Published in final edited form as:

Laryngoscope. 2013 January ; 123(1): 220–225. doi:10.1002/lary.23638.

Endoscopic Cold Incision, Balloon Dilation, Mitomycin C Application, and Steroid Injection for Adult Laryngotracheal Stenosis

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Abstract

Objectives/Hypothesis—To describe the presentation, stenosis characteristics, etiological differences, and outcomes of adult laryngotracheal stenosis treated with endoscopic cold incision, balloon dilation, topical mitomycin C application, and steroid injection.

Study Design—Retrospective chart review.

Methods—Demographic and clinical data were extracted for patients treated between March 2000 and December 2010. Prolonged intubation and idiopathic patient data were utilized for comparative analysis.

Results—Eighty patients (65 females; 15 males; 220 procedures; 2.9 years mean follow-up) presented with dyspnea (81%) and/or exercise intolerance (40%). Most commonly, etiologies were idiopathic (53 of 80; 66%) or prolonged intubation (14 of 80; 18%). Mean procedures per patient and interval between procedures were 2.8 procedures and 405 days, respectively. Mean stenosis length and distance from the caudal phonating edge of the true vocal folds were 9 mm and 19 mm. Complication, tracheotomy, and open-procedure rates were 1.8%, 1.4%, and 10.0%, respectively. Patients with more than two procedures demonstrated a mean 4-mm reduction in stenosis length and a 2-mm cephalad progression of stenosis over time. More caudal stenoses required more frequent procedures. Procedures were less frequent as more procedures were performed. Stenosis characteristics, interval between procedures, and total procedures were similar between idiopathic patients with or without intubation histories, but different between idiopathic and prolonged intubation patients.

Conclusions—This procedure was shown to be a viable option in adult laryngotracheal stenosis. Repeat dilation was likely, but was performed without adversely affecting stenosis characteristics.

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Presented at the Annual Meeting of the American Laryngological Association held with the Combined Otolaryngological Spring Meetings.

G.S.G. is a paid consultant for Apnex Medical, Inc.

The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Stenoses farther from the vocal folds required procedures more frequently. Idiopathic patients with a history of brief, elective intubation had stenosis characteristics and responses to therapy similar to idiopathic patients without an intubation history. Both idiopathic groups together demonstrated stenosis characteristics and responses to therapy dissimilar to patients with a history of prolonged intubation.

Keywords

Subglottitis; trachea; stenosis; endoscopic; balloon; mitomycin C; steroid

INTRODUCTION

The surgical management of laryngotracheal stenosis (LTS) can be approached using open or endoscopic approaches. Endoscopic approaches can achieve significant symptomatic improvement through a procedure of short duration that avoids skin incisions and often allows the patient to discharge home the day of surgery.¹ Endoscopic management is thought to be appropriate for patients with ongoing inflammation, lack of cartilage involvement, or unknown etiologies.² External or internal trauma to the trachea is associated with cartilage injury and the potential for loss of structural support, whereas inflammatory conditions, such as Wegener granulomatosis or laryngopharyngeal reflux, are not directly associated with cartilage involvement.² A need for tracheotomy or open resection despite endoscopic treatment has been associated with cicatricial stenoses, stenoses >1 cm in vertical length, tracheomalacia and loss of cartilage, previous history of severe bacterial infection associated with tracheostomy, and posterior laryngeal inlet stenosis with arytenoid fixation.³

Since introductory reports on endoscopic carbon dioxide laser treatments in the larynx in 1972⁴ and radial incisions and rigid dilation of LTS in 1985,⁵ the endoscopic treatment armamentarium of LTS has grown to involve cold instruments or various lasers^{4,5} to incise stenotic bands; balloons⁶, dilators,¹ or rigid bronchoscopes² for dilation of the stenotic segment; and adjunct medications that can be applied in an effort to decrease stenosis formation and contracture. In vitro and animal models demonstrating the promise of the antineoplastic agent mitomycin C as a potential topical antifibrotic material^{7,8} led to its use in idiopathic subglottic stenosis in humans in 2002.⁹ A follow-up study by the same group showed improved success rates independent of the complexity of the lesion.¹⁰ It is thought that mitomycin C acts by cross-linking DNA, which leads to inhibition of fibroblast proliferation and alterations in the extracellular matrix at the genetic level.¹¹ A number of studies have since sought to better understand the efficacy and optimal use of mitomycin C.^{1-3,12,13} In addition to this material, direct laryngeal injection of corticosteroids has been utilized since the 1970s¹⁴ for inflammatory and noninflammatory LTS to take advantage of the anti-inflammatory characteristics thought to reduce granulation and stenosis.¹⁵

Since 2000, the senior author (G.S.G.) has utilized a systematic combination of procedures and intraoperative measurements in adult patients with LTS. Specifically, stenoses have been treated by endoscopic incision, balloon dilation, topical mitomycin C application, and steroid injection, and vertical stenosis length and distance from the true vocal folds have been measured and documented in each case. After a decade of consistent and systematic

practice, this retrospective study was performed to 1) describe the clinical picture of patients presenting with LTS in terms of presentation and stenosis characteristics, 2) evaluate outcomes of this technique through measures of safety and effectiveness, and 3) attempt to identify differences in stenosis characteristics and/or outcomes through a comparative analysis of patients with LTS of various etiologies.

MATERIALS AND METHODS

Institutional review board approvals at a tertiary care academic center (University of Minnesota Medical Center, study #1012M94106) and a metropolitan county hospital (Hennepin County Medical Center, study #11-1931X) were obtained. All patients treated with endoscopic cold incision, balloon dilation, mitomycin C application, and steroid injection for LTS between March 2000 and December 2010 were identified. Patients were included if demographic, presentation, and surgical data were available as defined below. Patients were excluded if any of these categories was missing. Clinical data through December 2011 were extracted to include a minimum 1-year interval from the most recent procedure.

Surgical Technique

Patients were positioned supine and under general anesthesia. Direct laryngoscopy was performed; laryngotracheal anesthesia was administered. A ventilating laryngoscope was inserted and suspended. Jet ventilation was utilized. A 0° telescope was used to visualize the airway down to the carina. The stenosis was characterized by measuring its vertical length and the vertical distance of the cephalad edge of the stenosis to the caudal phonating edge of the true vocal folds. Radial incisions were made to release the stenosis with a 7300 Beaver blade. Two to four incisions were made at the midportion of the areas of greatest contracture. Angiocatheter balloons (Boston Scientific, Natick, MA) were inserted and inflated by hand and held at full inflation for 10 seconds. Repeat dilation was performed for a total of two to three dilations depending on stenosis response. Mitomycin C (1 mg/mL) soaked pledgets were applied directly to the incised area for a total of 4 minutes, after which saline pledgets were applied three times to cleanse the wound surface. Finally, triamcinolone (40 mg/mL) was injected endoscopically into the stenosis using a 27-gauge butterfly fly needle with the lateral phalanges trimmed and held with laryngeal forceps. Typically, two to four submucosal injections were utilized just adjacent to the radial incisions for a total volume of 0.4 to 0.8 mL. Representative pre- and postprocedure images are shown in Figure 1. Early in the series, patients were admitted for overnight observation for the initial procedure. Over the past several years, all patients have been discharged the day of the procedure if stable postoperatively. Proton pump inhibitors were prescribed twice daily preoperatively to outpatients and to all patients postoperatively for at least 6 months. Patients were seen postoperatively in 2 to 6 weeks from their procedure with subsequent follow-up as needed.

Clinical Presentation and Stenosis Characteristics

Demographic and presentation data included age, gender, presenting symptoms, duration of symptoms, presence of reflux history, smoking history, intubation history, tracheotomy

history, and etiology. Determination of reflux was made during the initial consultation by patient report of subjective gastroesophageal or laryngoesophageal reflux symptoms or by prior diagnosis and treatment with medical therapy; pH probe data and validated self-report instruments were not available. Prolonged intubation was designated if intubation was >24 hours and was temporally associated with onset of symptoms. Idiopathic was designated if patients had no other underlying etiology, including negative rheumatologic serology, and either no history of intubation or a history of elective intubation for a surgical procedure with immediate extubation. The idiopathic category was subdivided based on whether a patient had any history of intubation. Intraoperative measurements included vertical stenosis length and stenosis distance from the vocal folds as described above. Patients who presented with stenoses longer than 2 cm or with inadequate cartilage support and who were medically appropriate were considered for open resection; thus, some patients with stenoses >2 cm in length were not included in this analysis.

Safety and Effectiveness

Descriptive data included intraoperative and/or postoperative complications, decannulation rates for patients presenting with tracheostomy tubes, progression to tracheotomy, progression to open surgical reconstruction, interval between procedures, total number of procedures, and duration of follow-up. Changes in characteristics of stenosis were evaluated among patients who underwent three or more procedures, which allowed for evaluation of change over time. This was performed by calculating the difference between the measured vertical stenosis length at the initial and the final recorded procedure. Mean and standard deviation were calculated. The same calculations were performed for stenosis distance from the vocal folds. Associations between the interval between procedures and stenosis characteristics were compared by simple linear regression of the interval over stenosis length or stenosis distance from the vocal folds. To determine whether the interval between procedures increased or decreased over time relative to the procedure number, we used a generalized estimating equation (GEE) model with an unstructured variance–covariance matrix.¹⁶ The GEE model accounts for the clustering induced by the interval between procedures for the same subject at various time points.

Subgroup Analysis

To identify differences between patients with the most common etiologies, a nonparametric Kruskal–Wallis (KW) test¹⁷ was used to compare three groups of patients (intubated idiopathic, nonintubated idiopathic, and prolonged intubation) for six characteristics (initial stenosis length, final stenosis length, initial stenosis distance from the true vocal folds, final stenosis distance from the true vocal folds, mean interval between repeat procedures, and total number of procedures). The idiopathic patients were subdivided because the presence of an intubation history puts into question the idiopathic diagnosis. After the KW test, two-group comparisons were conducted between the three comparison groups using nonparametric Wilcoxon rank sum (WRS) tests.¹⁷ These tests were performed for each of the six characteristics described above. Nonparametric tests were chosen specifically to yield robust inference accounting for possible non-normality of the responses, and moderate sample sizes. All results were based on their respective two-sided test, with significance set at <.05.

RESULTS

Clinical Presentation and Stenosis Characteristics

Over the 10-year period, 85 consecutive, eligible patients were identified for review. Five patients were excluded due to insufficient data, which resulted in 80 patients undergoing 220 procedures that were included in the final analyses. Demographic, presentation, and pertinent historical data are shown in Table I. Symptoms were present for a mean of 28.1 months (standard deviation [SD], 42.5 months; range, 3 days to 20 years) prior to presentation. One patient was seen for consultation as an inpatient; all others were seen initially in the outpatient setting. Etiological data are shown in Table II. Of the 53 patients fulfilling criteria for idiopathic etiology, 23 patients (22 female, one male) had no history of intubation. The iatrogenic etiology was a result of excision of papilloma. The mean number of days from the presentation date to the first surgical date was 81 (SD, 211.6 days; range, 0 days to 3 years). Surgical data and stenosis characteristics are shown in Table III. Five patients who had stenoses >2 cm in length were referred for evaluation of open resection (prolonged intubation [n = 3], tracheotomy trauma [n = 1], and idiopathic [n = 1]). Three opted for endoscopic management following the initial procedure, whereas two patients of prolonged intubation etiology opted for open resection. The mean follow-up from presentation was 2.9 years (SD, 2.9 years). Overall, five patients did not follow up in clinic after their initial procedure; the range of follow-up for the other 75 patients was 3 days to 10.2 years.

Safety and Effectiveness

Acute complications occurred after 5 of 220 procedures (2.3%), including two episodes of shortness of breath and one episode each of subcutaneous emphysema, true vocal fold laceration, and temporary vocal fold paralysis. All symptoms resolved with medical intervention and/or observation alone. There was no known development of malignancy at the site of mitomycin C application. Of 11 patients who presented with tracheostomy tubes, five were decannulated (45.5%), and two were under consideration for decannulation because they were able to plug their tracheostomy tubes 24 hours a day at final follow-up. Tracheotomy was performed in one of 69 patients who presented without tracheostomy tubes (1.4%); this patient was decannulated after the third endoscopic procedure. Open procedures were performed in eight of 80 patients (10.0%), including five cricotracheal resections and three tracheal resections with reanastomoses. Etiologies underlying those patients progressing to open resection included: idiopathic (three of 53; 5.7%), prolonged intubation (two of 14; 14.3%), infection (two of two; 100%), and external trauma (one of one; 100%).

Twenty-nine patients underwent three or more procedures (mean, 5.1; SD, 2.6; range, 3–13 procedures). Between the initial and final procedure for each patient, there was a mean reduction in stenosis length of 4 mm (SD, 4.8; range, 17-mm reduction to 3-mm increase) and a mean cephalad progression of stenosis position of 2 mm (SD, 6.3; range, 18 mm cephalad to 11 mm caudad). The three patients with stenoses >2 cm in length who had repeat procedures showed a reduction in length from the initial to the final procedure with a 1- to 2-mm vertical migration of the stenosis from its initial distance from the vocal folds.

From the linear regression analysis, no association was observed between interval between procedures and stenosis length ($P = .22$). However, there was an association between interval and stenosis distance from the vocal folds ($P = .021$), where stenoses that were farther from the vocal folds required procedures at more frequent intervals. GEE analysis revealed that the number of procedures positively influenced the interval ($P < .001$); the interval between procedures increased with an increase in the number of procedures performed.

Subgroup Analysis

Table IV displays means and SDs of the six characteristics utilized for analysis of the three comparison groups. The null hypotheses of equality of the three groups in the KW test were rejected (P values ranged between .001 and .036) for each characteristic, which revealed that at least two of the three groups were different for each. Probability values produced from WRS tests utilized to identify the specific groups that differed are found in Table V. These results demonstrated that nonintubated idiopathic patients had significantly more procedures than intubated idiopathic patients, but there was no difference in stenosis length, stenosis distance from the vocal folds, or mean interval between procedures. Intubated and nonintubated idiopathic patients combined had significantly shorter stenoses in more cephalad positions, longer mean intervals between procedures, and greater numbers of procedures per patient than prolonged intubation patients.

DISCUSSION

This study provides a 10-year retrospective analysis of the characteristics and treatment of adult LTS using consistent surgical technique and intraoperative measurements. Patients in our series most commonly presented with shortness of breath and exercise intolerance. More than half of the patients had an intubation or smoking history. A strong association of pH-probe–measured laryngopharyngeal reflux and subglottic stenosis has been reported.¹⁸ A minority of patients in our series reported subjective reflux disease, but several were being treated for reflux and were asymptomatic at presentation. Whereas postintubation injury has been noted to be the most common cause of LTS,^{19,20} it was the second most common etiology at 18% in this report. Approximately two thirds of the patients had symptoms and findings without an identifiable underlying cause, including negative screening tests for rheumatologic disease. Series focusing on idiopathic subglottic stenosis^{9,17} demonstrated a significant female preponderance, which was also the case in our series (94% female). Gender predominance was not noted in the prolonged intubation group, whereas a greater male representation was reported in other postintubation reports.^{19,20}

Descriptive outcome data showed a low complication rate (1.8%), tracheotomy rate (1.4%), and rate of progression to open procedures (10%). Decannulation of half of the patients who presented with ($n = 11$) or required subsequent ($n = 1$) tracheostomy tube placement was observed. Tracheotomy was avoided in the majority of patients by employing the technique even on an emergent basis. Whereas some endoscopic reports indicate minor complications such as postoperative nausea and increased secretions,² others report either no complications²¹ or do not mention complications. Studies vary in reports of tracheotomy, but 6% to 26% rates have been reported in idiopathic patients.^{21,22} Similarly, reports describing

both open and endoscopic approaches have reported 6%¹⁹ to 100%²² rates of progression to open procedures. The wide range of progression to open procedures may be dependent on the providers' preference for or different criteria for recommending open or endoscopic approaches. The criteria for recommending open surgical management in this study is patient preference, stenosis length >2 cm, and patient dissatisfaction with frequency of dilations. Whereas some patients suitable for endoscopic management have chosen open procedures from the outset, others have preferred multiple dilations to open surgery.

Patients who underwent three or more procedures had an overall decline in vertical stenosis length and a relatively stable position in terms of distance from the true vocal folds. This reduction in stenosis length was also shown by Dedo and Catten,²¹ where a 0.7-cm reduction was noted in the thickest portion of stenoses of idiopathic patients. The reduction in stenosis length after multiple treatments is consistent with the limited local trauma afforded by the technique described, where cold incision minimizes collateral tissue damage, dilation allows for expansion of the airway, and mitomycin C and steroid reduce fibrosis. Controlled studies would be required to delineate which treatment or combination of treatments makes the greatest impact, but we suspect that each participates in the reduction in stenosis length observed. The superior migration of the level of stenosis in some patients may be secondary to the technique of stenosis incision, which is made in an inferior to superior direction and may be more likely to create trauma on the superior aspect of the stenosis. It should be noted that our data are most relevant to idiopathic patients, as they constituted 23 of 29 patients (79.3%) undergoing three or more procedures.

A 9-month interval between procedures was reported by Roediger et al.² The mean interval of >400 days between procedures for patients of all etiologies in this study seems to be a reasonable interval for patients choosing to continue with endoscopic management. Reinforcing this was the positive influence of procedure number on mean interval between procedures, which indicated that patients tended to require procedures less frequently over time. Overall, the reduction in stenosis length and minimal change in stenosis proximity to the vocal folds over time combined with the decrease in frequency of procedures over time suggest that endoscopic management of LTS does not lead to unfavorable changes in stenosis characteristics.

No association was found between interval between procedures and stenosis length. This may be influenced by recommending open resection to patients with stenoses >2 cm, although the overall reduction in stenosis length with either stenosis <2 cm or >2 cm in length is encouraging. A decrease in the interval between procedures was noted for stenoses situated farther from the true vocal folds. This more caudal stenosis location was seen more commonly in patients with prolonged intubation.

Patients with LTS fulfilling our criteria for intubated idiopathic, nonintubated idiopathic, and prolonged intubation diagnoses were the only subgroups with reasonable patient numbers for comparison. We did combine, in some of the analyses, patients with elective intubation with immediate extubation in our idiopathic group as has been done in prior studies,^{9,19} which some might consider an etiological factor. However, it was interesting to note that these idiopathic patients had only a difference in total number of procedures when compared

directly. The similarity between the two idiopathic groups suggests that a brief, uncomplicated intubation may play less of a role in the development of stenosis in idiopathic patients. A brief intubation could be an inciting factor in an already subclinical LTS in these patients, which then could precipitate symptoms. Ultimately, these data are not definitive with regard to the role of short-duration intubation in patients who would otherwise be considered idiopathic, although they are suggestive of a possible similarity between intubated and nonintubated idiopathic patients.

Overall, patients with prolonged intubation histories lacked a female predominance, and had longer stenoses in more caudal positions, shorter intervals between procedures, and a smaller total number of procedures compared to idiopathic patients. The impact of the endotracheal tube and cuff would be expected to play a greater role in stenosis formation during prolonged intubation than in stenoses associated with no intubation or a brief, uncomplicated one. Perhaps the more caudal location and greater length of stenosis in prolonged intubation patients is related to mechanical trauma caused by a deep position of the endotracheal tube, which is placed to minimize risk of injury to the glottis. Meanwhile, differences in procedure interval and number may be related to pathogenesis. Postintubation LTS has been characterized by a transition from early inflammation, including mucosal ulceration and perichondritis, to granulation tissue and, ultimately, to fibrotic scar.¹⁹ Conversely, idiopathic LTS has been characterized by chronic inflammation.^{9,21} Perhaps a more fibrotic stenosis in prolonged intubation LTS requires multiple initial procedures more frequently, although the lack of persistent inflammation allows for improved healing and permanent relief of symptoms earlier than idiopathic patients. The identification of different stenosis characteristics and responses to therapy across different etiologies may allow for development of more targeted therapy based on etiology.

This study is limited by flaws inherent in a retrospective analysis. Analyzing the interval between procedures carries inherent error. Subjectively, patients tend to return at symptom levels that are less severe, and the timing of symptom return is affected by the patients' level of activity. Objective data regarding reflux diagnosis and management were not available. Availability of follow-up data was variable. Statistical analyses, despite not assuming normal distributions, still reflect the quality of data retrieved by a retrospective analysis. Finally, because these data describe a consistent combination of procedures without comparison groups, they do not allow examination of the differential benefit of each of the procedures alone or in various combinations.

CONCLUSION

Endoscopic cold incision, balloon dilation, topical mitomycin C application, and steroid injection as a combined treatment was shown to be a viable option for adults with LTS. Repeat procedures were likely, but were performed without adversely affecting stenosis characteristics. Stenoses farther from the true vocal folds required procedures more frequently. Nonintubated and intubated idiopathic patients shared similar stenosis characteristics and procedure frequencies, whereas idiopathic and prolonged intubation etiologies appeared dissimilar.

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Fig. 1.
Subglottic stenosis (A) before and (B) after endoscopic treatment.

TABLE I

Demographic and Presentation Data.

Characteristic	Total No. (%)
Total	80
Gender	
Female	65 (81.3)
Male	15 (18.8)
Presenting symptoms	
Shortness of breath	65 (81.3)
Exercise intolerance	32 (40.0)
Stridor	23 (28.8)
Hoarseness	10 (12.5)
Cough	7 (8.8)
Other pertinent history	
Intubation history	47 (58.8)
Cigarette smoking	45 (56.3)
Reflux	13 (16.3)

TABLE II

Etiological Data.

Etiology	Total, No. (%)	Males, No. (%)	Females, No. (%)
Idiopathic	53 (66.3)	3 (5.7)	50 (94.3)
Prolonged intubation	14 (17.5)	7 (50.0)	7 (50.0)
Rheumatologic	4 (5.00)	0	4 (100.0)
Malignancy	3 (3.8)	1 (33.3)	2 (66.6)
Tracheotomy	2 (2.5)	1 (50.0)	1 (50.0)
Infection	2 (2.5)	2 (100.0)	0
Other iatrogenic	1 (1.3)	1 (100.0)	0
External trauma	1 (1.3)	1 (100.0)	0

TABLE III

Stenosis Characteristics and Surgical Data Overall.

Characteristic	Mean	SD
Age at surgery, yr	46.3	15.1
Stenosis length, mm	9.1	6.3
Stenosis distance from vocal folds, mm	19.4	8.7
Interval between procedures, d	404.7	343.2
No. of surgeries per patient	2.8	2.4

SD = standard deviation.

TABLE IV

Stenosis and Surgical Characteristics by Etiology, Mean (Standard Deviation).

Groups	Initial* Stenosis Length, mm	Final* Stenosis Length, mm	Initial* Stenosis Distance, mm	Final* Stenosis Distance, mm	Mean Interval Between Procedures, d	Total No. of Procedures
Intubated idiopathic, [†] n = 30	7.3 (5.1)	6.2 (4.6)	20.8 (9.4)	19.4 (8.9)	425.7 (367.0)	2.5 (1.9)
Nonintubated, idiopathic, [†] n = 23	9.3 (4.7)	6.7 (2.7)	18.1 (5.0)	16.2 (4.8)	453.2 (328.4)	4.2 (3.3)
Prolonged intubation, n = 14	15.5 (11.5)	14.3 (9.5)	32.0 (14.5)	33.0 (15.5)	142.6 (285.8)	1.9 (1.4)

* Initial refers to the measurements on the first operative procedure. Final refers to the measurements at the most recent operative procedure. Distance refers to the distance from the caudal phonating edge of the true vocal folds.

[†] Idiopathic was the designation for patients who had no other underlying etiology and either no history of intubation (nonintubated idiopathic) or a history of elective intubation for surgery with immediate extubation (intubated idiopathic). Prolonged intubation was the designation if intubation was >24 hours and was temporally associated with onset of symptoms.

TABLE V

Wilcoxon Rank Sum Test Results (P Values).

Comparison Groups	Initial	* Stenosis Length	Final	* Stenosis Length	Initial	* Stenosis Distance	Final	* Stenosis Distance	Mean Interval Between Procedures	Total No. of Procedures
II vs. NI	.0488		.0171		.3601		.1259		.3038	.0363 [†]
II vs. PR	.0126 [†]		.0014 [†]		.0300 [†]		.0038 [†]		.0278 [†]	.1611
NI vs. PR	.1848		.0105 [†]		.0089 [†]		.0006 [†]		.0234 [†]	.0062 [†]
IIpNI vs. PR	.0331 [†]		.0016 [†]		.0101 [†]		.0006 [†]		.0160 [†]	.0273 [†]

* Initial refers to the measurements on the first operative procedure. Final refers to the measurements at the most recent operative procedure. Distance refers to the distance from the caudal phonating edge of the true vocal folds.

[†] Statistically significant ($P < .05$).

II = intubated idiopathic; NI = nonintubated idiopathic; PR = prolonged intubation.