



Complications of using Gore-Tex in medialization laryngoplasty: case series and literature review

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Abstract

Purpose This study was performed to evaluate the incidence and contributing factors of complications associated with medialization laryngoplasty using Gore-Tex in patients with unilateral vocal fold paralysis.

Methods A retrospective chart review was conducted for all patients who underwent medialization laryngoplasty using Gore-Tex at Tohoku University Hospital between January 2014 and April 2018. A search of series and case reports in PubMed was performed to determine the incidence of complications following medialization laryngoplasty using Gore-Tex.

Results Sixty-eight patient charts were reviewed. Two patients (2.9%) had complications (infection and extrusion into the airway) related to the Gore-Tex implant after surgery. In the 555 medialization laryngoplasty cases reported in both our current data and eight additional articles, there were 11 complications related to the Gore-Tex implant (2.0%). The most common event was extrusion into the lumen, which occurred in six cases (1.1%), followed by persistent inflammation with the granulation formation (0.5%). There were 12 cases of Gore-Tex extrusion (one male, six female, and five of unknown gender). The interval to onset ranged from 1 month to 10 years (median, 49 months).

Conclusions Our findings serve as a reminder that complications can occur with Gore-Tex implants following medialization laryngoplasty in patients with unilateral vocal fold paralysis, even in the long-term. We suggest that the use of excessively large implants in women and occurrence of postoperative hematoma followed by infection are factors that may cause complications. Nevertheless, Gore-Tex has been proven to be a relatively safe and reliable material for medialization laryngoplasty.

Keywords Medialization laryngoplasty · Gore-Tex · Unilateral vocal fold paralysis · Type I thyroplasty · Extrusion · Airway compromise

Introduction

Of the several surgical methods available to treat unilateral vocal fold paralysis (UVFP) in patients presenting with severe breathy voice and aspiration, the most widely used laryngeal framework surgery technique is medialization laryngoplasty (ML). ML is also known as type I thyroplasty, as proposed by Isshiki et al. [1]. This technique originally involved placement of a silicon implant through a window created in the thyroid ala cartilage, which resulted in adjustment of glottic insufficiency caused by UVFP.

ML using placement of a Gore-Tex (GT, expanded polytetrafluoroethylene) implant in patients with UVFP was subsequently described by McCulloch et al. [2]. GT is an inert polymer with a microporous structure and a pore size of 10–30 µm that allows tissue ingrowth and cell attachment. It has been used in vascular, cardiac, and abdominal surgery with minimal complications. During the past decade, GT has had multiple applications in facial plastic and reconstructive surgery. It is proving to be a reliable alloplastic material, as its microstructure allows grafts to adhere sufficiently to the surrounding tissue to prevent migration, but loosely enough to enable removal. As a result, GT products can be extracted easily without causing a permanent deformity in the patient. It is, therefore, also well-accepted for phonosurgery, including framework surgery, due to its biocompatible nature and easy handling.

In the field of laryngoplasty, ML using a GT implant in patients with UVFP, as described by McCulloch et al.

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[2] has become widely used in many countries. A questionnaire study of otolaryngologists in the United States by Young et al. encompassed 29,748 laryngeal framework surgeries, including ML and arytenoid adduction (AA) [3]. Although several different materials were used to produce ML implants, many surgeons in fact recently routinely used GT in ML. A study by Rajkumar et al. [4] reported histological changes in a human laryngectomy specimen previously implanted with GT during ML. The authors found a mild foreign-body giant cell granulomatous reaction with some associated fibrosis. However, there was no significant neutrophil or lymphocyte inflammation. The findings of the above study are consistent with those previously reported in studies using rabbits and porcine models demonstrating host tolerance of the implant with no evidence of granuloma formation, resorption, extrusion, or migration of the implant [5, 6].

While there are numerous reports on the effectiveness of GT in ML, several studies have described postoperative complications associated with the use of GT. However, the number of reported cases was limited and these studies did not focus on the complications themselves. The purpose of this study was to evaluate the rate and contributing factors of complications following ML using GT. We also reviewed other publications focused on the safety and reliability of GT.

Methods

First, we performed a retrospective chart review of all patients who underwent ML using GT at Tohoku University Hospital (Sendai, Japan) between January 2014 and April 2018. We evaluated the following parameters: sex, age, etiology, surgical method, number of surgeries per surgeon, operation time, intraoperative bleeding volume, follow-up period after surgery, emergent tracheostomy, and complications of GT.

ML was performed as reported previously [2, 7], with some modification. The thyroid cartilage was exposed and a window was created at the vocal fold level using a fine-cutting otological burr, scalpel, or chisel. This allowed preservation of the inner perichondrium. The decision to remove or retain the cartilage window was made by each surgeon. GT was fashioned into a single 6- to 7-mm-wide ribbon, passed through the window, and placed into the sub-perichondrial space beneath the window. The volume of GT used was determined using flexible laryngeal fiberoptic and assessment of vocal quality during the operation. Before wound closure, a Penrose drain was placed during ML alone, or a suction drain was placed during ML combined with AA. The patients received intravenous broad-spectrum antibiotics routinely for 3 days in the hospital.

We performed a search of PubMed to determine the incidence of complications following ML using GT. We reviewed studies that included more than ten cases of ML using GT and contained information regarding complications. We also reviewed all reported series and case reports of patients with extrusion complications following ML using GT.

Approval for the study was obtained from the ethical review board of Tohoku University Graduate School of Medicine (#2018-1-185). Because of the retrospective nature of this study, the requirement for informed consent was waived by the review board.

Results

Sixty-eight patient charts were reviewed. In total, our study included 16 cases of ML alone and 52 cases of AA/ML (Table 1). The patients comprised 48 men and 20 women with a median age of 64 years (16–87 years). The most frequent cause of UVFP was cardiovascular disease (25.0%), and the second most frequent causes of UVFP were lung cancer and thyroid disease (19.1%). The median operation time was 113.3 min (65–175 min), the median intraoperative bleeding volume was 2 ml (little bleeding to 22 ml), and the median follow-up period was 19 months (2–53 months). One patient required emergent tracheostomy due to the occurrence of cervical hematoma postoperatively. Two patients (2.9%) had postoperative complications related to the GT implant. The characteristics of these patients are summarized in Table 1. We found no specific factors, including age, sex, etiology, surgeon, operation time and intraoperative blood loss, associated with the occurrence of complications. Nevertheless, case 1 was the only patient who underwent emergent tracheostomy after developing cervical hematoma on postoperative day 1. After discharge, the patient repeatedly developed granulomas at the surgical site on his neck 3 months later. Computed tomography revealed continuous contrast findings from the neck surface to the implant site at the thyroid cartilage (Fig. 1). Discharge from the granuloma contained methicillin-resistant *Staphylococcus epidermidis* and *Pseudomonas aeruginosa*. The patient's symptoms had not improved following administration of antibiotics. He developed laryngeal edema, and the GT implant was removed 6 months after surgery. Another patient who had an uneventful course developed unresolved edematous changes on the affected side of her larynx 1 month after the surgery. She then developed neck swelling. We found that the GT implant had extruded from the ventricle of the larynx 2 months after the surgery (Fig. 2). Removal of the implant through the patient's neck promptly resolved her symptoms. Results of the cultural examination of the implant were negative.

Table 1 Characteristics of the patients who underwent ML, and of two cases with Gore-Tex complications

	Total (n=68)	Case 1	Case 2
Age (median, years)	64 (16–87)	73	34
Sex			
Male	48 (70.6%)	M	F
Female	20 (29.4%)		
Etiology			
Cardiovascular disease	17 (25.0%)	Lung cancer operation	Congenital esophageal stenosis operation in infancy
Lung cancer	13 (19.1%)		
Thyroid disease	13 (19.1%)		
Idiopathic	8 (11.8%)		
Vagal nerve schwannoma	4 (5.9%)		
Esophageal disease	3 (4.4%)		
Others	10 (14.7%)		
Method of surgery			
ML alone	16 (23.5%)	AA/ML	AA/ML
AA/ML	52 (76.5%)		
Number of surgeries per surgeon	A: 15, B: 13, C: 33, D: 2, E: 5	B	A
Operation time (median, minutes)	113.3 (65–175)	100	106
Intraoperative blood loss (median, ml)	2 (little to 22)	Little	2
Follow-up period (median, months)	19 (2–53)		
Tracheostomy after surgery	1 (1.5%)	+	–
Complications associated with Gore-Tex	2 (2.9%)	+	+

AA Arytenoid adduction, ML medial laryngoplasty



Fig. 1 Axial CT in Case 1 showing continuous contrast findings from the neck surface to the GT implant at the level of thyroid cartilage (arrow)

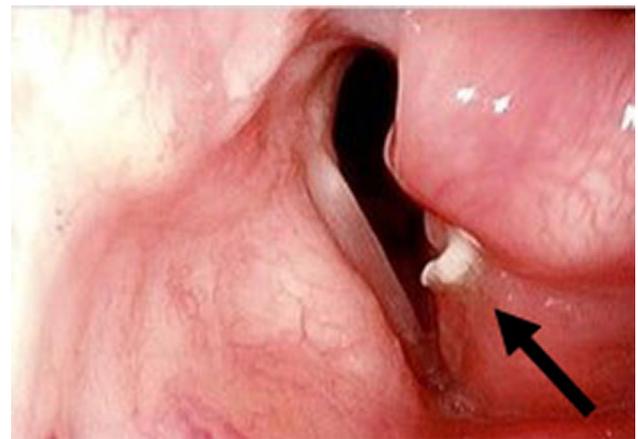


Fig. 2 Laryngoscopy in Case 2 showing extrusion of the GT implant into the left ventricle of the larynx (arrow)

We carried out a search to investigate the rate of complications following ML using GT. We found eight articles matching our criteria (Table 2). The largest case series among these articles comprised 156 cases and was reported by Cohen [8]. We found six reports concerning ML alone, and two reports on both ML and ML/AA. Three of the studies reported no complications associated with GT. Of the

Table 2 Summary of reports including present study regarding complications following ML using Gore-Tex

Author	Year	Total	Sex	Surgery	Inner perichondrium	Complications related to GT	Event
Giovanni	1999	11	M:F=7:4	ML	Preserved	1	Hyperthermia and granulation tissue
McCulloch	2000	62	NA	ML: 40, ML/AA: 22	Incised	0	
Zeitels	2003	152	M:F=81:61	ML: 74, ML/CT: 24, ML/AA: 6, ML/AA/CT: 48	Preserved	1	Recalcitrant mucosal granulation and extrusion
Laccourreye	2003	27	NA	ML	Removed	1	Endolaryngeal extrusion
Nouwen	2004	24	M:F=18:6	ML	Incised	2	One persistent inflammation, one endolaryngeal extrusion
Cohen	2004	156	NA	ML	Incised	4	Two extrusion, two implant displacement
Elnashar	2015	11	M:F=5:6	ML	Preserved	0	
Rosow	2015	44	M:F=17:27	ML	Preserved	0	
Watanabe (current study)	2018	68	M:F=48:20	ML/AA: 52, ML: 16	Preserved	2	One extrusion, one inflammation and granulation
Total		555				11	Six extrusion, three persistent inflammation, two displacement

NA Not addressed, ML medialization laryngoplasty, AA arytenoid adduction, CT cricothyroid subluxation

555 ML cases reported in the eight articles and our cases, 11 had complications associated with GT (2.0%). The most common event was extrusion into the lumen, which occurred in six cases (1.1%). Whether the perichondrium was incised or preserved depended on the judgment of each surgeon. However, there was no significant difference in the incidence of GT extrusion between patients with a preserved perichondrium (2 in 286) and those without a preserved perichondrium (4 in 269) ($p=0.44$, Fisher's exact test). The second most common event was inflammation with granulation

formation, which occurred in three cases (0.5%). In all cases, since the symptom persisted for several months, each GT implant was removed finally. There was no specific description about the causative factors except in our case, where the patient developed postoperative hematoma and required tracheostomy.

We also reviewed 12 cases of extrusion of the GT implant, including our case, reported in series and case reports indexed in PubMed (Table 3). The GT implant extrusions occurred in one man, six women, and five patients

Table 3 Summary of patients who had extrusion of Gore-Tex implant

	Author	Year	Sex	Surgery	Inner perichondrium	Period to onset	Treatment	Voice function after GT implant removal
1	Zeitels	2003	NA	ML	Preserved	NA	Removed	Without substantive vocal deterioration
2	Laccourreye	2003	F	ML	Removal	49 months	Removed	Speech and voice remained altered
3	Nouwen	2004	NA	ML	Incised	Over 1 month	NA	NA
4	Cohen	2004	NA	ML	Incised	NA	Removed	NA
5	Cohen	2004	NA	ML	Incised	NA	Removed	Injection of autologous fat to remedy glottal insufficiency
6	Halum	2005	F	ML	NA	NA	Removed	NA
7	Halum	2005	NA	ML	NA	NA	Removed	NA
8	Feinberg	2010	F	ML	NA	6 years	Removed	All symptoms resolved, remained asymptomatic
9	Chowdhury	2013	M	ML	NA	2 months	Removed	NA
10	Krane	2016	F	ML	Preserved	5 years	Removed	Voice had not changed significantly
11	Morris	2016	F	ML	NA	10 years	Removed	Voice had recovered
12	Watanabe (present study)	2017	F	ML/AA	Preserved	2 months	Removed	MPT and perceptual vocal evaluation revealed slight deterioration

NA Not addressed, ML medialization laryngoplasty, AA arytenoid adduction, MPT maximum phonation time

with unknown gender. All patients with the exception of one underwent ML alone. The interval to onset ranged between 1 month and 10 years (median, 49 months). One case reported by Feinberg [9] had undergone radiotherapy decades earlier. All cases had an uneventful course with no catastrophic damage after removal of the GT implant. In most patients with GT implant extrusion, there were no significant changes in voice function over 5 years after removal of the GT implant.

Discussion

In this study, we evaluated the incidence and contributing factors of complications associated with ML using GT in patients with UVFP.

Previously, Herbst et al. have reviewed five case series including a total of 466 patients in whom GT implants were used in rhinoplasty [10]. There were a total of ten complications (2.1%) in these patients: eight infections and two soft tissue reactions, including one case of an extrusion that developed approximately 18 months after placement. Jin et al. [11] performed a retrospective multicenter study involving 853 patients who had undergone rhinoplasty using GT. The overall complication rate associated with the use of GT was 2.5% (21 cases), among which 18 (2.1%) cases of complication were due to infection. In a report by Conrad et al., 13 (1.9%) of 685 patients undergoing GT implantation during rhinoplasty had biological complications requiring GT implant removal. These complications included seven cases of infection, four cases of soft tissue reaction, and two cases of extrusion [12].

We performed AA combined with ML using GT simultaneously for most patients with UVFP due to the excellent functional improvements reported by some researchers using this technique [13–15]. We used ML alone in patients with limited UVFP and small glottal chinks during phonation.

We calculated the incidence of complications associated with the use of GT in laryngoplasty to be 2.0%, which is comparable to that reported for rhinoplasty. However, one should consider that the majority of extruding implants were moved into the airway. A survey of American otolaryngologists conducted by Rosen in 1998 encompassed 14,621 cases of ML. In these cases, the majority of ML implants that were extruded had moved into the airway (92%, $n=93$) [16]. Once an implant is moved intraluminally, we must treat the patient immediately and cautiously so as to avoid airway compromise or asphyxia. Examination may reveal laryngeal inflammation or granulation tissue, or localized ventricular or subglottic fullness. In other cases, the implant may be visible [17]. Although it is in fact unclear why the implants extrude intraluminally, Cotter et al. have suggested that extrusion occurs in patients who also had violation of the laryngeal

perichondrium and mucosa [18]. In our study, we found no significant difference between patients with and without a preserved perichondrium. Nevertheless, the perichondrium may have been unintentionally damaged to some extent during the operation. Extrusion has also been reported to more likely occur in women than in men as women generally have smaller larynxes [18, 19]. Consistent with the above reports, we found a larger number of GT implant extrusions in women than in men in our study. GT implant extrusions may also be due to the use of an excessive amount of GT for the implant. Although there are only a few reports on the length of the extruded GT implant, one study reported a length of 39.5 cm, while another reported a length of 76 cm required to achieve vocal fold medialization [9, 20]. Large posterior glottis gaps require large GT implants when ML is performed alone to correct glottal insufficiency. In such cases, it is recommended to carry out ML combined with AA, which can result in better closure of the posterior gap by rotating the vocal process to a more physiological position [7, 19, 21]. This would also help avoid the excessive use of GT.

Considering our case with the occurrence of the prolonged inflammation accompanied by the formation of granulation, we conclude that the surgical field contamination after surgery was the principal cause. It is hardly necessary to mention, but postoperative hematoma followed by infection should be meticulously avoided. In contrast, there were no specific descriptions about the postoperative courses for the other two cases presenting the persistent inflammation with granulation; one of these revealed that bacterial culture from the removed GT yielded negative results [22]. In ML using GT, the risk of granulomatous reaction remains unpredictable [22]. We must bear in mind that any patient undergoing ML using GT may develop a foreign-body reaction against GT unexpectedly at late stages, although this complication has a low incidence rate. To reduce the risk of postoperative problems associated with GT, some researchers have proposed the use of other materials or methods. In 1999, Friedrich et al. first introduced a novel titanium implant for ML [23], and Matsushima recently reported performing ML using original easy-adjustable titanium plates [24]. Yumoto et al. have described nerve muscle pedicle flap implantation instead of ML combined with AA [25]. Recently, Chao et al. have developed the fascia lata thyroplasty technique, which utilizes a ribbon of autologous tensor fascia lata harvested at the time of surgery [26].

In 1975, Isshiki originally proposed the technique for ML, also called type I thyroplasty, involving the use of a silicone block [1]. However, in addition to the manual effort for adjusting the appropriate size intraoperatively, several surgeons encountered well-documented drawbacks with ML using a silicon block, such as migration or extrusion into the airway [16, 18, 19, 27]. In 1998, a national survey

in the United States included 1039 surgeons who had performed 12,644 ML and 1977 AA procedures, and 93% of the respondents had performed ML with a silicone block. When reporting the complications for the ML implant, the rate of extrusion into the airway was approximately 0.8%, and approximately 20% of the respondents reported implant movement or migration and suboptimal voice quality [16]. In recent years, ready-made ML implant systems—e.g., Montgomery[®] Thyroplasty Implant System (Boston Medical Products, MA, USA), which is made of Customizable Silastic[®], and VoCoM[®] (GYRUS ACMI, TN, USA), which is made of hydroxyapatite—have been developed to decrease the time involved in customization and to reduce complications. These systems consist of implants of different sizes with their applicators, and the frequency of their use has gradually increased in the United States [3].

When there are complications associated with the use of GT, the implant usually requires removal, either endoscopically or via an external surgical approach. Despite the possibility of airway compromise, removal of the GT implant was accomplished with no damage to laryngeal structures, as reported in our patients. Some of the patients retained adequate glottal closure despite implant extrusion [18, 20, 27]. This may be explained by continuous scarring followed by inflammatory changes [18, 20]. In our patients, voice function was slightly worse after GT implant removal than immediately after surgery, as determined using MPT (maximum phonation time) and perceptual voice evaluation. Voice function after GT implant removal may depend on the interval between the surgery and GT implant removal. Thus, there may not be much deterioration if several years have passed after the surgery.

One major limitation of this study was that the follow-up time was not sufficient based on our patient's charts, and that was also unclear in other studies. As the complications with GT implant can occur in the long-term postoperatively, the inadequate follow-up time could have affected the results. Second limitation was that we could not identify whether the complications with GT implant were caused by infection or foreign-body reaction. Third was that even though the cause of most cases who underwent ML using GT was UVFP in the article cited in Tables 2 and 3, there were some other cases of post-cordectomy, sulcus vocalis, vocal fold atrophy, and etc. or of unknown causes.

Conclusion

Our results provide us with a reminder that complications associated with GT implants may occur following ML in patients with UVFP, even if a long interval has passed after surgery. We believe that it is important to avoid using excessively large GT implant with women having smaller larynxes

and postoperative hemorrhage leading to infection for prevent the occurrence of the GT complications. We should pay close attention to avoid airway compromise. However, there is little concern regarding the deterioration of laryngeal structure or voice function after removing the implant. GT has been proven to be relatively safe and reliable for ML in patients with UVFP. Further studies with larger number of cases and extended periods of follow-up are expected to reveal the exact rate of complications of using GT implants in ML.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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