

# Acoustic Outcomes Comparison Injection Versus Medialization Laryngoplasty

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**Objectives:** To determine whether injection laryngoplasty or medialization thyroplasty is more effective in the treatment of unilateral vocal fold paralysis. **Methods:** A prospective study of 75 patients with unilateral vocal cord paralysis who underwent autologous fat injection laryngoplasty or medialization laryngoplasty at the First Central Hospital of Mongolia between 15<sup>th</sup> Nov 2016 and 15<sup>th</sup> Jan 2020. The data analyzed included patient characteristics and type of intervention, along with the before treatment, 1 and 6 months after treatment voice parameters of electroglottography and patients' subjective voice assessment. **Results:** Seventy-five patients were evaluated. The average time from intervention to post-treatment evaluation was 1 and 6 months. Improvements were demonstrated in all voice parameters (Maximum Phonation Time, Jitter, Shimmer, and Harmonic Noise Ratio) in both the injection and the medialization groups. **Conclusions:** In this study, objective and subjective voice analysis confirmed that injection and medialization laryngoplasty were effective in unilateral vocal cord paralysis. Both of these methods can be used to treat unilateral vocal cord paralysis.

**Keyword:** Unilateral Vocal Cord Paralysis, Injection Laryngoplasty, Medialization Thyroplasty

## Introduction

The larynx provides the main tool for human social interaction. The vocal folds are innervated by the recurrent laryngeal nerve (RLN) and when this nerve supply to one vocal fold is interrupted, unilateral vocal cord paralysis (UVCP) ensues [1]. UVCP is an increasingly common and debilitating neurological condition caused by injury to one recurrent laryngeal nerve. Surgical injury is the most common cause of UVCP. Increased prevalence of

head, neck, spine and cardiothoracic surgeries has increased the population at risk for UVCP; these procedures account for 50% of UVFP cases [2,3]. Specifically, UVCP complicates up to 15% [4] and 11% [5] of thyroidectomies and anterior spine procedures, respectively. In recent decades, these procedures have increased threefold and eightfold [6], with a corresponding rise in UVCP incidence [7]. The incidence of vocal fold paralysis caused by thyroid surgery is reported to be 1.5% to 5.3%, among whom 15% to 17% of cases will have permanent vocal fold palsy [8].

UVCP causes glottic insufficiency, resulting in a breathy voice, voice fatigue, and aspiration further limiting the patient's quality of life [9]. Proper glottal closure protects the airway from aspiration of respiratory secretions or food materials. Also, it provides an adequately high expiratory flow to remove aspirated material from the airway. Therefore, irrespective of the etiology, glottal incompetence may predispose patients to weak tussive reflex, thus leading to weakened cough and increased risk of aspiration. In stroke patients, who are vulnerable to aspiration pneumonia, glottic insufficiency may lead to catastrophic respiratory consequences [10].

In 2016-2019, 26.5% of the clients who visited the Voice center of the First Central Hospital of Mongolia had vocal cord paralysis, and 172 cases were diagnosed per year, of which 162 had unilateral vocal cord paralysis [11].

The aim of treatment for UVFP is, firstly, to decrease aspiration, and secondly, to improve voice quality. One treatment paradigm is medialization of the paralyzed vocal cord to allow for contact with the mobile vocal fold. Two options for medialization include Type 1 medialization thyroplasty (MT) and injection laryngoplasty (IL). MT, as described by Isshiki et al., is considered the gold standard treatment and involves permanent medialization of the vocal fold with an alloplastic stent in the paraglottic space [12]. Isshiki type I thyroplasty with nonresorbable biomaterials such as silicone, Gore-Tex, hydroxylapatite, titanium, and expanded polytetrafluoroethylene has also been performed in the past few decades [13]. On the other hand, injection laryngoplasty was introduced in 1911 by Brunings [14] Arnold who introduced Teflon injection in 1962, and it remained the standard treatment for vocal cord paralysis for approximately 30 years [15].

The original materials used in injection augmentation, such as paraffin, silicone and Teflon, caused foreign body reactions [16] and safer materials have since replaced them. Injectable materials are currently categorized as temporary or long-term. The temporary materials available are collagen-based, hyaluronic acid based, and carboxymethyl cellulose based. The long-term materials available are calcium hydroxyapatite and autologous fat [1, 15-18].

The diagnosis of vocal cord paralysis is improving in our country, but there is still a lack of effective treatment. Therefore, in this study, we aimed to determine whether fat injection laryngoplasty or medialization thyroplasty is more effective in

the treatment of unilateral vocal fold paralysis, and compared the acoustic results.

## Materials and Methods

### Subjects

This is a prospective study on 75 patients (21 males, 54 female) aged 20-75 years, diagnosed with vocal cord paralysis from 15<sup>th</sup> Nov 2016 to 15<sup>th</sup> Jan 2020 at the First Central Hospital of Mongolia. All the patients were considered to have permanent paralysis. The patients underwent surgical rehabilitation by injection laryngoplasty (IL) (n=39) or medialization thyroplasty (MT) (n=36). Acoustic parameters were studied before, after 1 and 6 months' post-surgery.

Inclusion criteria for UVCP were breathy voice dysphonia and aspiration without structural involvement of the larynx by tumors, lack of vertical displacement of the paralyzed vocal cord, and no contraindication for general anesthesia for any reason.

### Objective voice analysis

The speech recordings were made in a quiet room. Before, after 1 and 6 months from surgery, patients were examined by objective voice analysis. The maximum phonation time, Jitter, Shimmer and Harmonic Noise Ratio were measured with WEVOSYS Ling WAVES EGG (Germany). Acoustic parameters were analyzed with Software Praat.

### Subjective voice assessments

Voice-related quality of life was measured using the validated VHI-10. Participants self-administered the questionnaires at baseline, 1 and 6 months, and sound was assessed on a 120-point VHI with a special questionnaire that determined the degree of sound change.

### Surgical technique autologous fat injection

The 39 patients underwent surgical rehabilitation by autologous fat injection laryngoplasty. Acoustic parameters were studied before, 1 and 6 months after surgery.

The surgery was performed in the operation room of the hospital. Autologous fat harvesting and injection procedures were performed under general anesthesia. Twenty mL of 1:100000 adrenalin in normal saline solution was injected under the

skin of the lower abdomen. Abdominal fat was harvested via a 3 mm incision and a 20-gauge liposuction needle connected to a 20-mL disposable syringe. The extracted fat was centrifuged at 3,000 rpm for 3 minutes.

The harvested fat was loaded into a 5 mL guarded 18-19 gauge needle via trans-cutaneous thyrohyoid approach (by Milan Amin's method) to inject the prepared fat in the middle 1/3 the vocal cords. We use a Hollinger anterior commissure laryngoscope and fibro-laryngoscopy with monitor. Approximately 0.5-2.5 mL (mean 1.5) of fat was injected into the paraglottic space of the paralyzed vocal cord. The vocal cord was augmented to achieve a 30% to 50% bulge across the midline. Patients were discharged 4 to 5 days after surgery. Objective and subjective voice analysis were repeated 1 and 6 months after treatment.

### **Surgical technique of thyroplasty**

Medialization thyroplasty was performed on 36 patients in the operating room by local anesthesia. In all cases, a custom-carved Netterville Phonofom silicone Block (Medtronic, Inc., Jacksonville, FL) was utilized for vocal fold medialization, and techniques used were similar to those described by Isshiki et al. and Netterville et al [19-21]. For the local anesthesia, 10 mL of saline with 2% lidocaine and 1: 100000 adrenalin were injected into the subcutaneous tissue of the periodical opening of the thyroid cartilage. Wedge-shaped silastic blocks were made of various sizes preoperatively. In women, the average block measured 3 mm wide by 6 mm tall by 2 mm deep anteriorly and 3-5 mm deep posteriorly. In men the average block was 4 mm wide by 8 mm tall by 2-3 mm deep posteriorly. The thickness of the block was around 2 to 2.5 mm. The size of the window in men was measured 7 mm by 3 mm and in women 9 mm by 4 mm. After the window was created, the mobile segment was displaced (depressed) medially. The prefabricated silicone block was inserted through the window to medialize the vocal fold and adjusted to get the optimal voice by making the patient to phonate. Postoperatively, the patient was managed with oral antibiotic and analgesics.

### **Comparison of vocal outcomes**

Acoustic parameters were compared before and after surgery within each group, and then a direct comparison of each parameter was made between groups. For the intergroup comparison, subtraction of the pre-operative value from the post-

operative value was performed, and the difference was used for the comparison as representing the degree of improvement.

### **Statistical analysis**

For categorical data in Table 1, the likelihood Chi square and Fisher's exact tests were used to test the hypothesis. For continuous data, we utilized paired t-test to compare the improvement in means before and after procedures for both surgical methods in Table 2. We carried out unpaired t-test to test the mean values between injection and medialization laryngoplasty groups in Table 3. The statistical analysis was performed using SPSS-25 software.

### **Ethical statement**

The study was approved by the Research Ethics Committee of the Mongolian National University of Medical Sciences) (No 2019/3-08). All patients provided written informed consent before participating in the study.

## **Results**

Seventy-five patients (21 male and 54 female) aged 20-75 years with unilateral vocal cord paralysis underwent preoperative acoustic measurements and postoperative measurements. The average time from intervention to post-treatment evaluation was 1 to 6 months range. There was 49 (65%) left, and 26 (35%) right vocal cord paralysis. The preoperative complaints of patients were UVCP, breathy voice dysphonia 75 (100%), aspiration of fluids (63%), aspiration of solid foods (13.7%).

All participants had hoarseness, the longest lasting 36 years. Fifty-four (72%) were female and twenty-one (28%) were male. Their ages ranged from 20 to 75 years, with a mean of  $47.5 \pm 12.3$  in injection group, while the mean age in the medialization group was  $56.3 \pm 10.0$ , respectively. Left vocal cord paralysis was forty-nine (65%), and right was twenty-six (35%). Surgery was 61.3% of all causes (Table 1).

Electroglottography before, after 1 and 6 months post surgery was performed to assess the MFT, vocal cord fluctuations by jitter, shimmer, and harmonic-noise ratio. The two treatment groups were compared using the above parameters. It is likely that electroglottography improved after injection and medialization laryngoplasty ( $p < 0.05$ ). Postoperative evaluation

**Table 1.** Patient characteristics of injection and medicalization groups

Variables	Overall (n=75)	Injection (n= 39 )	Medialization (n= 36)	P-value
	Mean ± SD	Mean ± SD	Mean ± SD	
Age (years)	51.7 ± 12.0	47.5 ± 12.3	56.3 ± 10.0	0.000
	N (%)	N (%)	N (%)	
Gender				
Male	21(28)	11 (28.2)	10 (27.8)	0.584
Female	54 (72)	28 (71.8)	26 (72.2)	
Paralyzed side				
Left	49 (65)	28 (71.8)	21 (58.3)	0.326
Right	26 (35)	11 (28.2)	15 (41.7)	
Cause of paralysis				
Surgery				
Yes	46 (61.3)	22 (56.4)	24 (66.7)	0.500
No	29 (38.7)	17 (43.6)	12 (33.3)	
Idiopathic				
Yes	15 (20.0)	7 (17.9)	8 (22.2)	0.862
No	60 (80.0)	32 (82.1)	28 (77.8)	
Neoplasm				
Yes	6 (0.1)	4 (10.3)	2 (5.6)	0.675*
No	69 (99.9)	35 (89.7)	34 (94.4)	
Trauma				
Yes	5 (6.7)	3 (7.7)	2 (5.6)	0.999*
No	70 (93.3)	36 (92.3)	34 (94.4)	
Stroke				
Yes	4 (5.4)	2 (5.1)	2 (5.6)	0.999*
No	71 (94.6)	37 (94.9)	34 (94.4)	
Lung tuberculosis				
Yes	4 (5.4)	2 (5.1)	2 (5.6)	0.999*
No	71 (94.6)	37 (94.9)	34 (94.4)	

\* Fisher’s Exact Test p-value

was after 1 and 6 months from surgery. Patients were rated on the voice handicap index. In both treatment groups, the preoperative objective acoustic assessments and voice handicap index improved after surgery ( $p < 0.05$ ) (Table 2).

Table 3 shows comparison result injection and medialization

groups. The intergroup comparisons showed no significant differences in the degree of improvement of the MFT, shimmer, HNR and VHI ( $p > 0.05$ ,  $p > 0.10$ ). Only jitter value was significantly better in medialization group than in the injection group ( $p < 0.05$ ).

**Table 2.** Voice parameters before and after surgery between injection and medialization groups

	Injection (n = 39)		P-value	Medialization (n = 36)		P-value
	Pre-operation	Post-operation		Pre-operation	Post-operation	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
MFT(s)	6.93 ± 2.42	10.75 ± 2.32	0.001	7.32 ± 3.14	11.21 ± 3.75	0.000
Jitter	5.70 ± 1.26	0.98 ± 0.26	0.001	11.30 ± 4.08	1.44 ± 0.66	0.000
Shimmer	12.22 ± 3.85	5.00 ± 1.21	0.000	14.15 ± 3.96	6.17 ± 3.09	0.000
HNR	0.59 ± 0.34	0.34 ± 0.35	0.014	0.69 ± 0.27	0.42 ± 0.29	0.004
VHI	92.16 ± 20.7	24.2 ± 6.9	0.003	94.48 ± 13.1	22.1 ± 7.1	0.000

Note: MFT = Maximum Fonation Time; HNR=Harmonic-to-Noise Ratio; VHI = Voice Handicap Index

**Table 3.** Statistical comparison between injection and medialization groups

	<b>Injection (n=39)</b>	<b>Medialization (n=36)</b>	<b>P-value</b>
	Mean ± SD	Mean ± SD	
MFT(s)	3.82 ± 1.4	3.89 ± 3.2	0.100
Jitter	4.72 ± 0.26	9.86 ± 0.79	0.017
Shimmer	7.62 ± 0.47	7.98 ± 1.89	0.050
HNR	0.25 ± 0.07	0.27 ± 0.01	0.100
VHI	67.96 ± 2.44	72.38 ± 3.55	0.050

Note: MFT = Maximum Phonation Time; HNR=Harmonic-to-Noise Ratio; VHI = Voice Handicap Index

## Discussion

Patients with UVCP may report breathy voice dysphonia, aspiration, or ineffective cough [18]. In a relatively short period of time, our study involved a larger number of people. This is due to the lack of effective treatment for vocal cord paralysis in our country. Symptoms of UVCP of the vocal cords lasted the longest, 36 years.

There were no complications of laryngeal surgery, and the patient underwent postoperative follow-up. However, two patients did not return for their second appointment, 6 months after surgery. After the IL, two patients underwent general anesthesia. When waking up after general anesthesia, stridor of breathing occurred for 3-5 minutes. There was one case of cervical skin ulcer inflammation after MT, which was treated and healed at that time.

In this study, the results of vocal cord IL and MT were improved before surgery. However, the results of the two treatments differed slightly from each other, and were similar to the results of IL and MT by Melissa Mortensen and Atsushi Suehiro [13, 22].

Literature on both MT and IL has reported the vocal outcomes using different materials, but only a few articles have attempted to compare IL and MT. Lundy et al [23] compared IL using micronized acellular dermis vs MT at 1-month follow-up. Their analysis revealed comparable outcomes between these 2 treatment modalities. Morgan et al [24] analyzed vocal outcome in both IL with either CaHA or micronized acellular dermis and then compared these to the vocal improvement achieved from MT with or without arytenoid adduction. They showed that IL and MT were comparable in their improvement of subjective and objective voice outcomes.

The maximum phonation duration increased from 6.93 and

7.32 seconds preoperatively to 10.75 and 11.21 seconds; jitter from 5.70 and 11.30 to 0.98 and 1.44, and shimmer 12.22 and 14.15 to 5.00 and 6.17 in injection and medialization group postoperatively. This observed value was consistent with previous studies [13, 25- 28].

In patients with vocal fold paralysis, an improvement of 4 points on the VHI-10 scale has been suggested to be the minimal clinically important difference that results in a perceivable voice change [29]. Misono et al. also reported on patients with a variety of vocal fold disorders and found that the minimal important difference on the VHI-10 scale was 6 points. In the fat-injection group, only half of the patients who were improved at their final visit did so by at least 4 points on the VHI-10 scale. Of the improved patients in the ML group, nearly 90% improved their VHI-10 scores by at least 4 points [30]. VHI improved from 92.16 and 94.48 to 24.2 and 22.1 in injection and medialization group in our study, which indicates good score. Even at the point of lowest/best VHI-10 score, the patients in the MT group still reported better voice [31].

It was noteworthy that in the postoperative VHI of this study, participants were significantly improved compared to the results of the two treatments in the subjective voice assessment of Vinson et al and Dominguez et al [29, 32].

A weakness of this study is that all the surgical procedures were performed by different surgeons according to his or her capability, thus could not eliminate the effects on surgical outcome of the study. However, participated surgeons had been trained for achieving the mastery in each surgery techniques, hence the surgical level was thought to be the best in the current institution.

According to the reports which are based on the high degree of patient satisfaction, both techniques were suggested to be beneficial. As might be expected, both techniques have

advantages and disadvantages, such as the length of the procedure, anesthesia type, surgeon's training and experience as well as providing materials. Further study is required in order to solve the issues, in particular regarding to the relatively low cost of surgery and more available implant materials.

Our study found that young patients with mild dysphonia were more likely to receive injections, while older patients with severe dysphonia were more likely to receive medialization. However, vocal cord injections are performed under general anesthesia and cannot be corrected. While the MT takes over an hour, the injection can be done in 50 minutes. The young patients in our study chose injections because they did not want to leave small scars on their necks. On the other hand, older people preferred long-lasting or permanent sound improvement. It was important to consider the patient's job, occupation, the risk of general anesthesia, and their requests when proposing options for vocal cord injections and implant surgery. In the future, the research team believes that the participants should be re-examined after 12, 24 and 36 months to study the changes in sound over time.

### Conclusions

In this study, objective and subjective voice analysis confirmed that injection and medialization laryngoplasty were effective in unilateral vocal cord paralysis. Both of these methods can be used to treat unilateral vocal cord paralysis.

### Conflict of Interest

The authors state no conflict of interest.

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