

Preliminary Investigation of Adjustable Balloon Implant for Type I Thyroplasty

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Objective: We present the adjustable balloon implant (ABI), a novel implant to be used in type I thyroplasty for the treatment of vocal fold paralysis. The ABI offers the same medialization provided by other implants, but can easily be catered to individual patient anatomy as well as modified postoperatively without the need for a revision thyroplasty.

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

Methods: Medialization thyroplasty (MT) with the ABI was performed on five excised canine larynges. Mucosal wave, aerodynamic, and acoustic parameters were measured for three conditions: normal; right vocal fold paralysis; and paralysis with the ABI.

Results: Insertion of the ABI resulted in significant decreases in both phonation threshold pressure and phonation threshold flow. Perturbation parameters of percent jitter and percent shimmer were also significantly decreased and restored to normal levels. Signal-to-noise ratio was significantly increased to the normal level as well. The mucosal wave was preserved after implant insertion.

Conclusions: This preliminary experiment showing significant improvements in aerodynamic and acoustic parameters demonstrates the potential of the ABI as a thyroplasty implant. Effective medialization and preservation of the mucosal wave combined with postoperative adjustability makes it a potentially valuable clinical device.

Key Words: Adjustable balloon implant, medialization thyroplasty, vocal fold paralysis.

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INTRODUCTION

Vocal fold paralysis (VFP) is a disorder caused by damage to the recurrent laryngeal nerve (RLN) that innervates the intrinsic muscles of the larynx. VFP impairs breathing, swallowing, and vocal function.¹ A number of surgical approaches to treating VFP have been proposed, most notably injection laryngoplasty (IL), laryngeal framework surgery including type I medialization thyroplasty (MT) and arytenoid adduction (AA), and laryngeal reinnervation.

IL medializes a paralyzed vocal fold by increasing vocal fold volume. Commonly used materials include fat, collagen, micronized dermis, and calcium hydroxyapatite.² Injections are less invasive than framework surgery and can be performed in the clinic under local anesthesia.³ Despite the utility of IL, it has several limitations such as possible decreased mucosal wave amplitude,^{4,5} absorption of the injection material into adjacent tissues,⁶ and difficulty revising incorrect injection volume or placement.⁷

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Type I thyroplasty, introduced by Isshiki,⁸ can be employed in patients with more severe glottic insufficiency. MT has several benefits over IL, including improved preservation of the mucosal wave,^{5,9} permanence, ability to revise or remove the implant, and the ability to correct a more severe glottal gap. However, numerous challenges encountered by MT have been the subject of extensive clinical and basic science research into improving the procedure. Carving a Silastic implant during surgery can result in suboptimal shaping and prolong procedural duration,^{10–12} resulting in increased intraoperative edema and decreased ability to judge intraoperative voicing accurately. Several alternatives to Silastic have been proposed, including hydroxyapatite,¹⁰ the titanium vocal fold medializing implant (TVFMI),¹³ and Gore-Tex.⁹ These implants represent valuable innovations and can be used effectively to treat VFP; however, they cannot be modified postoperatively without a revision thyroplasty. Postoperative complications such as penetration and breathy phonation due to hypoadduction or dyspnea and pressed phonation due to hyperadduction are not uncommon; therefore, being able to adjust the degree of medialization postoperatively is desirable.

Dean et al.¹⁴ sought to address this issue with the titanium adjustable laryngeal implant. Although promising, the implant was rather complex and requires six screws to secure the implant to the thyroid cartilage. Although medialization can be controlled with the micro-metric screw, the limited number of implant sizes precludes complete customizability according to patient anatomy. Conversely, Gore-Tex and the TVFMI offer

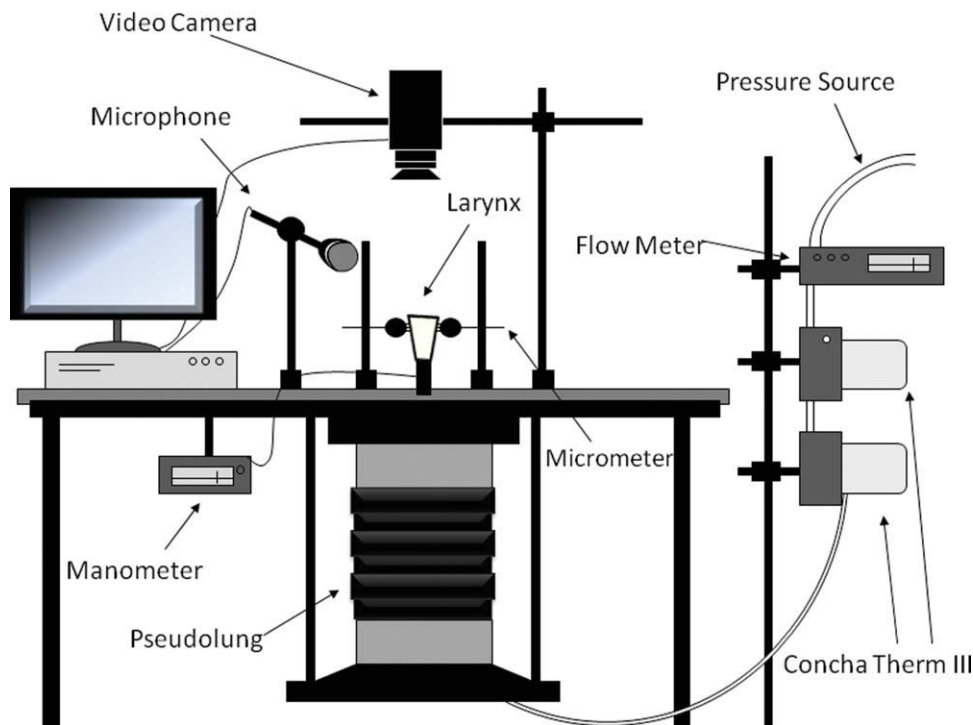


Fig. 1. Schematic of the excised larynx bench apparatus. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

patient customizability but cannot be easily modified postoperatively. We present the adjustable balloon implant (ABI), which combines customizability with postoperative adjustability. Additionally, the ABI offers the benefits of traditional thyroplasty and injection laryngoplasty. It is reversible, does not alter the structure of the lamina propria, and preserves the mucosal wave as with thyroplasty. It also offers incremental medialization as with IL. A silicone balloon that can be filled with saline is introduced into the larynx via a standard thyroplasty window and stabilized with a metal frame that prevents implant extrusion and ensures the force of the implant is directed medially.

MATERIALS AND METHODS

Larynges

Five larynges were excised postmortem from canines sacrificed for nonresearch purposes according to the protocol described by Jiang and Titze.¹⁵ Canine larynges are much more widely available at our institution than human larynges. As the size and histologic properties of the canine and human larynx are similar,¹⁶ it is an appropriate model for studying human laryngeal physiology. Both ex vivo and in vivo canine larynges have been used previously to study interventions for vocal fold paralysis.^{16–18} There are several anatomic differences between the human and canine larynx. The thyroid and cricoid cartilages and more angulated and not as tall in the canine larynx, and there is no well-defined vocal ligament.¹⁶ These differences did not negatively impact the procedure that was evaluated, as the size of the thyroid cartilage was sufficient for the creation of a thyroplasty window. Larynges were examined for evidence of trauma or disorders; any larynges exhibiting trauma or disorders were excluded. Following visual inspection, larynges were frozen in 0.9% saline solution.

Apparatus

Prior to the experiment, the epiglottis, corniculate and cuneiform cartilages, and ventricular folds of the larynx were removed to expose the true vocal folds. The superior cornu and posterosuperior part of the thyroid cartilage ipsilateral to the normal vocal fold were also removed to facilitate insertion of a lateral three-pronged micrometer into the arytenoid cartilage. The larynx was mounted on the apparatus (Fig. 1) as specified by Jiang and Titze.¹⁵ A metal hose clamp was used to stabilize the trachea to a tube connected to a pseudolung that served as a constant pressure source. Insertion of one three-pronged micrometer in the arytenoid cartilage ipsilateral to the dissected thyroid cartilage allowed for adduction of one vocal fold, simulating UVFP in the unadducted vocal fold as in Czerwonka et al.¹⁷ and Inagi et al.¹⁹ Methodological consistency was maintained by always adducting the contralateral arytenoid (simulated normal) to the midline. Micrometer positioning remained constant across sets of trials within the same larynx. Tension on the vocal folds and 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 adduction remained constant for all trials.

The pseudolung 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, CA) in series to humidify and warm the air. The potential for dehydration was further decreased by frequent application of 0.9% saline solution between trials. Airflow was controlled manually and measured using an Omega airflow meter (model FMA-1601A, Omega Engineering Inc., Stamford, CT). Pressure measurements were taken immediately before the air passed into the larynx using a Heise digital pressure meter (901 series, Ashcroft Inc., Stratford, CT).

Acoustic data were collected using a dbx microphone (model RTA-M, dbx Professional Products, Sandy, UT) positioned at a 45° angle to the vocal folds. The microphone was placed approximately 10 cm from the glottis to minimize acoustic noise

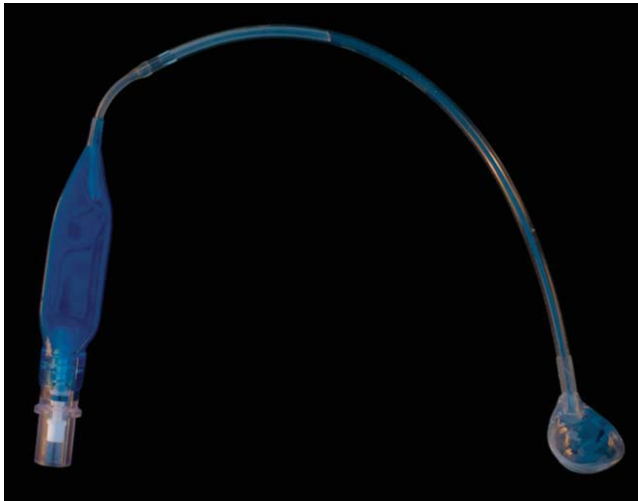


Fig. 2. The adjustable balloon implant. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

produced by turbulent airflow. Acoustic signals were subsequently amplified by a Symetrix preamplifier (model 302, Symetrix Inc., Mountlake Terrace, WA). A National Instruments data acquisition board (model AT-MIO-16; National Instruments Corp, Austin, TX) and customized LabVIEW 8.5 software were used to record airflow, pressure, and acoustic signals on a personal computer. Aerodynamic data were recorded at a sampling rate of 100 Hz and acoustic data at 40,000 Hz. Experiments 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 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 4,000 frames/sec.

Adjustable Balloon Implant

The implant (Fig. 2) was manufactured by Hood Laboratories (Pembroke, MA) based on the authors' design. A round balloon with diameter of 12 mm and wall thickness of 0.5 mm

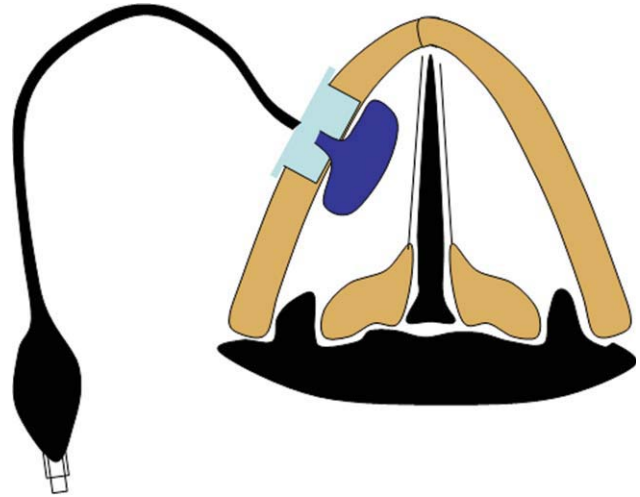


Fig. 3. Position of the implant within the larynx. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

was connected via tubing to a luer slip one-way check valve. The tubing had an outside diameter of 1.5 mm. Both the balloon and tubing were made using 50 durometer medical grade silicone. The implant was placed lateral to the thyroarytenoid muscle (Fig. 3) and secured inside the larynx using an aluminum frame (Fig. 4). The selected frame was suitable for five larynges of differing size used in this study; however, multiple frame sizes could easily be made to accommodate small or large larynges.

Although aluminum was used in this preliminary study on excised canine larynges, the frame would be manufactured from titanium if the implant were applied to human patients. Superior and inferior flanges prevented extrusion of the implant while lateral flanges with holes allowed the frame to be sutured to the thyroid lamina.

A balloon with maximum volume of 1.5 cc was used for all larynges. The selected size was based on knowledge of volume required for effective injection laryngoplasty, with added volume to compensate for the manipulations to the larynx made when creating the thyroplasty window. A main advantage of the ABI is that the size of the balloon is not as important as the volume of saline injected into it. Although only one implant was used in

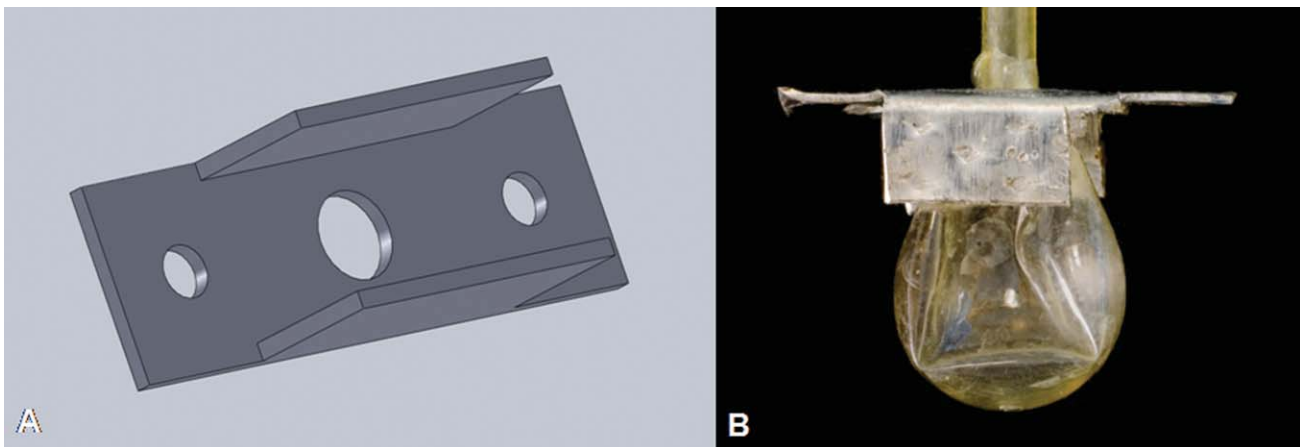


Fig. 4. (A) Schematic of aluminum frame used to secure the adjustable balloon implant within the larynx and prevent implant extrusion. Suture is passed through the smaller lateral holes to secure the frame to the thyroid cartilage, while the tube extending from the balloon is passed through the larger middle hole. (B) The position of the frame relative to the implant. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

this study, it worked for a variety of larynges. The amount of saline injected depended upon the size of the larynx and width of the glottal gap. Saline was injected into the balloon via a luer slip syringe until the paralyzed fold approximated the normal fold. Fine adjustments were then made according to perceptual analysis of vocal quality and quantitative analysis of threshold aerodynamics. Care was taken to avoid overinjection and resultant balloon bulging. If bulging was observed, saline was removed until an optimal volume was reached.

Experimental Methods

Trials were conducted as a sequence of 5-second periods of phonation, followed by 5-second periods of rest. Five trials were performed for each condition. To simulate normal, both arytenoids were adducted with lateral prongs. To simulate unilateral VFP, only the left arytenoid was adducted to the midline; the right was left unadducted. This same setup was used for the ABI condition, but the implant was inserted and filled to an optimal volume. During each trial, airflow passing through the larynx was increased gradually and consistently until the onset of phonation. Larynges were thoroughly hydrated with 0.9% saline solution between trials and between sets of trials to eliminate any potentially confounding effects of dehydration.

Data Analysis

Phonation was evaluated in three conditions: normal; simulated right VFP; and right VFP with the ABI. 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. PTF, PTP, and PTW were determined manually using customized LabVIEW 8.5 software. Aerodynamic parameters were used to provide information on vocal effort and glottal gap.

Measured acoustic parameters included fundamental frequency (F_0), 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 the mucosal wave were analyzed using a customized MATLAB program (The MathWorks, Natick, MA). Vibratory properties of each of the four vocal fold lips (right-upper, right-lower, left-upper, left-lower) were quantified via digital videokymography (VKG). VKG represents a valuable research tool that can quantify the mucosal wave. Threshold-based edge detection, manual wave segment extraction, and nonlinear least squares curve fitting using the Fourier Series equation were applied to determine the most closely fitting sinusoidal curve. This curve was used to derive the amplitude and phase difference of the mucosal wave of each vocal fold lip, both before and after treatment. Mucosal wave amplitude was calculated as the average of the amplitudes of the upper and lower paralyzed vocal fold lips. Although only relative rather than absolute values could be obtained due to current technological limitations, this was sufficient for pre/posttreatment comparisons.

Statistical Analysis

One-way repeated-measures analysis of variance (ANOVA) was performed to determine if there were differences in the parameters of interest across the three conditions. Paired *t*-tests were performed to determine if significant differences occurred between paired conditions (normal and VFP, VFP and ABI, normal and ABI). If data were not normal according to a Shapiro-

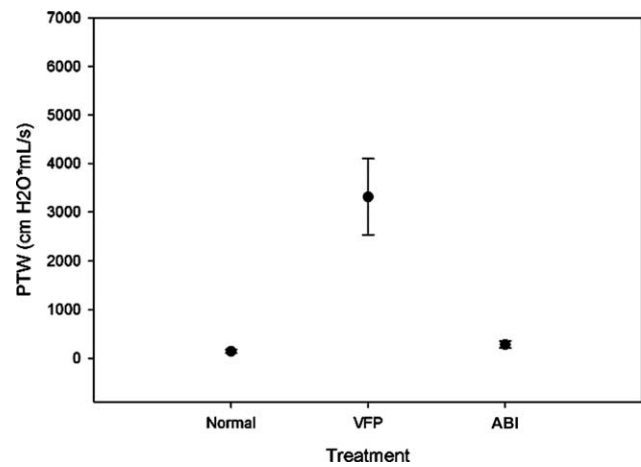


Fig. 5. Phonation threshold power (PTW) across the three experimental conditions.

Wilk test or did not display equal variance according to a Levene's test, an ANOVA on ranks or Wilcoxon-Mann-Whitney paired rank sum test was performed. Tests were two-tailed and a significance level of $\alpha = 0.05$ was used.

RESULTS

Aerodynamics

Summary data are presented in Table I (TBLI). Inserting the ABI significantly decreased PTP ($P = .038$), PTF ($P < .001$), and PTW ($P = .016$) relative to the VFP condition (Table II and Fig. 5). PTF ($P = .039$) and PTW ($P = .038$) remained significantly higher relative to normal (Table II).

Acoustics

Summary data are presented in Table I. The ABI had significant effects on SNR ($P = .005$), percent jitter ($P = .034$), and percent shimmer ($P = .037$) (Table II and Figs. 6 and 7). These values were restored to the levels observed for the normal condition (Tables I and II). Fundamental frequency decreased discernibly.

Mucosal Wave

Summary data are presented in Table I. Mucosal wave amplitude of the normal fold discernibly increased from the normal to paralyzed condition ($P = .055$). Amplitude of this fold remained elevated after insertion of the implant (Table I and Fig. 8). Amplitude of the right vocal fold (simulated paralysis) was the same in the normal and ABI conditions ($P = .966$).

DISCUSSION

We present a novel implant for type I thyroplasty, which offers customizability according to patient anatomy as well as postoperative adjustability. Even at this preliminary prototypical stage, the implant provided effective medialization which improved vocal performance.

Glottal gap was decreased upon insertion of the ABI, placing the paralyzed vocal fold in a position more

TABLE I.
Summary Aerodynamic, Acoustic, and Mucosal Wave Data Including *P*-Values Obtained from One-Way Repeated-Measures Analysis of Variance (ANOVA) Statistical Tests.

Parameter	Normal	VFP	ABI	<i>P</i> -Value
PTF (mL/sec)	17.12 ± 6.86	99.12 ± 57.51	25.08 ± 4.14	<.001*
PTP (cmH ₂ O)	7.976 ± 3.38	20.72 ± 11.88	10.71 ± 5.09	.002*
PTW (cmH ₂ O*mL/sec)	142.8 ± 88.9	2298 ± 2355	281.9 ± 167.7	.002*
F ₀ (Hz)	306 ± 96	177 ± 26	246 ± 45	.024*
SNR	13.71 ± 4.94	3.945 ± 1.94	13.43 ± 4.06	.003*
Percent jitter	1.089 ± 0.98	3.156 ± 1.38	0.968 ± 0.480	.024*
Percent shimmer	19.26 ± 4.99	49.41 ± 19.1	21.47 ± 4.91	.007*
Amplitude (R)	3.794 ± 1.93	4.511 ± 1.62	3.878 ± 3.92	.367
Amplitude (L)	3.509 ± 1.22	6.812 ± 2.17	6.176 ± 5.65	.275

VFP = vocal fold paralysis; ABI = adjustable balloon implant; PTF = phonation threshold flow; PTP = phonation threshold pressure; F₀ = fundamental frequency; SNR = signal-to-noise ratio; R = right vocal fold (simulated paralysis in VFP and ABI conditions); L = left vocal fold. Asterisks indicate significant *P*-values.

conductive for voicing and increasing phonatory efficiency. PTP, PTF, and PTW were all significantly decreased, although not to the levels observed for the normal condition. This can likely be attributed to a slight posterior glottal gap caused by the round shape of the implant. Such a posterior glottal chink could be corrected with an arytenoid adduction. Evaluating the effect of combined arytenoid adduction with ABI thyroplasty will be the subject of future study.

The ABI not only improved the acoustic parameters of interest, but also restored SNR, percent jitter, and percent shimmer to normal or near normal levels. Although it did increase F₀, the resultant frequency was discernibly, although not significantly, less than normal. Improvement of perturbation parameters to approximately normal levels can be attributed to restoration of vocal fold contact and vibrational periodicity. Increased SNR occurred due to decreased airflow required for phonation as well as increased acoustic output.

Interestingly, insignificant increases in the mucosal wave amplitude of the right and left vocal folds were observed from the normal to paralyzed condition. Based on experimental observations, this appeared to be due to

the high airflow through the glottis required for phonation. However, without vocal fold contact, vocal quality was poor despite the large amplitude. Insertion of the ABI closed the glottal gap and preserved mucosal wave amplitude, resulting in improved vocal quality. Following insertion of the ABI, the mucosal wave was preserved.

There are several limitations to the experimental design and implant that will be the subject of future investigations. Although the excised larynx setup is a valuable research tool and has been used frequently to study VFP,^{5,16,17,19,20} it cannot simulate all clinical concerns of thyroplasty such as physiological tissue response to implant insertion and long-term effectiveness of the implant. Second, a round balloon was used in this study, which has the natural tendency to expand uniformly in all directions. This was mitigated by the use of the aluminum frame, which compressed the balloon superiorly and inferiorly, ensuring that the primary force of the balloon on the vocal fold was directed medially. Third, although silicone is a widely used in medical applications including thyroplasty, allergic reaction has been reported.²¹ Covering the implant with a

TABLE II.
P-Values Obtained from Paired *t*-Tests between Treatments.

Parameter	Normal, VFP	VFP, ABI	Normal, ABI
PTP (cmH ₂ O)	0.007*	0.038*	0.103
PTF (mL/sec)	<0.001*	<0.001*	0.039*
PTW (cmH ₂ O*mL/sec)	0.016*	0.016*	0.038*
F ₀ (Hz)	0.044*	0.069	0.169
SNR	0.018*	0.005*	0.901
Percent jitter	0.092	0.034*	0.733
Percent shimmer	0.031*	0.037*	0.349
Amplitude (R)	0.597	0.735	0.966
Amplitude (L)	0.055	0.777	0.813

VFP = vocal fold paralysis; ABI = adjustable balloon implant; PTF = phonation threshold flow; PTP = phonation threshold pressure; F₀ = fundamental frequency; SNR = signal-to-noise ratio; R = right vocal fold (simulated paralysis in VFP and ABI conditions); L = left vocal fold. Asterisks indicate significant *P*-values.

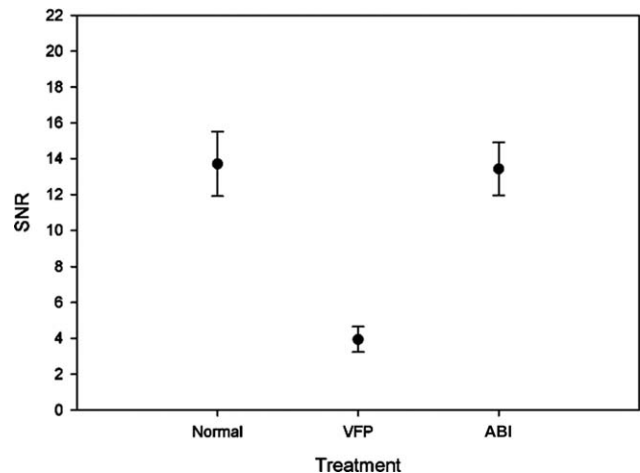


Fig. 6. Signal-to-noise ratio (SNR) across the three experimental conditions.

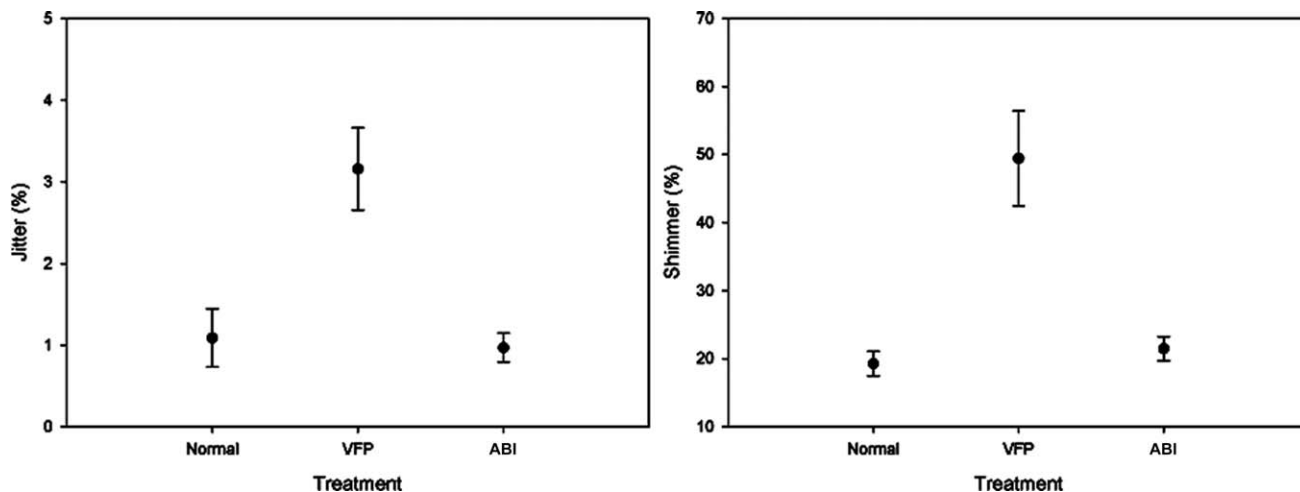


Fig. 7. Perturbation measures of percent jitter (left) and percent shimmer (right) across the three experimental conditions.

biointegratable material such as Gore-Tex could address this concern, preserving the advantages of the ABI while eliminating the possibility of an adverse reaction. Continued use of the excised larynx setup will allow us to evaluate implant modifications objectively and quickly before they are applied to human patients.

Application of the ABI to human patients would require several steps not required for this preliminary excised larynx experiment. After insertion of the implant, 2 to 3 cm of tubing would be left protruding from the balloon to allow for postoperative adjustments to implant volume. The tubing would be sealed with surgical glue prior to closure of the surgical site. Tubing could be left external to the skin similar to a wound drainage tube or, alternatively, left along the inferior margin of the thyroid cartilage. A minor incision at the anteroinferior aspect of the thyroid cartilage would allow for access to the tubing, whereas blue prolene suture attached to the most distal aspect of the tubing could facilitate visualization. Initial closure of the implant tubing is accomplished with a one-way valve and distal occlusion of the tube lumen with surgical glue. Adjusting the volume can be accomplished by severing the tubing proximal to the seal, increasing or decreasing the amount of saline injected, and then reoccluding the lumen with surgical glue.

To increase procedural effectiveness and the simplicity of ABI insertion, implant and methodologic modifications will be evaluated. The spherical balloon shape used in this study is the primary limitation of the ABI. Using a wedge-shaped balloon instead could close the posterior glottal chink as well as prevent overadduction at the anterior commissure. This could also eliminate the need for the supporting frame, opening up the possibility for implant insertion via an anterior microthyrotomy approach. Standard landmarks used in traditional thyroplasty such as the inferior margin of the thyroid cartilage and the anterior commissure could be used to ensure proper vertical placement is maintained. Such an approach would not require the traditional large neck incision currently used for thyroplasty and may also prevent cracking of the thyroid cartilage, particularly in

elderly patients, that can occur when making a thyroplasty window. This procedure would be easily reversible, as only a small hole in the anterior thyroid lamina would be needed for implant insertion.

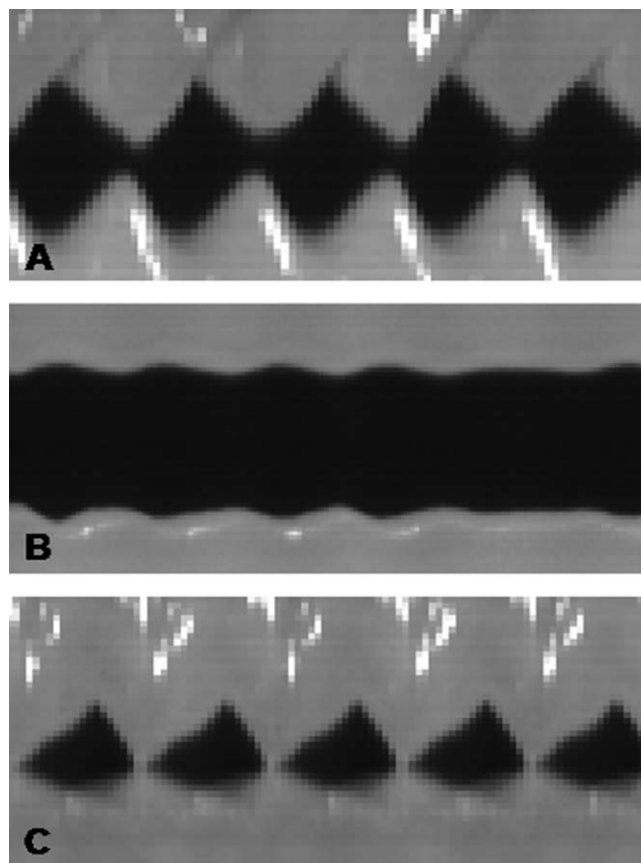


Fig. 8. Kymograms from one larynx for the three experimental conditions: normal (A); simulated vocal fold paralysis (B); and the adjustable balloon implant (C). The left vocal fold is on the top of each image and the right vocal fold in which paralysis was simulated is on the bottom. The glottal gap present in B is eliminated in C.

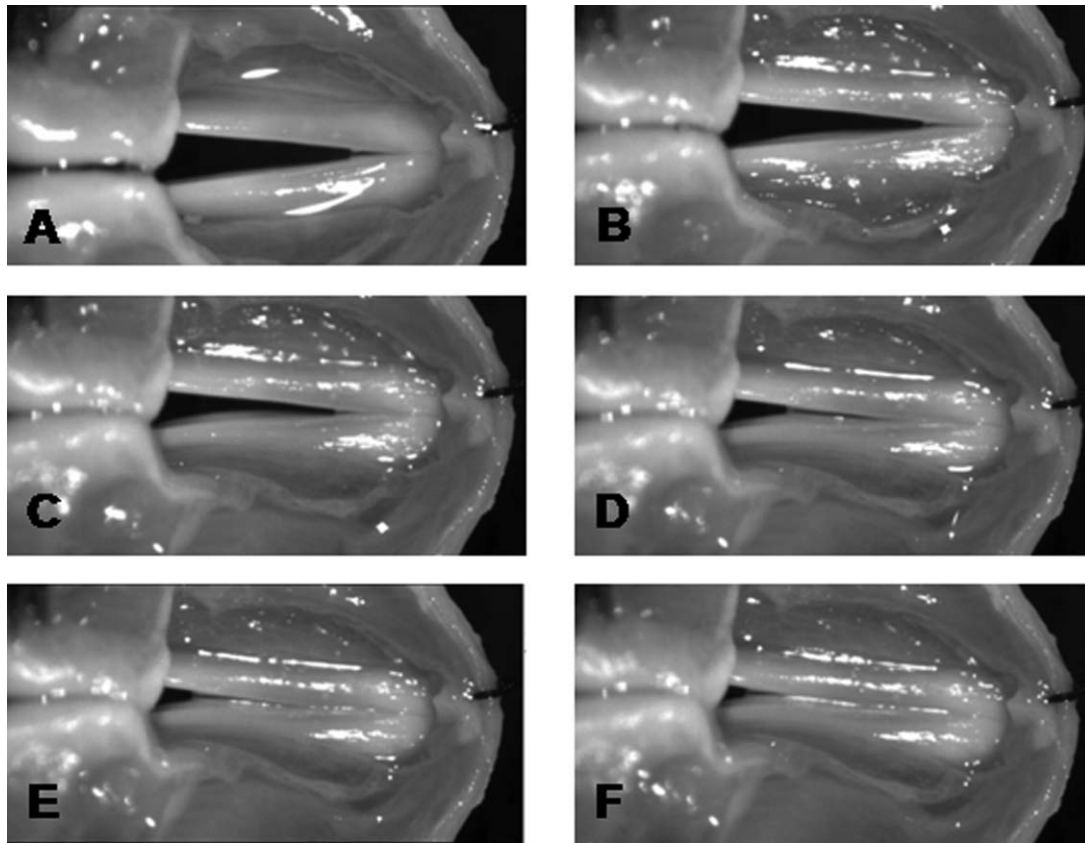


Fig. 9. Incremental adjustments to the volume of saline injected into the implant. (A) Larynx with simulated right vocal fold paralysis; (B) larynx with the implant inserted but no saline injected; (C) 0.4 cc injected; (D) 0.6 cc injected; (E) 1.0 cc injected; (F) 1.2 cc injected.

Although these modifications could be valuable as the ABI is improved, it is important to note the advantages of the ABI even at this early stage. One implant was used for all larynges in this study, which included specimens of varying size, and provided adequate medialization in all cases. The ABI was easy to insert and required no pre- or intraoperative modifications, such as carving with a Silastic implant. It was easy to adjust medialization incrementally and determine the optimal degree of medialization for a superior vocal outcome (Fig. 9). If excess saline was injected and pressed phonation resulted, the excess could easily be removed until optimal vocal quality returned. As modifications to the ABI are made, these benefits will be preserved.

CONCLUSION

A novel implant for type I thyroplasty is presented that has the potential to offer patient customizability and postoperative adjustability. The ABI provided adequate medialization while significantly decreasing the aerodynamic power required for vocal fold vibration, restoring acoustic parameters to normal levels, and preserving the mucosal wave. Although the potential of the ABI has been demonstrated in this preliminary excised larynx experiment, it has not yet been tested in human patients. Modifications to implant shape and insertion method could increase its clinical utility and will be the subject of future research.

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