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Original Article

Voice Outcomes of Autologous Fat Injection Laryngoplasty for Unilateral Vocal Fold Paralysis

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Abstract:

Background: *Autologous fat injection laryngoplasty is a surgical procedure for unilateral vocal fold paralysis (UVFP) to medialize the nonfunctioning vocal fold to allow for complete glottic closure and, thus, improve phonation, protect the airway and improve symptoms of aspiration and dysphagia.*

Objective: *This study compares the pre-and postoperative voice outcomes of autologous fat injection laryngoplasty in patients with UVFP.*

Materials and Methods: *A prospective observational study was conducted in the Department of Otolaryngology-Head & Neck Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka, from January 2021 to June 2022, with 20 patients having UVFP. The subjects were selected based on inclusion and exclusion criteria. Diagnosis of UVFP was identified by indirect laryngoscopy (IL) and confirmed by Fiber Optic Laryngoscopy (FOL). Patients were investigated by Voice Handicap Index (VHI) scores at four-time points: (1) Day before operation (T0), (2) 3 days post injection (T1), (3) 1 month post injection (T2), and (4) 3 months post injection (T3). All*

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the VHI information was recorded in a prefixed questionnaire to analyze and calculate the results.

***Results: T**he age of the patients ranged from 19-55 years, with a mean age of 38.8±9.93 years. Among them, 13 were female (65%), and 7 were male (35%). Male: Female ratio was 1:1.8. Most patients (55%) had thyroid surgery, and the rest were idiopathic (45%). 75% of the vocal cord are paralyzed on the left side and 25% on the right-sided. The VHI scores improved significantly from 75.85±13.04 preoperatively to 58.70±12.38 at 3 days postoperatively (P < 0.0001); 47.50±9.51 at 1 month postoperatively (P < 0.0001), and 37.35±8.50 at 3 months postoperatively (P < 0.0001).*

***Conclusion:** Autologous fat injection laryngoplasty is a simple, safe, and cost-effective temporary phonosurgical procedure for the treatment of unilateral vocal fold paralysis, thus improving acoustic and voice-related quality of life (QOL).*

***Keywords:** injection laryngoplasty; unilateral vocal fold paralysis; autologous fat; Voice Handicap Index (VHI)*

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Introduction:

Unilateral vocal fold paralysis (UVFP) is a disorder affecting muscles of the larynx or voice box commonly seen in otolaryngological practice. The Larynx or voice box is essential for normal phonation and airway protection. When we speak, air from the lungs is pushed between the two vocal cords with sufficient pressure to cause them to vibrate, producing a voice. Protection of the lower airway is another essential function of the larynx in different ways, like sphincteric closure of the laryngeal opening, cessation of breathing, and cough reflex. All intrinsic laryngeal muscles, except the cricothyroid, are innervated by the recurrent laryngeal nerve (RLN), and the cricothyroid is supplied by the superior laryngeal nerve (SLN). Unilateral RLN injury produces fixed hemilarynx with decreased tension, mobility, and volume of the vocal folds, resulting in incomplete closure of the vocal folds, which is defined as UVFP, often leading to glottic incompetence and tending respiratory dysphonia, choking and aspiration.[1]

Recurrent laryngeal nerve palsy can be due to various causes, including a spectrum of temporary partial neurapraxia to complete nerve disruption. The leading etiological causes of UVFP are iatrogenic (41.66%): especially after thyroid surgery, neck surgery, anterior approach for cervical spine surgery, cardiothoracic surgery; idiopathic (33.33%): probably post-viral and other defined causes (25%): central or systemic neurological cause, glomus vagale/jugulare, blunt trauma, mediastinal/pulmonary neoplasm, neuroma/ vagus neurofibroma, cystic hygroma. The management of glottic insufficiency in UVFP is guided by concerns regarding morbidity from dysphagia and aspiration, the patient's own perception of the severity of the vocal handicap, and expectations about the eventual outcome without treatment. Patients with hemilaryngeal paralysis, especially of short duration, may simply be observed. Voice therapy may be used as needed during this observation period but there is no convincing evidence that voice therapy affects the course and symptoms of vocal fold paralysis. The main surgical interventions for correction of UVFP are vocal fold augmentation by injection

laryngoplasty, laryngeal structure surgery (thyroplasty, arytenoid adduction) and laryngeal nerve re-innervation.[2]

Injection laryngoplasty, one of the surgical options used in treating this disorder, aims to medialize the non-functioning vocal fold to allow complete glottis closure, correct glottic incompetence, and thus improve phonation, protect the airways and minimize the symptom of aspiration. Several materials can be used to correct glottis incompetence to increase the volume of the vocal folds. However, most of them, such as Teflon and silicone, can cause a foreign body reaction, and even biomaterials, such as collagen, can cause a reaction like delayed hypersensitivity and vocal fold rigidity due to fibrosis. Autologous fat and calcium hydroxylapatite (CaHA) are frequently used to obtain short-term and long-term results; however, autologous fat is available worldwide and rarely induces rejection reactions.[3]

Injection laryngoplasty is the oldest method of surgical treatment of UVFP. Brnings described this technique in 1911 using paraffin as an injection material. Several materials have been used in the vocal fold and paraglottic space to improve glottis efficiency by repositioning the vocal fold and increasing volume. Teflon became the preferred material for this surgery by the mid-century. Clinical experience and reports of complications with Teflon have led to the investigation of alternative injection materials. In 1978, Schramm described the injection of Gelfoam paste that he hoped would be completely absorbed and was used to treat these symptoms for only a short period[4]. Fat injection laryngoplasty was introduced by Brandenburg in 1987 as an alternative to Teflon with the hope that it would provide long-term voice results without the potential side effects associated with Teflon injection [5]. Mikaelian and associates, in 1991, were the first authors to describe the intralaryngeal injection of autologous fat. The main advantages of autologous fat are its immunological tolerance, availability, and comfort of use.[6]

The feasibility of using autologous fat injection laryngoplasty in the treatment of UVFP has been reported in several articles showed improvement in the quality of voice by autologous fat injection laryngoplasty in treatment of UVFP by using different tools like Grade of Hoarseness, Roughness, Breathiness, Asthenia and Strain (GRBAS) ratings, Maximum Phonation Time (MPT), Jitter (%), Shimmer (dB) and Voice Handicap Index (VHI).[7-11] Pagano et al. (2016) used videolaryngostroboscopy and VHI to assess the pre-and postoperative treatment outcome at three different times.[12] They found a significant improvement in the quality of voice. Jacobson et al. (1997) saw the relationship between the VHI score to voice disorder severity.[13] Voice Handicap Index is the key tool in assessing the impact of a voice disorder on patients' quality of life and evaluating the outcome of the treatment.

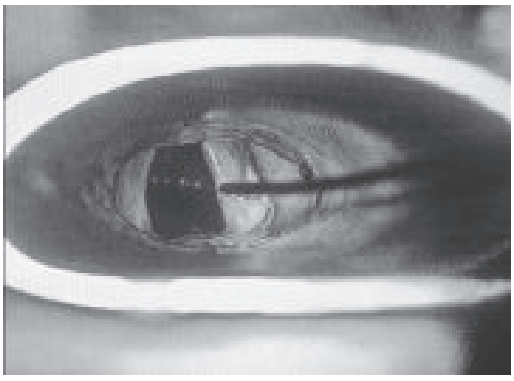
Materials and Methods:

This prospective observational study was performed in the Department of Otolaryngology-Head & neck surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka, from January 2021 to June 2022.

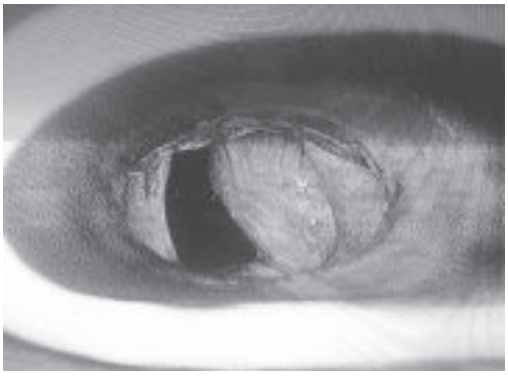
After obtaining clearance and approval from the Institutional Review Board (IRB), Bangabandhu Sheikh Mujib Medical University (BSMMU), all patients of UVFP in the Department of Otolaryngology-Head & Neck Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), who fulfilled the inclusion and exclusion criteria were recruited as subjects in the study. All patients were

assessed by history, clinical examinations, and related investigations before injecting autologous fat. Thorough ear, nose, throat, and head-neck examinations and related systemic examinations were done. If clinically indicated, radiological exclusion of lesions of the brain, skull base, neck, and mediastinum was obtained. Diagnosis of UVFP was identified by indirect laryngoscopy (IL) and confirmed by Fiber Optic Laryngoscopy (FOL). Informed written consent was taken from all patients.

This surgical procedure was done under general anaesthesia. Injection laryngoplasty was performed by using a suspension microscope. The patient was in a supine position, with the neck slightly bent to the trunk and the head hyperextended to the neck. After complete relaxation of the cervical and laryngeal muscles, the Kleinsasser laryngoscope was inserted. During the procedure, visibility was improved by pressing one hand on the laryngeal cartilage. After infiltration with lidocaine and epinephrine (1:100000), autologous fat was harvested from the patient's infra-umbilical region under strictly sterile conditions, and the fat lobules were separated from the surrounding connective tissue, cut into 1–2 mm pieces, and rinsed in saline. Fat was pulverized into micro molecules by interchanging both the 5cc syringes containing fat connected through a tri-channel connector at least 50 times. Then the pulverized fat-containing syringe was connected through Brüning laryngeal needle. Total fats of 0.7 to 1.6 cc were injected into the paralyzed vocalis muscle about 4 mm outside the anterior end of the vocal process in the musculoligamentous area at multiple sites, usually 1 to 4 sites, using an operating microscope at a focal length of 400 mm. The ideal injection depth was around 2-3 mm. The injection was continued until inflation of the paralyzed vocal fold exceeded the midline to ensure the convexity of the whole vocal fold.



Fat was injected into paralyzed vocal fold through Brüning laryngeal needle



Medialized vocal fold after autologous fat injection

During fat injection, the needle was gradually retracted to allow the fat to diffuse into different layers of the paralyzed vocal fold.[3,12,14] Injection ceftriaxone 1 gm was given on the day of surgery, oral cefixime 400 mg twice daily for the next six days, prednisolone (30 mg) for three days, and a cough-relieving agent for seven days were given. Voice rest for 48 hours was recommended.

Patients were assessed by recording their VHI scores at four-time points: (1) Day before operation (T0), (2) 3 days post injection (T1),

(3) 1 month post injection (T2) and (4) 3 months post injection (T3).

Voice Handicap Index is the most popular and widely used instrument for evaluating voice disorders. It is divided into functional (F), physical (P) and emotional (E) subscales. The questionnaire consists of 30 questions (each subscale has ten questions). The Answers are rated on a five-point scale "0 = never", "1 = almost never,""2 = sometimes,""3 =almost always", and "4 = always" each of the parts has a maximum score of 40 points that corresponds to the serious pathological situation and a total score ranging from 0 to 120 was generated. After summating three subscales (functional, physical, and emotional), we can get the total VHI score. The score between 0-30, 31-60, and 61-120 is regarded as mild, moderate, and severe disease, respectively.[13]

To evaluate the functional (F), physical (P) and emotional (E) subscales of the VHI, the prefixed questionnaire was provided to the patient. In addition, the researcher was also providing a Likert scale to the patients to assess the voice outcome in three domains at different time points. Moreover, three separate questionnaires were designed for the functional (F), physical (P) and emotional (E) status of voice to assess individually. The scores obtained from each questionnaire was used as VHI. This VHI represents the functional (F), physical (P) and emotional (E) status of voice outcome.

The analysis of different variables was done according to standard statistical analysis. Data were expressed as mean and standard deviation. For statistical analysis, a Paired t-test and Chi-squared test were done. The data were calculated in an excel spreadsheet and then exported to SPSS 26.0 (Statistical Package for the Social Sciences) for analysis. A P-value less than 0.05 was considered statistically significant.

Results:

The purpose of the study was to assess the voice outcomes before and after autologous fat injection laryngoplasty in UVFP patients. The findings of the study are presented in different Tables and Figures below-

Table-I

Age distribution of the study patients (n=20)

Age group (years)	Frequency	Percentage
<30	4	20.0
30-40	5	25.0
40-50	8	40.0
>50	3	15.0
Total	20	100.0

Mean±SDRange (min-max)
38.8±9.93(19-55) years

Table I shows the age distribution of the study patients. The mean±SD age among 20 patients with UVCP was 38.8±9.93 years (age range: 19-55 years). Maximum (40.0%) patients aged 40-50 years, followed by 25% of patients aged 30-40 years and 20% below 30 years.

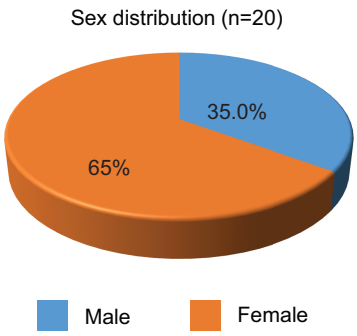


Figure-1: *Pie diagram showing the sex distribution of the study patients*

Figure 1 shows the sex distribution of the patients, 13 were female (65%), and 7 wer male (35.0%). Male: female ratio 1:1.8.

Table-II

Distribution of the study patients by presenting complaints (n=20)

Presenting complaints	Frequency	Percentag
Hoarseness of voice	20	100.0
Phonatory dyspnea	09	45.0
Choking/aspiration	04	20.0
Dysphagia	01	5.0

Table II shows the presenting complaints of UVFP patients, 100% of patients had hoarseness of voice, 45% of patients had phonatory dyspnea, 20% of patients had choking/aspiration, and 5% of patients had dysphagia.

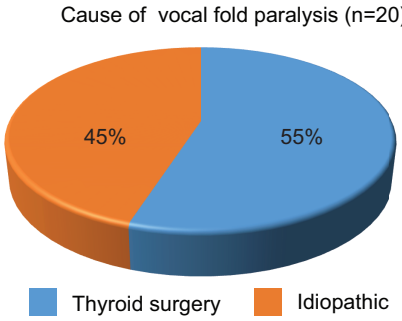


Figure-2: *Pie diagram showing the etiology of vocal fold paralysis*

Figure 2 shows that most patients (55%) had thyroid surgery, and the rest were idiopathic (45%).

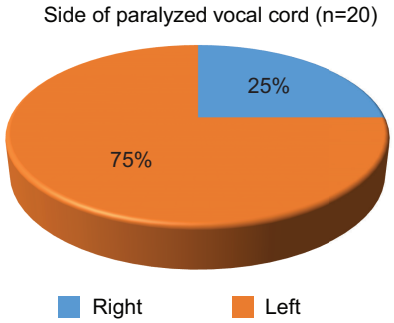


Figure-3: *Pie diagram showing involved paralyzed side of vocal cord*

Figure 3 shows the maximum number of patients (75.0%) with vocal cord paralyzed on the left side and 25% on the right side.

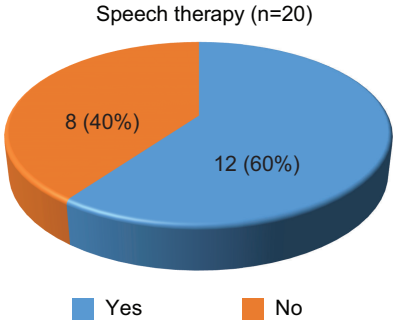


Figure-4: *Pie diagram showing the distribution of patients by speech therapy*

Figure IV shows that 12 (60%) patients were receiving speech therapy, and 8 (40%) patients not received speech therapy.

Table-III

Comparison of preoperative and postoperative 3 days VHI scores (n=20)

Variables	Preoperative Mean±SD (n=20)	Postoperative 3 days Mean±SD (n=20)	Mean changes	p-value
Functional	25.50±5.05	20.00±5.37	5.50±1.88	<0.0001*
Physical	28.40±5.17	22.10±4.55	6.30±2.74	<0.0001*
Emotional	21.95±5.51	16.60±5.36	5.35±2.52	<0.0001*
VHI score	75.85±13.04	58.70±12.38	17.2±4.48	<0.0001*

P-value obtained by Paired t-test, *significant

Table III compares the preoperative and postoperative 3 days VHI results. Surgery led to a significant improvement in total and subscale scores (P <0.0001).

Table-IV

Comparison of preoperative and postoperative 1 month VHI scores (n=20)

Variables	Preoperative Mean±SD(n=20)	Postoperative 1 month Mean±SD(n=20)	Mean changes	p-value
Functional	25.50±5.05	16.30±4.24	9.20±10.55	<0.0001*
Physical	28.40±5.17	17.85±4.23	10.55±3.42	<0.0001*
Emotional	21.95±5.51	13.35±4.07	8.60±2.52	<0.0001*
VHI score	75.85±13.04	47.50±9.51	28.35±6.62	<0.0001*

P-value obtained by Paired t-test, *significant

Table IV compares the preoperative and postoperative 1 month VHI results. Surgery led to a significant improvement in total and subscale scores (P <0.0001).

Table-V

Comparison of preoperative and postoperative 3 months VHI scores (n=20)

Variables	Preoperative Mean±SD(n=20)	Postoperative 3 months Mean±SD(n=20)	Mean changes	p-value
Functional	25.50±5.05	12.45±3.97	13.05±4.36	<0.0001*
Physical	28.40±5.17	15.05±3.94	13.35±5.91	<0.0001*
Emotional	21.95±5.51	9.85±3.59	12.10±3.97	<0.0001*
VHI score	75.85±13.04	37.35±8.50	38.50±11.62	<0.0001*

P-value obtained by Paired t-test, *significant

Table V compares the preoperative and postoperative 3 months VHI results. Surgery led to a significant improvement in total and subscale scores (P <0.0001).

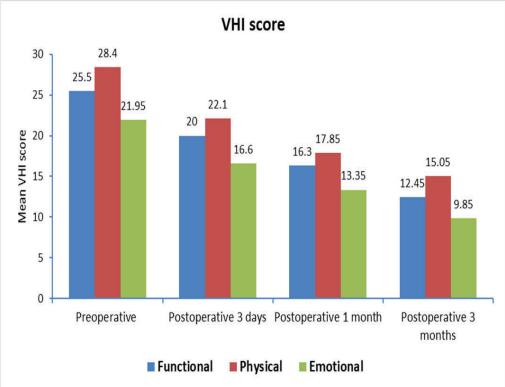


Figure-5: *Bar diagram showing the subscale scores of VHI preoperative and postoperative 3 days, 1 month and 3 months follow up.*

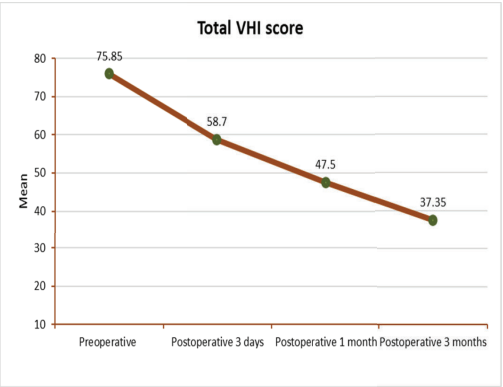


Figure-6: *Line diagram showing the total VHI scores preoperative and postoperative 3 days, 1 month and 3 months follow up.*

Table-VI

Association of VHI severity in preoperative and postoperative 3 days, 1 month and 3 months follow up (n=20)

VHI severity	Time			
	Preoperative (T0)	Postoperative after 3 days (T1)	Postoperative after 1 month (T2)	Postoperative after 3 months (T3)
Mild (0-30)	0(0.0%)	0(0.0%)	1(5.0%)	4(20.0%)
Moderate (31-60)	1(5.0%)	12(60.0%)	17(85.0%)	15(75.0%)
Severe (61-120)	19(95.0%)	8(40.0%)	2(10.0%)	1(5.0%)
Total	20(100%)	20(100%)	20(100%)	20(100%)
Statistical analysis by Chi-square test				P-value
Preoperative vs Postoperative 3 days				0.0002*
Preoperative vs Postoperative 1 month				<0.0001*
Preoperative vs Postoperative 3 months				<0.0001*

Table VI shows the association of preoperative VHI severity with postoperative 3 days, postoperative 1 month and postoperative 3 months follow up. The Chi-square test indicates significant improvement in postoperative 3 days, 1 month and 3 months follow up (P <0.0001).

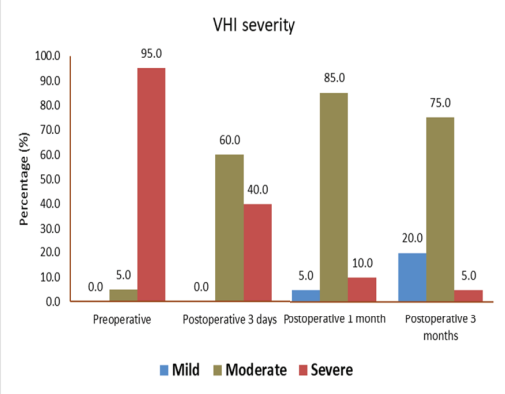


Figure-7: *Bar diagram showing the VHI severity in preoperative and postoperative 3 days, 1 month and 3 months follow up.*

Discussion:

Unilateral vocal fold paralysis is not an uncommon problem encountered in an Otolaryngology practice. UVFP is secondary to many causes, including iatrogenic, especially after thyroid surgeries and other head and neck procedures, malignant growth causing pressure on the nerve, and idiopathic, most probably a post-viral infection. As the etiology is concerned in this study, most patients (55%) had thyroid surgery, and the rest were idiopathic (45%). In accordance with this study, Bowen et al. (2017) reported that surgical trauma (iatrogenic) was the most encountered etiology in 49.6% of cases, and 31% were idiopathic [15]. Khadivi et al. (2016) reported that the etiology of UVCP was thyroidectomy (40%) and idiopathic (45%) [10]. Spataro et al. (2014) noted that the common etiology of UVFP was iatrogenic trauma (55.6%) due to either manipulation or transection of the nerve.[16]

When considering the age and sex distribution in this study, the age of the patients ranged from 19-55 years, with a mean age of 38.8±9.93 years. Maximum (40.0%) patients in age 40-50 years, followed by 25% of patients aged 30-40 years and 20% of patients below 30 years. Among them, 13

were female (65%), and 7 were male (35.0%). Male: female ratio 1:1.8. Fang et al. (2010) reported the mean±SD age among 33 patients with UVCP was 45.9±16.6 years (age range, 15-78 years); 24 were female (72.7%), and 9 were male (27.3%).[17] Al-Khtoum et al. (2013) reported nearly double the incidence in females 2.1:1.[18] Similar observation was reported by Rosenthal et al. (2007).[19] Another study by Ko et al. (2009) reported nearly double the incidence in females.[20]

In present study showed the presenting complaints of UVFP patients; 100% of patients had hoarseness of voice, 45% of patients had phonatory dyspnea, 20% of patients had choking/aspiration, and 5% of patients had dysphagia. Fang et al. (2010) reported most common presenting symptoms of vocal cord dysfunction are hoarseness, conversational dyspnea, aspiration or choking, and dysphagia.[17]

Maximum patients (75.0%) had left vocal cord paralyzed and 25% on the right side. Elbadan et al. (2017) reported a greater incidence of left-sided vocal cord disease than right-sided disease (81.25% vs. 18.75%).[9] Another study by Pagano et al. (2016) reported that two-thirds of the patients had a paralyzed left vocal fold (66.7%), and the other third had paralysis of the right vocal fold (33.3%).[12]

The present study compares the preoperative and postoperative 3 days, 1 month, 3 months follow up using the VHI scores. The VHI scores improved significantly from 75.85±13.04 preoperatively to 58.70±12.38 at 3 days postoperatively (P < 0.0001); 47.50±9.51 at 1 month postoperatively (P < 0.0001), and 37.35±8.50 at 3 months postoperatively (P < 0.0001). Surgery led to a statistically significant improvement in subscale and total VHI scores (P<0.001) between different time points using the Paired t-tests. The Chi-square test also indicates a significant improvement in postoperative 3 days, 1 month and 3 months follow up (P <0.0001).

Regarding autologous fat injection laryngoplasty for unilateral vocal fold paralysis findings, the results demonstrated significant improvement of voice assessed by all subscale and total scores of VHI. In agreement with the current study, Chen et al. (2022) reported an improvement in voice disability and perceptual voice quality among UVFP patients after office-based structural autologous fat injection laryngoplasty [21]. Another agreement with Pagano et al. (2016) reported the long-term efficacy of medialization laryngoplasty via injection of autologous fat in patients with unilateral laryngeal paralysis. The VHI score was collected before the operation (T0), immediate postoperatively (T1) and >1 year postoperatively (T2). The VHI global score improved significantly from 64±19.85 preoperatively (T0) to 29±22.17 at immediate postoperatively (T1) (p<0.001) and 33.5 ± 18.67 at >1 year postoperatively (T2) (p<0.001).[12] Benninger et al. (2015) reported good results for VHI and MPT in UVFP patients treated with trans-oral injection laryngoplasty (IL) with non-centrifuged autologous fat under general anaesthesia.[11] Elbadan et al. (2017) treated 16 patients with UVFP with the same laryngoplasty, reporting significant voice improvement.[9] Several studies found a significant difference between pre-and postoperative voice outcomes by using the VHI; this seems to suggest progressive voice improvement by autologous fat injection laryngoplasty (Hadded et al., 2021; Hu et al., 2019; Maccarini et al., 2018; Saibene et al., 2015).[22,7,8,23]

The advantages of fat compared to other injectable materials are that it is readily available, autologous, biocompatible, non-reactive, and low cost; any excess can be stored for future use. Although resorption can

occur, this is minimized with collection techniques that maintain lipocyte integrity and meticulous placement. Overall, we have found fat to be the preferred injection material due to its ease of use, safety, and sustained effect.

Conclusion:

Autologous fat injection laryngoplasty is a safe, effective, simple, inexpensive, and reliable temporary phonosurgical procedure, which can be done immediately after patients with aspiration and breathy voice dysphonia resulting from iatrogenic or idiopathic UVFP and thus improving acoustic and voice-related quality of life.

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