

Voice Outcome after Gore-Tex Medialization Thyroplasty

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Abstract

Introduction Although medialization thyroplasty utilizing Gore-Tex (Gore and Associates, Newark, Delaware, United States) has been discussed in the literature, few reports have assessed voice quality afterward, and they did not use a full assessment protocol.

Objective To assess the improvement in voice quality after medialization thyroplasty utilizing Gore-Tex in patients with glottic insufficiency of variable etiology.

Methods Eleven patients with glottic insufficiency of different etiologies that failed compensation were operated by type 1 thyroplasty utilizing Gore-Tex. Pre- and postoperative (1 week, 3 months, and 6 months) voice assessment was done and statistical analysis was performed on the results.

Results In all postoperative assessments, there was significant improvement in the grade of dysphonia ($p < 0.004$) and highly significant reduction in the size of glottic gap and prolongation of maximum phonation time ($p < 0.0001$). The difference in voice parameters in the early (1 week) and the late (3 and 6 months) postoperative period was not significant. None of the patients developed stridor or shortness of breath necessitating tracheotomy, and there was no implant extrusion in any patient during the study period.

Conclusion Gore-Tex medialization provides reliable results for both subjective and objective voice parameters. It leads to a satisfactory restoration of voice whatever the etiology of glottic incompetence is. This technique is relatively easy and does not lead to major complications. Further studies with larger number of patients and more extended periods of follow-up are still required to assess the long-term results of the technique regarding voice quality and implant extrusion.

Keywords

- ▶ thyroplasty
- ▶ voice
- ▶ Gore-Tex

Introduction

Glottic incompetence (GI) can be defined as incomplete glottic closure during phonation. It is a common finding in patients with vocal fold immobility, paresis, atrophy, and scar.¹

Unilateral vocal fold paralysis (UVFP) is the most common cause of GI and usually presents with dysphonia and possibly with severe symptoms such as aspiration, poor coughing effort, or pneumonia, which may be life-threatening in debilitated

patients.^{2–4} It was estimated that 23 to 53% of patients with UVFP demonstrated evidence of aspiration on videofluoroscopic examination.^{3–5} If there is no recovery or if there is inadequate compensation after UVFP, procedures aiming to restore glottic competence include permanent and temporary vocal fold injections or laryngeal framework surgery, such as type 1 thyroplasty.⁶

Type I thyroplasty, with or without adjunctive arytenoids procedures, is widely considered the surgical management of choice for glottic insufficiency resulting from vocal fold

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immobility. Medialization using laryngeal implants has been shown to improve voice handicap index and perceptual voice measures as well as acoustic parameters of the voice.⁷⁻⁹ Both Silastic and Gore-Tex (both Gore and Associates, Newark, Delaware, United States) thyroplasty implants have been shown to provide excellent long-term surgical rehabilitation of paralytic dysphonia.^{10,11} The ideal surgical management of GI in patients with mobile vocal folds, however, is far less well established.

Gore-Tex, expanded polytetrafluoroethylene, was developed by Gore and Associates in the late 1960s. The first application was in general vascular surgery, and the first vessel implants were described in 1971.¹² Since that time, the material has been described as a semiporous material with excellent tissue integration, minimal tissue inflammation, and low rates of extrusion and is easily removed when necessary.^{13,14}

Gore-Tex medialization laryngoplasty was first described by McCulloch and Hoffman in 1998.¹⁰ The technique is fast and not technically demanding because the implant is simply layered into the paraglottic region and does not need to be carved. Medialization is reached in an incremental manner (inserting or removing portions of the Gore-Tex strip) until satisfactory vocal outcome is achieved, allowing fine intraoperative adjustments that do not involve removal and replacement of the entire implant.¹⁵

Although medialization thyroplasty utilizing Gore-Tex was discussed in the literature, few reports assessed the voice quality after the surgery, and even these did not use full assessment protocol.^{1,2,5} The aim of this study was to assess the improvement in voice quality after Gore-Tex medialization thyroplasty in patients with uncompensated GI using a full assessment protocol and comparing the immediate postoperative results to later results.

Methods

This study was conducted in between June 2007 and October 2013. The study included 11 patients who presented with insufficient glottic closure that failed to compensate at least 1 year after injury. Three patients were previously exposed to vocal fold injection at least 6 months prior to medialization, with poor results. The etiology of glottic insufficiency was vocal fold paralysis in 10 patients (post-thyroidectomy in 5 patients, idiopathic in 2, after spine surgery in 2, carotid body tumor in 1, and after cordectomy in 1). All the patients were operated using type 1 thyroplasty utilizing Gore-Tex. Preoperatively, all the patients had voice complaints in the form of breathy dysphonia, increased phonation effort, and vocal fatigue. All of them had glottic phonatory gap more than 3 mm at its widest point. Informed written consent was obtained from all included subjects. The patients were subjected to preoperative voice assessment protocol by the phoniatrician, who was blinded to the state of the patient (either preoperative or postoperative).¹⁶ This protocol passed through the following levels: elementary diagnostic procedures, clinical diagnostic aids, and additional instrumental measures.

Elementary Diagnostic Procedures

Diagnostic procedures included auditory perceptual assessment of the patient's voice as a subjective evaluation of the voice with careful laryngeal examination. The presence or absence of vocal fold visible mobility was determined, along with its side and degree (normal or restricted) and the direction of restriction (abductor or adductor), to confirm the diagnosis. The phonatory gap (gap between vocal folds during average phonation) and respiratory chink (maximal glottic gap during respiration) were determined. They were measured in millimeters at their widest point compared with the length of the visible membranous vocal fold (proposed to be 15 mm in men and 10 mm in women).¹⁷ Glottic gap was confirmed using the method described by Kotby et al.¹⁷ A millimeter-graded ruler was photographed in focus with the same magnification used in video laryngoscopy of the glottis. The printout of the glottis was obtained from the stroboscopy system, and a printout of the ruler image was obtained as well, and the gap was then measured.

Clinical Diagnostic Aids

This level of the protocol includes laryngo-video-stroboscopy using either flexible nasofibroscope or rigid 70-degree laryngoscope, from Xion Medicals (Germany), connected to a camera in association with stroboscopic light. Phonatory gap size was confirmed during stroboscopic image with average comfortable phonation at the widest point of the vocal folds. Then documentation of the auditory perceptual assessment was done by means of high-fidelity voice recording, which included reading a standardized text, a counting task, and sustained vowel prolongation including / α /, /i/ and /u/ vowels. The recordings were done in a sound-treated room to minimize environmental noise. The recorded materials for all patients were rated using the modified GRBAS (grade, roughness, breathiness, asthenia, strain) scale,¹⁸ which was confirmed by three experienced phoniatricians. This scale included 4 points (0 to 3; 0 for normal, 3 for severe) for determining the overall grade of dysphonia and character of voice including strained, leaky, breathy, and rough.

Additional Instrumental Measures

This level of assessment included acoustic analysis of voice using the Vocal Assessment Software from Dr Speech 4.5. The patient was asked to pronounce a prolonged / α / in front of a microphone as long as possible after taking a deep inspiration. The following parameters were analyzed automatically: jitter (%), shimmer (%), and noise-to-harmonic ratio. Maximal phonation time (MPT) could be measured simultaneously during the same task.

Patients with mild glottic insufficiency were selected for vocal fold injection and were only operated by medialization if voice quality was unsatisfactory immediately or later after injection. Patients with moderate and severe glottic insufficiency were operated directly by Gore-Tex medialization thyroplasty. All the surgeries were done initially under local anesthesia. Postoperatively, voice assessment was repeated at 1 week, 3 months, and 6 months from the date of surgery.

Pre- and postoperative data were compared and statistical analysis is done. SPSS (Statistical Package for the Social Sciences,

version 17; Chicago, Illinois, United States) was used to analyze the data. Data of this work were found to be homogenous using variance homogeneity test. Analysis of distribution of data revealed that parametric tests could be applied. The chi-square test was used for qualitative variables, and the analysis of variance was used for quantitative variables. Turkey honest significant difference post hoc test was used to compare individual groups. A *p* value less than 0.05 was considered significant.

Surgical Technique

During this study, the standard Gore-Tex medialization laryngoplasty following the basic steps described McCulloch et al,¹⁰ with some modification, was adopted. After the administration of monitored anesthesia, 10% topical xylocaine and Oxymetazoline-soaked pledgets were placed into the nose. Topical local anesthetic spray was applied to the pharynx and a flexible nasopharyngoscope was introduced so that a clear image of the larynx was obtained. The nasopharyngoscope was fixed to a table at the patient's head and could be handled by an assistant to maintain a clear image of the larynx during the procedure. Local anesthesia, 0.5% lidocaine 1:200,000 epinephrine with 0.25% bupivacaine, was then administered. A 3-cm incision was made in a natural skin

crease overlying the thyroid ala. The strap muscles were reflected laterally, and a laterally based perichondrial flap was elevated. The inferior thyrotomy as measured 5 mm above the inferior border of the thyroid cartilage, and a 5- to 7-mm window was then created with a no. 3 course diamond burr 5 mm from the midline in women and 7 mm from the midline in men. The inner perichondrium was identified and elevated carefully from the thyroid alae without incision. Utilizing flexible laryngoscopic guidance, the Gore-Tex was then placed with care to appropriately augment the posterior and mid-portions of the glottis. At the same time, the patient was asked to phonate until the best voice quality was reached. The perichondrium was draped back over the thyrotomy, and the incision was closed in layers with absorbable suture. A small drain as used and removed after 24 hours. Patients received 1 week of oral postoperative antibiotics and were discharged home the day after surgery.

Results

The study included 11 patients (5 men and 6 women) with ages ranging between 22 and 56 years. ►Table 1 shows the demographic characteristics of the patients and the etiology of glottic incompetence.

Table 1 Descriptive data for patients included in the study before surgery

Patient no.	Sex	Age (y)	Cause of paralysis	Side	Duration till surgery (mo)	Previous intervention	Glottic gap size (mm)
1	F	22	After thyroidectomy	Left	14	None	4
2	F	43	After thyroidectomy	Left	13	None	5
3	M	39	Spine surgery	Right	24	Vocal injection (fat)	4
4	F	28	Idiopathic	Left	12	None	4
5	M	53	Carotid body tumor	Right	15	Vocal injection (fat)	6
6	F	38	After thyroidectomy	Left	12	Vocal injection (Restylane®, USA)	5
7	M	55	Spine surgery	Right	16	None	4
8	F	47	After thyroidectomy	Right	12	None	4
9	M	33	idiopathic	Right	13	None	4
10	F	25	After thyroidectomy	Left	12	None	5
11	M	56	Cordectomy	Right	18	None	4

Table 2 Comparison between preoperative and postoperative results of the grade of dysphonia

Grade of dysphonia	Preoperative	1 wk postoperative	3 mo postoperative	6 mo postoperative	χ^2	<i>p</i>
0	0 (0%)	1 (9%)	2(18%)	2 (18%)	23.9	0.004 ^a
1	0 (0%)	5 (45%)	5 (45%)	4 (36%)		
2	2 (18%)	4 (36%)	3 (27%)	4 (36%)		
3	9 (82%)	1 (9%)	1 (09%)	1 (9%)		

^aSignificant difference.

There was satisfactory improvement in the grade of dysphonia after surgery. This was confirmed by the presence of a significant difference between preoperative and all postoperative results of the grade of dysphonia (►Table 2). The improvement in the grade of dysphonia continued throughout the follow-up period as comparison between postoperative results of the grade of dysphonia revealed nonsignificant difference (►Table 3).

It was clear in all postoperative assessment that there was a decrease in the size of glottic gap. This was evident from the highly significant difference between preoperative and postoperative measures of glottic gap size (►Table 4). Comparison between individual groups of the study confirmed the postoperative improvement (►Table 5). This improvement in the size of the glottic gap continued throughout the study period (►Table 6).

MPT was prolonged sufficiently after surgery, and this improvement continued throughout the study period. This was evident from the highly significant difference between preoperative and postoperative measurements (►Table 7) and the nonsignificant difference between postoperative measurements (►Table 8). These results were confirmed by comparison between individual groups (►Table 9).

Assessment of the preoperative acoustic analysis was impossible in all the patients due to the severe change in

voice, which was detected by the software as out of range signals. Immediately after surgery, acoustic signals could be detected and calculated. This means that there was improvement of voice after surgery, and this improvement continued until the end of the study.

The surgery was done under local anesthesia in all patients except one patient (no. 6), who was converted to general anesthesia due to severe irritability. Five patients developed minor postoperative complications: three with wound ecchymosis and two with vocal fold hematoma. All of them recovered within a few days without any intervention. None of the patients developed stridor or shortness of breath necessitating tracheotomy, and there was no implant extrusion in any patient during the study period.

Discussion

The laryngeal framework surgery medialization timeline began in 1915 with Payer and has had many recent important and landmark contributions from Isshiki and others.¹⁹⁻²¹

Relatively small glottic gaps between membranous vocal folds are generally accepted to be more appropriate for injection laryngoplasty, whereas larger glottic gaps with asymptomatic posterior glottic chinks are found to be ideal for medialization thyroplasty.¹⁵ In our study, glottic phonatory gaps ≤ 3 mm were excluded from study. Three of the

Table 3 Comparison between different postoperative results of the grade of dysphonia

1 wk postoperative	3 mo postoperative	6 mo postoperative	X ²	p
1 (9%)	2 (18%)	2 (18%)	0.725	0.99
5 (45%)	5 (45%)	4 (36%)		
4 (36%)	3 (27%)	4 (36%)		
1 (9%)	1 (09%)	1 (9%)		

Table 4 Comparison between preoperative and postoperative results of glottic phonatory gap

	Preoperative	1 wk postoperative	3 mo postoperative	6 mo postoperative	F	p
Size of glottic gap (mm)	4.5 ± 0.7	1.1 ± 0.6	1.5 ± 0.9	1.7 ± 0.8	46.16	<0.001 ^a

Note: Results are mean ± standard deviation. F: one-way analysis of variance.

^aHighly significant difference.

Table 5 Post hoc test for results of comparison between phonatory gap sizes

Comparison	Significant? (p < 0.05?)	t
1. Preoperative–1 wk postoperative	Yes	10.515
2. Preoperative–3 mo postoperative	Yes	9.278
3. Preoperative–6 mo postoperative	Yes	8.660
4. 1 wk postoperative–3 mo postoperative	No	1.237
5. 1 wk postoperative–6 mo postoperative	No	1.856
6. 2.43 mo postoperative–6 mo postoperative	No	0.619

Table 6 Comparison between postoperative results of glottic phonatory gap size

1 wk postoperative	3 mo postoperative	6 mo postoperative	F	p
1.1 ± 0.6	1.5 ± 0.9	1.7 ± 0.8	1.7	0.2

Note: Results are mean ± standard deviation. F: one-way analysis of variance.

Table 7 Comparison between preoperative and postoperative results of acoustic analysis and MPT

Acoustic analysis and MPT	Preoperative	1 wk postoperative	3 mo postoperative	6 mo postoperative	F	p
F0	Out of range	Male: 110 ± 15 Female: 249 ± 23	Male: 112 ± 12 Female: 251 ± 22	Male: 109 ± 19 Female: 247 ± 24	0.105 0.083	0.9 0.9
Jitter (%)	Out of range	0.9 ± 0.5	1.1 ± 0.3	1.2 ± 0.3	1.79	0.18
Shimmer (%)	Out of range	2.5 ± 1.2	2.3 ± 1.4	2.1 ± 1.3	0.25	0.77
F0 tremor	Out of range	0.7 ± 0.5	0.9 ± 0.1	0.9 ± 0.2	1.47	0.25
HNR	Out of range	20 ± 2.4	18 ± 3.1	21 ± 5	1.9	0.17
MPT	7 ± 5	21 ± 7	22 ± 5	20 ± 4	19	<0.001 ^a

Abbreviations: MPT, maximum phonation time; NHR, noise to harmonic ratio.

Note: Results are mean ± standard deviation. F: one-way analysis of variance.

^aHighly significant difference.

Table 8 Comparison between postoperative results of maximum phonation time (MPT)

	1 wk postoperative	3 mo postoperative	6 mo postoperative	F	p
MPT	21 ± 7	22 ± 5	20 ± 4	0.367	0.69

Note: Results are mean ± standard deviation. F: one-way analysis of variance.

Table 9 Post-hoc test for results of comparison between MPT

Comparison	Significant? (p < 0.05?)	t
1. Preoperative–1 wk postoperative	Yes	6.123
2. Preoperative–3 mo postoperative	Yes	6.561
3. Preoperative–6 mo postoperative	Yes	5.686
4. 1 wk postoperative–3 mo postoperative	No	0.437
5. 1 wk postoperative–6 mo postoperative	No	0.437
6. 3 mo postoperative–6 mo postoperative	No	0.875

included patients were previously exposed to vocal fold injection at least 6 months prior to medialization, with poor results. The poor results for injection of those patients are expected to be due to faulty selection of the surgical technique, as they had gap size more than 3 mm. Another reason may be atrophy and scarring of the vocal cord after injection.

Despite the great advantages of Gore-Tex medialization laryngoplasty, some studies reported delayed extrusion of the Gore-Tex prosthesis.^{22,23} In these studies, the inner perichondrium was incised or removed. We did not incise the inner perichondrium, and we did not have any cases of

implant extrusion. The importance of preservation of the inner perichondrium of the thyroid cartilage was also emphasized by other authors.²⁴ They recommend that one should proceed very carefully and cautiously while dissecting the inner perichondrium, otherwise hemorrhage may develop, and in performing hemostasis, the coagulation may damage the delicate structure.

The authors of this work agree with Bihari et al that when performing thyroplasties using the techniques reported by Isshiki et al.¹⁹ overcorrection is recommended.²⁴ After listening to the voice of the patient and obtaining an optimal result, medialization of the vocal cord 1 mm more is

advisable. This is important, because there is always some edema during surgery. If this overcorrection is not done, a small gap will result after the edema is eliminated. This occurred in some of our patients and was clear in the first postoperative assessment (1 week postoperatively). So both grade of dysphonia and size of glottic gap were better, though nonsignificant, than the later assessments. This occurs most probably due to the effect of edema, which was absorbed gradually later on. Although edema is absorbed in the late postoperative evaluations, results were still satisfactory until the end of study. The significant difference between the preoperative and postoperative grade of dysphonia revealed the success of the surgery in improving patients' voice. The highly significant difference between preoperative and postoperative gap size revealed the ability of Gore-Tex medialization in approximating the edges of the glottis and eliminating the gap.

In the current study, preoperative acoustic analysis, which is a more objective tool for assessment of voice, could not be assessed due to the large size of the gap, which led to very severe breathy dysphonia. This type of voice could not be detected by our software, although postoperatively the voice signals could be detected and analyzed easily. The comparison between different postoperative results revealed nonsignificant difference. This was evidence of constant improvement of voice signals until the end of the study.

In preoperative assessment, the mean MPT was 7 seconds, which is very short and reveals a great deficiency in the respiratory support for phonation. This was directly due to the large glottic gap, which permitted escape of large amount of air from the chest and larynx. This was corrected after surgery and was clear in the prolongation of MPT (the mean was 20 seconds at the end of the study). The presence of a highly significant difference between preoperative and postoperative MPT confirmed the improvement of the sphincteric mechanism of the glottis. Although the overall improvement of the voice was evident, we cannot deny heterogeneous results of postoperative assessments. This is a logical finding as the initial sample was also heterogeneous.

Piazza et al used type 1 thyroplasty for correction of major GI after endoscopic cordectomy.²⁵ When compared with Montgomery Thyroplasty Implant System, they found Gore-Tex to be easier and more reliable with a smaller extrusion rate. We had only one patient who had endoscopic laser cordectomy for carcinoma in situ. This patient showed significant improvement in his voice quality after Gore-Tex medialization.

The current study demonstrated that the main advantage of Gore-Tex medialization, in addition to the easiness and safety of the procedure, is the excellent and sustained postoperative voice quality. Other advantages include the biocompatibility and safeness of the material itself that was demonstrated by some reports,^{26,27} in which neither an allergic response nor a foreign material reaction were seen during Gore-Tex use. The material is highly compliant and easy to handle. The porous structure of Gore-Tex permits limited cellular infiltration with minimal capsule formation, allowing the material to be isolated from surrounding tissues

and easily removed to ensure the reversibility of the surgical procedure. Furthermore, the use of Gore-Tex does not preclude an association with other techniques (e.g., fat injection or anterior commissure laryngoplasty).²⁸

Conclusion

Gore-Tex medialization provides reliable, constant results for both subjective and objective voice parameters. It leads to satisfactory restoration of voice. This technique is relatively easy and does not lead to major complications. Further studies with a larger number of patients and more extended periods of follow-up are still needed to prove the exact efficiency of the technique.

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