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ORIGINAL RESEARCH

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Long-term treatment outcome of type 1 thyroplasty using novel titanium medialization laryngoplasty implant combined with arytenoid adduction for unilateral vocal cord paralysis: single-arm interventional study at a single institution

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Abstract

Objective: To evaluate the long-term treatment outcome of type 1 thyroplasty with novel rearrangeable titanium medialization laryngoplasty implant (TMLI) combined with arytenoid adduction (AA) for unilateral vocal cord paralysis (UVFP) in the authors' institution.

Methods: A total of 16 Japanese patients with UVFP who received type 1 thyroplasty using TMLI with arytenoid adduction was enrolled in this single-arm, non-randomized interventional study. The results of the auditory perceptual assessment, aerodynamic examination, acoustic measurement, and patient-based survey on these patients were evaluated preoperatively and at 3, 6, and 12 months postoperatively.

Results: Type 1 thyroplasty using TMLI with arytenoid adduction for our patient series presented significant improvements in maximum phonation time, mean flow rates, GRBAS scale, the Voice Handicap Index and the Voice-Related Quality of Life score over the 12-month postoperative period.

Conclusion: Type 1 thyroplasty using TMLI with arytenoid adduction was quite effective for obtaining satisfactory postoperative voice improvement without any surgical complication over the long-term period.

KEYWORDS
arytenoid adduction, titanium medialization laryngoplasty implant, type 1 thyroplasty, unilateral vocal fold paralysis

1 | INTRODUCTION

Unilateral vocal fold paralysis (UVFP) with the paralyzed vocal fold fixed at the paramedian or intermediate position usually causes deficient glottic closure resulting in dysphonia, dysphagia, or shortness of breath during physical activity, which may impact on the patient's quality of life. Furthermore, the bowing of the paralyzed vocal fold margin, the level difference between both vocal folds during phonation, and the possible lateral push of the arytenoid of the paralyzed side by the opposite vocal fold at the onset of voicing due to the loss of anchoring by the surrounding paralyzed muscles are often associated with the vocal fold immobilization and impede the sufficient glottal closure. For improving insufficient glottal closure in those patients, the external vocal fold medialization by type 1 thyroplasty with or without arytenoid adduction is widely accepted as an effective surgical approach since Issiki et al introduced in his report.[1] In these surgical procedures, the reproduction of sufficient vocal folds function as vibrating parts to compensate for the function of the internal laryngeal muscle that has been lost due to paralysis is required for the improvement in impaired voice quality.

To date, several implants for adequate medicalization of the paralyzed vocal fold have been reported. Since McCulloch et al reported the use of Gore-Tex, expanded polytetrafluoroethylene, as vocal fold medializing implant, the Gore-Tex medialization thyroplasty has been widely performed due to its ease of handling and rearrangement.[2] However, excessive use of Gore-Tex implants for women patients or unexpected outbreak of postoperative hematoma followed by infection could be factors related to complications of Gore-Tex medialization thyroplasty.[3] In fact, as Sims et al reported in their case report, there could be full extrusion of implanted material of Gore-Tex.[4]

Titanium is one of other major materials for type 1 thyroplasty, as reported previously as titanium vocal fold medialization implant (TVFMI).[5] This metallic material is widely used as medical devices, such as dental applications, and surgical implants for orthopedic surgical procedure due to its high strength-to-weight, corrosion resistance, and tissue affinity.[6] In fact, the significance of the long-term functional outcomes of type I or II thyroplasty using titanium implants was reported by Schneider-Stickler and Sanuki et al, respectively.[7-9] However, there is no surgical equipment for type I thyroplasty officially approved by Japanese Ministry of Health, Labor and Welfare at present.

We therefore have developed novel titanium medialization laryngoplasty implant (TMLI) for type 1 thyroplasty combined with arytenoid adduction (AA) for the purpose of the reproduction of sufficient vocal fold function in patients with UVFP. We then conducted a prospective clinical trial to evaluate the long-term treatment outcome of type 1 thyroplasty with our novel rearrangeable TMLI combined with AA for UVFP.

2 | MATERIALS AND METHODS

2.1 | Study design and patients

This prospective single-arm interventional study was conducted between February 2016 and January 2020 at Yokohama City University Hospital, Yokohama, Japan. A total of 16 Japanese patients with UVFP for the duration more than 6 months was enrolled. The etiology of UVFP was shown in Table 1 (post-surgery in 14 patients including post-carotid surgery in 4 and post-thyroidectomy in 3, and idiopathic in 2). There were no patients who had received any injection laryngoplasty, previously. The primary endpoint of this trial was the improvement in maximum phonation time (MPT). The secondary endpoints included the improvement in auditory perceptual assessment,

TABLE 1 Clinical characteristics

Patient	Sex	Age	Side	Cause of unilateral vocal cord paralysis	Duration till thyroplasty (mo)	Preoperative GRABS scale	Preoperative MPT (s)	Size of titanium implant (mm)
1	M	62	L	Idiopathic	9	G3R1B3A0S2	2.00	3 × 10 × 2
2	M	54	L	Post carotid surgery (tetralogy of Fallot)	540	G3R1B3A0S0	7.66	2.5 × 10 × 4
3	M	68	L	Post carotid surgery (aneurysm of the thoracic aorta)	9	G3R2B3A1S0	3.05	4 × 10 × 5
4	F	70	L	Post thyroidectomy (thyroid cancer)	32	G2R2B2A0S0	8.31	3.5 × 7 × 3
5	F	21	L	Post thyroidectomy (thyroid cancer)	5	G2R2B2A0S0	9.93	1 × 8 × 1
6	F	45	R	Idiopathic	60	G2R1B2A2S0	10.03	3 × 10 × 2
7	M	25	L	Post surgery (jugular foramen tumor)	54	G2R2B2A0S0	5.83	3 × 10 × 5
8	F	77	L	Post surgery (lung cancer)	21	G3R1B3A2S0	5.13	4 × 8 × 6
9	M	68	L	Post carotid surgery (aortic dissection)	4	G3R3B3A0S0	2.90	4 × 10 × 5
10	M	71	R	Post surgery (parathyroid cancer)	39	G3R3B3A0S0	2.96	3 × 10 × 7
11	M	74	L	Post surgery (esophageal cancer)	13	G3R3B3A0S0	5.69	4 × 10 × 6
12	M	46	L	Post surgery (esophageal cancer)	12	G2R1B2A0S0	5.68	3 × 10 × 7
13	M	65	L	Post surgery (lung cancer)	10	G3R0B3A0S0	2.53	3 × 10 × 9
14	M	61	L	Post surgery (esophageal cancer)	24	G2R2B2A0S0	4.84	3 × 10 × 5
15	M	74	L	Post carotid surgery (aortic dissection)	8	G2R1B2A0S0	2.73	5 × 9 × 8
16	F	49	L	Post thyroidectomy (thyroid cancer)	24	G2R1B2A1S0	3.75	2 × 7 × 1

aerodynamic parameters except MPT, acoustic parameters when possible, and patients' subjective evaluation of own postoperative voice. Computed tomography at 6 months postoperatively was also conducted to assure the stable placement of the titanium implant. All patients provided written informed consent and the protocol of the present study was reviewed and approved by the institutional review boards of our institution (approval IDs: B151203007, UMIN ID 000020616). Fourteen patients out of the 16 were evaluated preoperatively and at 3, 6, and 12 months post-operatively. Two patients (Nos. 11 and 13) who died from cancer were not evaluated at 12 months postoperatively.

2.2 | Titanium vocal fold medializing implant for type 1 thyroplasty

A specially devised titanium vocal fold medializing implant for type 1 thyroplasty invented by KM[10] was used for this study (Patent number: WO/2015/111340). Briefly, this titanium plate is composed of a fixing part for fixing at one end thereof to the thyroid cartilage, and a main body part capable of bending along bend lines drawn in two locations as shown in Figure 1. This titanium plate could be bended in these lines easily by surgical tools such as a hemostat. The plate could be tilted downward by 15°, when the implant was bended along the line applied a 105°/75°in the plate, so that this tilt counteracted the upward force of the plate tip, resulting in that the implant could be pushed parallel to the vocal folds as described in our previous literature. Thus, arbitrary bending this titanium plate enable us to adjust the degree of medialization of the paralyzed vocal fold.

2.3 | Operative procedure

All surgeries were performed under local anesthesia combined with intravenous sedation using propofol. The same surgeons (YI and YC) performed the surgery in all 16 patients. First, arytenoid adduction (AA) was performed as described previously.[11] The external vocal fold medialization by type 1 thyroplasty was then performed as described

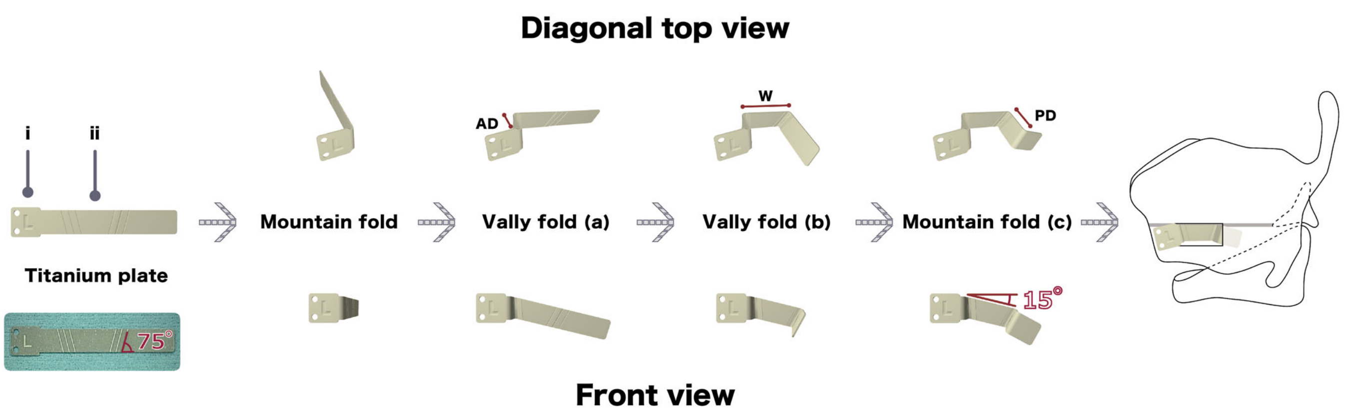

FIGURE 1 Titanium medialization laryngoplasty implant. The adjustment to achieve medialization is performed by molding the implant at a suitable site. The implant has the line applied a 105°/75° in the plate. (i) Handle. (ii) Medialization part. (a) This place adjusts the medialization of the vocal fold anteriorly. (b) Adjusting the width that carries out the medialization of the vocal fold. (c) This place adjusts the medialization of the vocal fold posteriorly. Abbreviations: AD, anterior depth; PD, posterior depth; W, width

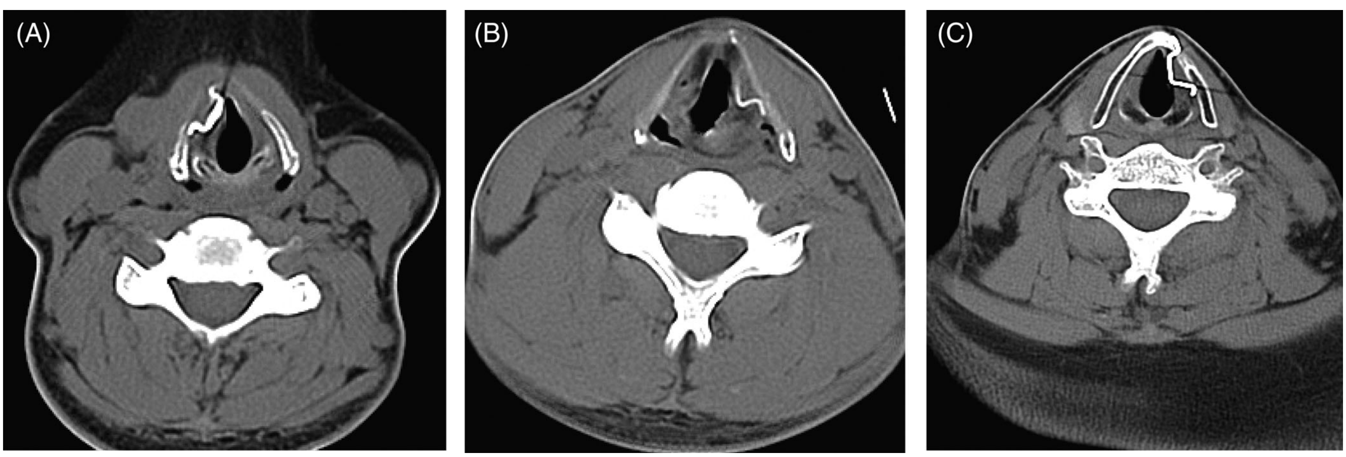

FIGURE 2 Postoperative CT images in representative three cases: A, case 6; B, case 7; C, case 12

previously.[1] The distance from the midline of the anterior thyroid cartilage border line to the anterior end of the thyroplasty window was 5–6 mm on the line corresponding to the horizontal level of the vocal folds, and the 5 × 10 mm of the thyroplasty window was designed. An arranged titanium plate with appropriate size was then temporarily implanted after the cartilage fenestration with preserving of the inner perichondrium.[12] The intraoperative assessment of glottal closure was finally adjusted using flexible videolaryngoscopy to rearrange the titanium plate with optimal size, and patient's own subjective and surgeons' objective auditory evaluations of his/her voice throughout the rearrangement of the size and placing of the titanium plate. Before the final adjustment of glottal closure, the patient was temporally awoken by the anesthetist to become able to phonate according to the instruction of the surgeons.

2.4 | Maximum phonation time (MPT) assessment

Improvement of MPT was the primary endpoint of this study. MPT of a sustained Japanese vowel /a/ following deep breath was evaluated preoperatively, at 3, 6, and 12 months postoperatively. Patients with MPT over 15 seconds at all postoperative time points were considered as successful.

2.5 | Auditory perceptual assessment

The patients were instructed to read a standardized passage and sustain Japanese the vowels /a/, /e/, /i/, /o/, and /u/ at a comfortable pitch and intensity levels, and evaluated according to the GRBAS scale in which the following parameters were rated on a four-point scale; 0 (normal) to 4 (severe): the overall grade (G) of dysphonia, roughness (R), breathiness (B), asthenia (A), and straining (S). The evaluation was conducted by speech therapists (YI) and otolaryngologists using our routine method according to the guideline of the Japan Society of Logopedics and Phoniatrics 2018.[13]

2.6 | Aerodynamic examination

Aerodynamic examination was performed using a phonation analyzer (PA-1000; Minato, Osaka, Japan). For assessing the aerodynamic data, each patient was required to phonate a sustained Japanese vowel /a/ into a cylindrical mouthpiece, and the mean flow rate (MFR) was obtained together with voice efficiency.

2.7 | Acoustic analyses

Acoustic evaluation was also performed pre- and postoperatively. A relatively stable 5-second duration segment of each voice samples were recorded using a condenser microphone (Audio Technica: ATM31a), directly stored in a personal computer through an audio-interface (Edirol: UA-25) at the rate of 24 bit/s with sampling frequency of 96 Hz, and then analyzed using the multi-dimensional voice program in a computerized

TABLE 2 Results of auditory perceptual assessment, aerodynamic examination and QOL

	Pre-op			3 months post-op			6 months post-op			12 months post-op			
	Mean	Range	SD	Mean	Range	SD	Mean	Range	SD	Mean	Range	SD	*P* value
Maximum phonation time (s)	5.63	2.00-10.03	2.72	20.73	10.00-38.22	7.55	20.85	9.76-38.22	8.81	21.52	9.35-38.00	8.61	<.001
GRBAS scale													
G	2.50	2–3	0.52	0.69	0–2	0.60	0.81	0-2	0.66	0.71	0-2	0.61	<.001
R	1.63	2–3	0.89	0.63	0–1	0.50	0.69	0–2	0.60	0.64	0–2	0.63	<.001
B	2.50	2–3	0.52	0.25	0–2	0.58	0.38	0–2	0.62	0.50	0–1	0.52	<.001
A	0.38	2–0	0.72	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	.489
S	0.13	2–0	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	.837
MFR (mL/s)	731.50	246-1762	406.00	221.21	101.5-376.5	82.09	238.38	116.5-464.5	92.54	232.29	98.5-38.4	76.60	<.001
VHI	61.19	15-94	28.69	15.88	0-75	21.73	16.19	0-88	28.89	5.86	0-27	7.85	<.001
VR-QOL	32.81	18-41	8.24	16.50	10-38	7.67	16.63	10-40	10.50	13.07	10-27	4.86	<.001

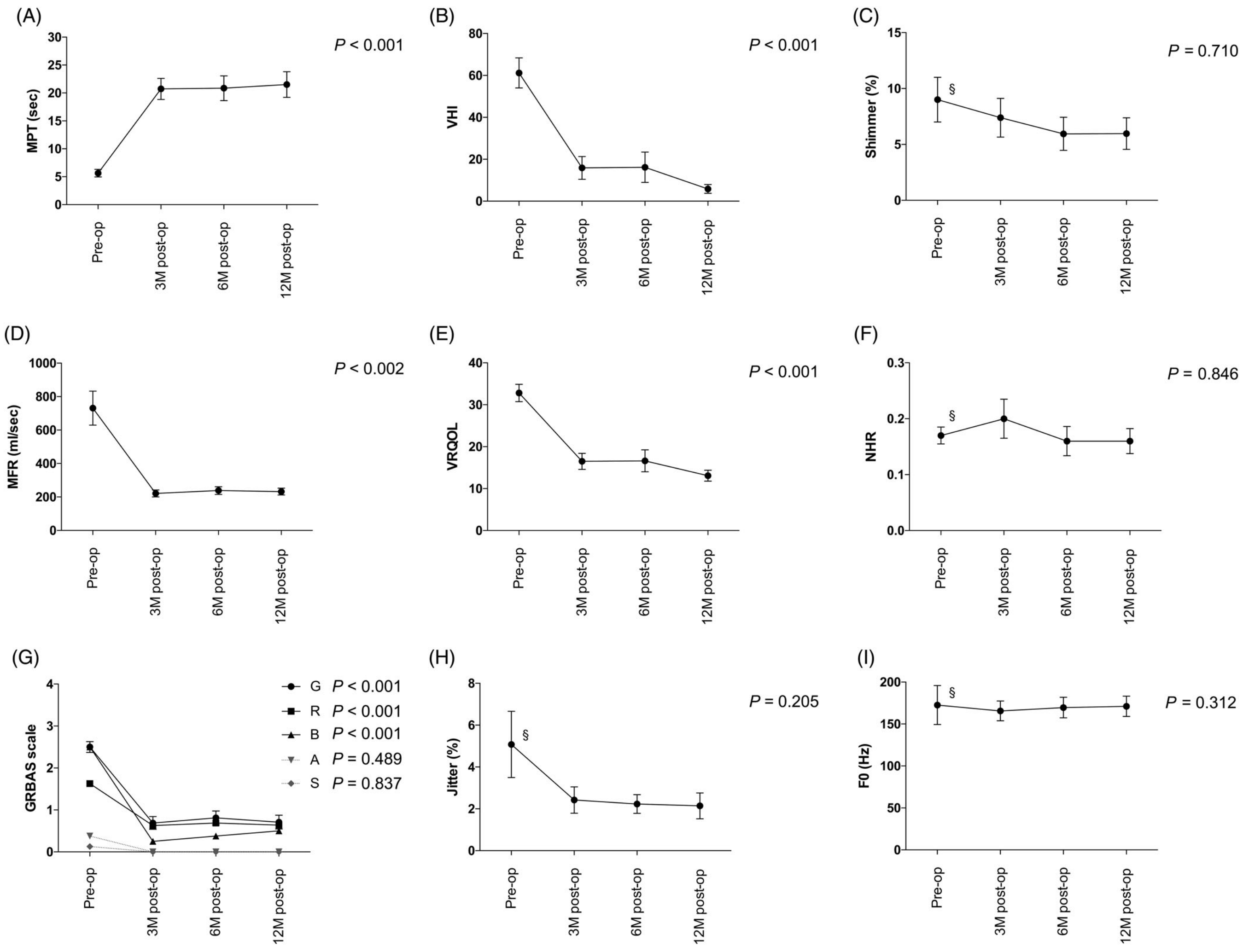

FIGURE 3 A, The significant improvement in MPT by surgery was observed over the 12-month postoperative period; $P < .001$. B. The significant improvement in MFR by surgery was observed over the 12-month postoperative period; $P < .001$. C, The significant improvement was observed over the 12-month postoperative period, Black line/circle, G ($P < .001$); black line/square, R ($P < .001$); black line/triangle, B ($P < .001$); gray line/triangle, A ($P = .489$); gray line/diamond, S ($P = .837$). D, The significant improvement in VHI by surgery was observed over the 12-month postoperative period; $P < .001$. E, The significant improvement in VRQOL by surgery was observed over the 12-month postoperative period; $P < .001$. F, The improvement in Jitter by surgery observed over the 12-month postoperative period; $P = .205$. G, The improvement in Shimmer by surgery was observed over the 12-month postoperative period; $P = .710$. H, The change in NHR by surgery was observed over the 12-month postoperative period; $P = .846$. H, The change in F0 by surgery was observed over the 12-month postoperative period; $P = .312$. §, eight patients who were not able to receive acoustic examinations preoperatively due to their severe hoarseness

speech laboratory system (CSL4500, Kay-Pentax, Tokyo, Japan) to determine the following acoustic measurements; percentage shimmer, percentage jitter, the harmonics-to-noise ratio (HNR: the ratio of energy in the harmonic vs the noise components), and the fundamental frequency (F0). In 8 patients (Nos. 1, 3, 8, 10, 13, 14, 15, 16) presenting preoperative MPT of less than 5 seconds, the acoustic analyses were not performed.

2.8 | Voice specific patient-reported outcome measures and other instrumental measures

The voice handicap index (VHI)[14]and voice-related quality of life (V-RQOL)[15] were administered pre- and postoperatively to quantify the psychosocial consequences of vocal handicap and the voice-related quality of life. In addition, all patient routinely received fibercopic videolaryngostroboscopy pre- and postoperatively. The examination was performed using a flexible fiberscopy (Fujifilm Corp., Tokyo, Japan) and a light source (Nagashima Medical Instruments, Tokyo, Japan). All patients also underwent computed tomography at 6 months post-operatively to evaluate the position of the titanium plate in the larynx after thyroplasty.

2.9 | Statistical analysis

Significant differences between the pre- and postoperative parameters were analyzed with the repeated measure ANOVA test. Statistical analysis was performed using the JMP software (Version 12.2.0, SAS

Institute Inc., Cary, NC). $P < .05$ was considered statistically significant.

3 | RESULTS

3.1 | Patient characteristics

The clinical characteristics of 16 patients in this study are summarized in Table 1. The median age of patients was 63.5 years (range, 28-77 years), and 11 patients (68.8%) were male. This series included 14 left and 2 right UVFP. The median duration time from onset of UVFP to type 1 thyroplasty combined with AA was 17 months. The median preoperative MPT was 4.99 seconds. No major postoperative complications such as sever postoperative hemorrhage, surgical site infection, or postoperative laryngeal edema necessitating tracheotomy, were observed in this series. Appropriate location of titanium vocal fold medializing implant in each patient was observed in CT image examination performed at 6 months postoperatively (Figure 2). No late adverse events related the surgery such as foreign body concerns, or extrusion, were not observed 12 months postoperatively. These results suggested that all patients presented no late complication associated with this surgical approach.

3.2 | Functional outcome of vocal parameters after type 1 thyroplasty

Results of auditory perceptual assessment, aerodynamic examination and QOL compared preoperatively, at 3, 6, and 12 months postoperatively were summarized in Table 2. The MPT improved immediately from 5.63 (preoperative mean) to 20.52 at 3 months postoperatively, and the improvement in MPT by surgery was observed over the 12-month postoperative period ($P < .001$) as shown in Figure 3A. The improvement in MFR was also observed from 731.50 mL/sec (preoperatively) to 165.65 3 months postoperatively and maintained over the 12-month postoperative period as shown in Figure 3B ($P < .001$). In addition, among GRBAS score, G, R, and B scores improved significantly over the 12-month postoperative period ($P < .001$, respectively, Figure 3C). Furthermore, the improvements in the VHI and the V-RQOL score were gradually observed over the 12-month postoperative period as shown in Table 2, and the difference between preoperatively and postoperatively showed significant ($P < .001$ and $P < .001$, respectively, Figure 3D,E).

Results of acoustic examination on eight cases out of the 16 compared preoperatively, and at 3, 6, and 12 months postoperatively were summarized in Table 3. On the remaining eight cases, the preoperative acoustic examination was not available due to their severe hoarseness. The mean Jitter improved immediately from 5.08 (preoperatively) to 2.42 at 3 months postoperatively, and the improvement of the Jitter by surgery was observed over the 12-month postoperative, however, there was no significant difference ($P = .205$, Figure 3F). The improvements in the Shimmer were gradually observed

TABLE 3 Results of acoustic analysis

	Pre-op			3 months post-op			6 months post-op			12 months post-op			
	Mean	Range	*SD*	Mean	Range	*SD*	Mean	Range	*SD*	Mean	Range	*SD*	*P* value
F0 (Hz)	172.60	86.5-250.4	65.73	165.65	119.0-237.4	43.89	169.63	100.8-294.1	49.19	171.12	124.3-248.3	45.08	.312
Jitter (%)	5.08	0.58-15.53	4.48	2.42	0.47-8.26	2.36	2.23	0.48-8.09	1.80	2.14	0.37-9.46	2.32	.205
Shimmer (%)	9.01	3.71-21.74	5.66	7.39	2.10-22.99	6.47	5.95	2.73-26.91	5.93	5.97	2.06-22.38	5.28	.710
NHR	0.17	0.10-0.24	0.04	0.20	0.11-0.56	0.13	0.16	0.09-0.54	0.10	0.16	0.09-0.44	0.08	.846

over the 12-month postoperative period, however, no significant difference was found using ANOVA (*P* = .710, Figure 3G). Lastly, there were no significant differences of mean NHR and F0 over the 12-month postoperative period (*P* = .846 and *P* = .312, respectively, Figure 3H,I).

Overall, type 1 thyroplasty using our novel TMLI combined with AA presented significant improvement of the subjective and objective functional voice outcomes of patients with UVFP without any complication associated with this surgical approach over the long-term postoperative period in this study.

4 | DISCUSSION

In this study, long-term good treatment outcome of type 1 thyroplasty using our novel TMLI for UVFP combined with AA, including significant improvements of MPT, MFR, GRBAS, the VHI and the V-RQOL score, was observed over the 12-month postoperative period as a prospective single arm study. Interestingly, our results showed that the voice-related quality of life was improved gradually over the 12-months, suggesting the satisfaction of patients with UVFP require a relatively long span of time after type 1 thyroplasty with AA.

The implants for type 1 thyroplasty to medialize the paralyzed vocal fold adequately are generally required to possess the following principal characteristics, (1) the material used to make the implant should have tissue affinity and homeostasis, (2) the manipulation of the implant should be easy in the surgical field, (3) the implant should have sufficient strength and stability in the fixed position, (4) the implant should be effective for voice improvement, and (5) surgical revisions should be possible after the initial implantation.

In the present study, the short and long-term significant improvements of MPT, MFR, GRBAS, the VHI and the V-RQOL score were observed. In particular, the improvements in MPT in this study was remarkable. On the other hand, there was no significant difference in the improvement in the results in our acoustic analyses over the 12-month postoperative period. Incidentally, the improvements in the mean Jitter and Shimmer were consistent with previous report using another titanium implant for type 1 thyroplasty.[7,16] No significant improvement in the treatment outcomes in our acoustic examinations over the 12-month postoperative period in the current study may be due to a small number of patients in our series, in which 8 patients were excluded from the preoperative analysis due to their severe hoarseness with too short MPT. Overall, these long-term good treatment outcomes of type 1 thyroplasty using our novel TMLI for UVFP combined with AA suggested that TMLI had good tissue affinity as well as enough elasticity and stability in the fixed position to withstand external forces during glottal closure when combined with AA.

A main body part of TMLI, capable of bending along bend lines drawn in two locations, also have good workability for the manipulation of the implant. In addition, our results showing significant improvement in the subjective and objective functional voice outcomes by type 1 thyroplasty using TMLI combined with AA, suggested that laser marking at 105°/75° applied in the plate of TMLI made it possible to push the plate parallel to the vocal cords, resulting in the adequate positioning of the implant for the medialization of the vocal fold during surgery. Thus, TMLI seems to have many required principal characteristics as the implants for type 1 thyroplasty. Although there were no patients who needed revision surgery type 1 thyroplasty with AA in the present study, the size of TMLI could be useful information to rearrange TMLI in revision surgery. Furthermore, the development of the instrument to measure vocal fold medicalization would be required to make surgeons possible to have the adequate adjustment of this type of implant for type 1 thyroplasty for better vocal function during surgery in the future.

In the present study, arytenoid adduction (AA) was performed in all cases. This direct manipulating the arytenoid cartilage approach, making the vocal cords fixed to adequate position with moderate tension when vocalization,[17] was generally performed for patients with unilateral laryngeal nerve paralysis whose glottal gap during vocalization and the level difference from the unaffected vocal cord are remarkable. Also, the arytenoid cartilage in the paralyzed side often does not act as an effective fulcrum in the posterior end of the vocal folds, resulting in insufficient physiological vibrating body due to unstableness of maintaining the tension of the vocal folds. Thus, we performed AA to obtain stability of the arytenoid cartilage and adequate tension of vocal fold for a high voice improvement effect by type I thyroplasty.

One of the big limitations of this study is that the present study comprised only a small number of patients in a single institution even evaluated in prospective manner. The single-arm design has another limitation, resulting in the difficulty in the accurate comparison of long-term treatment outcome between the present study and previous treatment approaches. Miscellaneous patient backgrounds might have potentially biases affecting the results of our analysis. In addition, AA performed with type 1 thyroplasty in the current study might make it difficult to examine the independent applicability of type 1 thyroplasty using TMLI as treatment outcomes. Although this study had the above-mentioned limitations, our findings on long-term follow-up may provide impact on usability of our novel TMLI for the treatment of patients with UVFP.

5 | CONCLUSION

We here present the long-term treatment outcome of type 1 thyroplasty using rearrangeable TMLI combined with AA for UVFP as single-arm interventional study in a single institution. We observed that type 1 thyroplasty using TMLI with arytenoid adduction significantly improved MPT, MFR, GRBAS, the VHI, and the V-RQOL score without any complication associated with this surgical approach over the long-term postoperative period in this study. To reveal the significance of our novel titanium implant for the treatment on patients with UVFP, further multi-institutional study would be required.

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CONFLICT OF INTEREST

The authors declare no conflicts of interests.

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