¹² Canine larynges have been used extensively to study laryngeal physiology including vocal fold paralysis.¹³⁻¹⁵ Following visual inspection to ensure no signs of trauma or disorders were present, larynges were frozen in 0.9% saline.

Apparatus

Supraglottic structures were removed to allow for imaging of vocal fold vibration. The superior cornu and posterosuperior part of the thyroid cartilage were also removed to facilitate insertion of a lateral three-pronged manipulator into the arytenoid cartilage. The larynx was mounted on the apparatus (Fig. 1) as specified by Jiang and Titze.¹² A metal hose clamp secured the trachea to a tube connected to a pseudolung, which served as a constant pressure source. Pressurized airflow was passed through two humidifiers (Fisher & Paykel Healthcare Inc., Laguna Hills, CA) to humidify and warm the air. Airflow was controlled manually and measured using an airflow meter (model FMA-1601A; Omega Engineering Inc., Stamford, CT). Subglottal pressure was recorded using a pressure transducer (series 3850A; Hans Rudolph, Inc., Kansas City, MO).

Acoustic signals were collected using a microphone (model RTA-M; dbx Professional Products, Sandy, UT) positioned at a 45° angle to the vocal folds, approximately 10 cm from the glottis, and amplified using a Symetrix preamplifier (model 302; Symetrix Inc., Mountlake Terrace, WA). A National Instruments data acquisition board (model AT-MIO-16; National Instruments, Austin, TX) and customized LabVIEW 8.5 software (National Instruments) were used to record airflow, pressure, and acoustic signals. Aerodynamic data were sampled at 100 Hz and acoustic data at 40,000 Hz. Experiments were conducted in a triple-walled, sound-attenuated room to stabilize humidity and reduce background noise.

Vocal fold vibration was recorded for 200 ms per trial using a high-speed digital camera (model Fastcam-ultima APX; Photron, San Diego, CA). Videos were recorded with a resolution of 512 × 256 pixels at a rate of 4000 frames/second.

Wedge-Shaped Adjustable Balloon Implant

The implant (Figs. 2 and 3) was manufactured by Hood Laboratories (Pembroke, MA) based on the authors' design. The balloon is wedge-shaped, with a triangular base comprised of legs that are 15 and 8 mm in length and a height of 6 mm. Dimensions were determined based on measurements of a variety of excised larynges and designed to be big enough to allow for medialization of larger larynges while still small enough to be folded and passed through a minithyrotomy. The implant has a wall thickness of 0.15 mm and is connected via tubing with an outside diameter of 2 mm to a luer slip one-way check valve (6.6-mm diameter) that does not require a special syringe. Both the balloon and tubing were made using 50 durometer medical grade silicone. Saline is used to inflate the balloon once

properly positioned within the larynx. If used in a human, the luer lock would not be retained within the patient; it would be removed and the tubing sealed with glue. Later adjustments would be made following puncture of the seal with a needle.

The implant was inserted via a minithyrotomy approach. A small opening, approximately 3 × 3 mm in size, was created in the thyroid cartilage, 2 to 3 mm lateral of the midline. The opening could be either circular and created by a drill, or rectangular and created by a scalpel; both methods were employed in this study, with no difference in ability to insert the implant. The level of the opening was created midway between the thyroid notch and inferior margin of the thyroid cartilage, which was presumed to be the level of the vocal fold. Prior to inserting the implant, a probe was passed through the opening and along the interior margin of the thyroid cartilage to expand the space lateral to the thyroarytenoid muscle where the implant would reside. The implant was empty at the time of insertion, and the rectangular base was folded lengthwise to further decrease the width of the implant as it was inserted. When not inflated, the implant is rather pliable and can be compressed, or folded, using a forceps. When passing the implant through the opening, it could either be pushed through the opening or guided with a forceps. Once inside, the implant was filled with saline to the desired volume until approximation to the contralateral fold was achieved. Further minor adjustments were made based on real-time measurements of aerodynamic (pressure and airflow) and acoustic (percent jitter, percent shimmer) parameters. Volume was modified so that threshold aerodynamic and perturbation parameters were at minimal values. Given the dimensions of the implant, approximately 0.36 mL is required to fill the balloon to a volume where all faces remain flat. This is a small volume, but sufficient to provide medialization with this shape implant in the relatively small dog larynx. As the balloon is somewhat pliable, it can be filled further while causing some rounding of the faces without putting the contents under excessive pressure (so that resistance to filling is felt); this corresponds to a volume of approximately 0.65 mL. The same implant was used for all larynges, which varied slightly in size.

To confirm that the implant did not leak, volume was evaluated 1 week after filling the implant with a predefined volume of saline (0.4 mL). Implant volume did not change. To confirm that implant volume did not decrease after phonation, implant volume was evaluated after filling the implant with a predefined volume of saline (0.4 mL), inserting it into a canine larynx, and inducing phonation. Implant volume was similarly unaffected. It is important to note that saline-filled silicone breast implants have a reported deflation rate of approximately 1% per year¹⁶; long-term evaluation of implant volume was not possible in this study and must be evaluated in animals or humans.

Experimental Methods

Five trials were performed for each larynx for each of three conditions: normal, unilateral vocal fold paralysis (VFP), and paralysis with the wABI inserted and filled to an optimal volume. Trials were conducted as a sequence of 5 seconds of phonation followed by 5 seconds of rest. To simulate normal, both arytenoids were adducted with lateral prongs. To simulate VFP, only the right arytenoid was adducted to the midline; the left was not adducted. This same setup was used for the wABI condition, but the implant was inserted

and filled. Control of vocal fold elongation was accomplished by connecting the thyroid cartilage, just inferior to the thyroid notch, to an anterior micrometer. Vocal fold elongation and contralateral adduction remained constant across trials within each larynx. During each trial, airflow was increased gradually until stable phonation was achieved. Larynges were hydrated with 0.9% saline solution to prevent dehydration.

Data Analysis

Phonation was evaluated in three conditions: normal, simulated VFP, and VFP with the wABI. Airflow and pressure at the phonation onset were recorded as the phonation threshold flow (PTF) and phonation threshold pressure (PTP), respectively. Phonation threshold power (PTW) was calculated as the product of these values.

Measured acoustic parameters included signal-to-noise ratio (SNR), percent jitter, and percent shimmer. Acoustic signals were trimmed to produce three 1-second segments per trial using GoldWave 5.1.2600.0 software (GoldWave Inc., St. John's, Canada), and these segments were analyzed using TF32 software (Madison, WI).

High-speed video recordings of vocal fold vibration were analyzed using a customized MATLAB program (The Math-Works, Natick, MA). Vibratory properties of each of the four vocal fold lips (right upper, right lower, left upper, and left lower) were quantified via digital videokymography (VKG). Threshold-based edge detection, manual wave segment extraction, and non-linear least squares curve fitting using the Fourier series equation were applied to determine the most closely fitting sinusoidal curve. This curve was then used to derive the amplitude and phase difference of the mucosal wave of each vocal fold lip. Mucosal wave amplitude was measured for each vocal fold and calculated as the average of the amplitudes of the upper and lower lips. Three parameters of interest relevant to this investigation included: interfold phase difference, which is reflective of vibrational phase symmetry between the two vocal folds; difference between right and left mucosal wave amplitudes, which was measured to confirm that vibrational amplitude symmetry was not lost due to implant insertion; and left vocal fold amplitude after insertion of the wABI, to confirm inserting the implant did not eliminate the mucosal wave. Interfold phase difference was determined using the method described by Krausert et al.,¹⁷ where a phase difference of π radians represents perfectly symmetric vibration, and a phase difference of zero radians represents perfectly asymmetric vibration.

Statistical Analysis

Repeated measures analysis of variance (ANOVA) with pairwise comparisons using the Student-Newman-Keuls method was performed to determine if significant differences occurred between paired conditions of interest (normal and VFP, to confirm that simulation of paralysis significantly affected voice production; VFP and wABI, to confirm that insertion of the wABI significantly improved voice production; and normal and wABI, to determine if insertion of the wABI restored voice to its normal state). If data did not meet assumptions of parametric testing, repeated measure ANOVA on ranks was performed. Overall tests were two-tailed with a significance level of $\alpha = .05$.

RESULTS

Summary data are presented in Table I.

Aerodynamics

Inserting the wABI significantly decreased PTP ($P < .001$), PTF ($P < .001$), and PTW ($P = .002$) relative to VFP (Table II, Fig. 4). There were no significant differences in aerodynamic parameters between the normal and wABI conditions.

Acoustics

The wABI significantly increased SNR ($P = .002$) and significantly decreased percent jitter ($P = .002$) and percent shimmer ($P = .007$) relative to VFP (Table II, Fig. 5). There were no significant differences in acoustic parameters between the normal and wABI conditions.

Mucosal Wave

Interfold phase difference was not significantly different between any of the pairs (Table II). The absolute difference between right and left vibratory amplitude was also not different (Table II). Left vocal fold vibratory amplitude for wABI trials was maintained (Fig. 6).

DISCUSSION

The wABI, a modified version of the adjustable balloon implant,¹³ provided effective medialization in our preliminary excised larynx experiment. The focused modifications appeared to have simplified implant insertion. Additionally, based on PTF values that more closely match those of the normal condition, the wABI provided improved closure of the posterior glottis. This is in contrast to our initial spherical implant, which exhibited PTF values greater than the normal condition.¹¹

Adequate medialization was achieved in all larynges, as demonstrated by restoration of aerodynamic parameters to near normal levels. This represents a key improvement over our previous implant design. A spherical shape did not allow for closure of the posterior glottis, leading to values of phonation threshold flow that were less than that for VFP but greater than normal. Using a wedge shape effectively closed the posterior gap and reduced air leakage through the posterior glottis. In female patients, such a posterior gap may be desirable, in which case a modified wedge with an angled postero-medial aspect could be used.

Significant improvements were observed in all acoustic parameters compared to the VFP condition. Decreased percent jitter and shimmer can be attributed to restored vibrational periodicity, whereas an increase in the SNR was due to decreased airflow and increased acoustic amplitude. It is important to note that perturbation parameters were slightly higher in the wABI condition compared to normal (Table I). Although these differences were not significant and values were within the range for a type 1 voice signal, more detailed intra-procedural acoustic monitoring or further implant refinements could be employed to ensure levels return to normal.

When placing an implant in the larynx, there is potential for placing pressure on the superficial lamina propria and disrupting the normal mucosal wave if the implant is too large. Filling the implant with an excessive amount of saline could cause bulging and eliminate normal vibration for that vocal fold. Stable phonation could still occur provided vocal fold approximation is achieved, as demonstrated in a hemilarynx experiment¹²; however, this situation is clinically suboptimal. To ensure that insertion of the wABI did not cause these adverse effects, we evaluated ipsilateral mucosal wave amplitude using VKG. Direct quantitative comparisons across conditions of mucosal wave amplitude could be performed, but would be confounded by different input pressures, as subglottal pressure is related to mucosal wave amplitude,¹⁸ and phonation threshold pressure for VFP trials may exceed phonation instability pressure for normal or implant trials. Visual assessment of the kymograms confirmed that the mucosal wave was preserved after implant insertion (Fig. 6). Additionally, the difference between right and left vibratory amplitude, a measure of vibrational symmetry, was determined. This measurement is relative and more immune to the afore-mentioned dependence on subglottal pressure. These tests revealed no significant differences across conditions, though the wABI trials did have the overall largest value. It may be beneficial to investigate the effects of inserting a smaller implant between the thyroid cartilage and inner perichondrium, which would provide medialization while not potentially affecting the mucosal wave. Using the appropriate amount of saline could also be sufficient.

It is important to acknowledge limitations that will be the focus of future investigations. Most importantly, this is a preliminary excised larynx study. Although this is sufficient to evaluate the ability of the implant to medialize a vocal fold, we were unable to evaluate long-term stability or host response. Second, a relatively modest sample size was included. The significant differences between the wABI and VFP conditions are not likely to change; however, some differences between the wABI and normal conditions may become statistically significant with a larger sample. A relatively large base for the wedge shape was selected to ensure the same implant could be used for larynges of varying size. Although this medialization was adequate, superior results may potentially be obtained by using different-sized implants for different larynges. Last, it was not possible to record the vocal output for each condition at the same subglottal pressure. The high pressure needed for phonation in the VFP condition could cause chaotic vibration in the normal or wABI conditions. If a consistent input of approximately 10 cm H₂O were used, the vast majority of larynges simulating VFP would be aphonic, precluding quantitative comparisons.

As with our previous design, the chief advantage is the potential for postoperative adjustability without a revision thyroplasty. Modifications would be primarily to implant volume rather than position. Not every patient would benefit from an adjustable implant; however, there are specific situations when the ability to perform minimally invasive postoperative adjustments would be valuable. For less experienced surgeons, the ability to revise a suboptimal result would be beneficial. Second, professional voice users, in whom high-quality voice is critical to livelihood, may require multiple fine adjustments to ensure optimal voice is achieved.⁹ Third, persons with progressive disorders such as presbylaryngis may require modifications as severity of their voice disorder increases.¹⁰

A key consideration when designing the implant was creating something that could eventually be inserted using only a minimally invasive procedure, potentially accomplished in a minor procedure room rather than an operating room. Insertion in this study required only a small opening (approximately 3×3 mm) in the thyroid cartilage (Fig. 7) and resulted in complete closure of the glottal gap (Fig. 8). Although implant shape and method of insertion provide the possibility of a minimally invasive approach, initial human trials would naturally need to be conducted in the controlled setting of the operating room. Determining feasible implant insertion methods will be a key focus of future animal and human studies.

CONCLUSION

A wABI to be used in medialization thyroplasty is presented. This retains the key benefit of our original implant, namely postoperative adjustability, and also offers closure of the posterior glottal gap and a less invasive method of insertion. Taking advantage of the wedge shape may mean that implants of different size must be used for different patients, though a single implant was sufficient in our six canine larynges. This study provides preliminary support for the biomechanical effects of the implant. Investigations evaluating implant insertion and postoperative adjustment in living animals will be the subject of future research.

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Fig. 1.
Schematic of excised larynx bench apparatus.

Fig. 2.

Wedge-shaped adjustable balloon implant with three degrees of inflation: empty (left), filled to appropriate volume (middle), and overfilled (right). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Fig. 3. Position of implant within larynx. Implant in position within partially dissected larynx but not inflated (A), implant in position within partially dissected larynx and filled so that the glottal gap is eliminated (B), and a schematic (C). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Fig. 4. Phonation threshold flow across the three experimental conditions. VFP 5 vocal fold paralysis; wABI 5 wedge-shaped adjustable balloon implant.

Fig. 5. Perturbation measures of percent jitter (left) and percent shimmer (right) across the three experimental conditions. VFP 5 vocal fold paralysis; wABI 5 wedge-shaped adjustable balloon implant.

Fig. 6. Sample kymograms obtained from one larynx for normal (A), simulated paralysis (B), and wedge-shaped adjustable balloon implant conditions (C). The mucosal wave was preserved after implant insertion.

Fig. 7. Minithyrotomy opening through which the implant was passed. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Fig. 8.

Superior view of glottal configuration for simulated vocal fold paralysis (A) and wedge-shaped adjustable balloon implant (B) trials. (C-D) Same conditions for a larynx with the spherical adjustable balloon implant inserted.¹¹ A small posterior glottal gap is present that does not occur with the wedge-shaped implant.

TABLE I

Summary of Aerodynamic, Acoustic, and Mucosal Wave Data.

Parameter	Normal	VFP	wABI	P Value
PTF (L/min)	18.5 ± 6.8	111.7 ± 17.9	21.0 ± 7.3	<.001
PTP (cm H ₂ O)	7.23 ± 2.49	18.57 ± 3.97	8.13 ± 3.65	<.001
PTW (cm H ₂ O*L/min)	124.6 ± 33.8	2120.6 ± 798.7	164.9 ± 94.6	.006
SNR	16.74 ± 3.99	3.51 ± 2.08	13.67 ± 3.73	<.001
Percent jitter	0.51 ± 0.31	5.77 ± 2.08	0.79 ± 0.31	<.001
Percent shimmer	4.21 ± 2.43	26.90 ± 11.66	6.25 ± 1.70	.006
Interfold PD (radians)	2.54 ± 0.38	2.55 ± 0.35	2.44 ± 0.29	.650
R-L amplitude (pixels)	1.13 ± 0.88	0.85 ± 0.66	1.48 ± 1.66	.501

P values represent results of one-way repeated measures analysis of variance.

L=left; PD=phase difference; PTF=phonation threshold flow; PTP=phonation threshold pressure; PTW=phonation threshold power; R=right; SNR=signal-to-noise ratio; VFP=vocal fold paralysis; wABI=wedge-shaped adjustable balloon implant.

TABLE II

P Values Obtained From Repeated Measures Analysis of Variance or Analysis of Variance on Ranks Pairwise Comparisons Using the Student-Newman-Keuls Method.

Parameter	Normal, VFP	VFP, wABI	Normal, wABI
PTP	<.001 *	<.001 *	.439
PTF	<.001 *	<.001 *	.724
PTW	<.05 *	<.05 *	>.05
SNR	<.001 *	.002 *	.225
Percent jitter	<.001 *	<.001 *	.681
Percent shimmer	<.05 *	<.05 *	.249
Interfold PD	†	†	†
R-L amplitude	†	†	†

Pairwise comparisons were not performed for nonsignificant analysis of variance tests.

L=left; PD=phase difference; PTF=phonation threshold flow; PTP=phonation threshold pressure; PTW=phonation threshold power; R=right; SNR=signal-to-noise ratio; VFP=vocal fold paralysis; wABI=wedge-shaped adjustable balloon implant.

* Significant *P* values.

† Test not performed due to nonsignificant *P* value for analysis of variance.