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ORIGINAL SCIENTIFIC REPORT

Is There Any Reliable Predictor of Functional Recovery Following Post-thyroidectomy Vocal Fold Paralysis?

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Abstract

Background Predicting definitive outcomes of post-thyroidectomy vocal fold paralysis (VFP) is challenging. We aimed to identify reliable predictors based on intraoperative neuromonitoring (IONM) and flexible fiberoptic laryngostroboscopy (FFL) findings.

Methods Among 1172 thyroid operations performed from April to December 2021, all patients who exhibited vocal fold paralysis (VFP) at post-operative laryngoscopy were included. IONM data, including type of loss of signal (LOS), were collected. Patients underwent FFL, with arytenoid motility assessment, at 15, 45 and 120 days post-operatively. Patients were divided into two groups: those who recovered vocal fold motility (VFM) by the 120th post-operative day (recovery group) and those who did not (non-recovery group).

Results Fifty-nine VFP cases (5.0% of total patients) met the inclusion criteria. Eight patients were lost at follow-up and were excluded. Overall, 9 patients were included in the non-recovery group (0.8% of total patients) and 42 in the recovery group. Among various predictive factors, only arytenoid fixation (AF) at the 15th post-operative day and Type I LOS were significant predictors for no VFM recovery ($p = 0.007$, RR = 9.739, CI:1.3–72.3 and $p = 0.001$, RR = 9.25, CI:2.2–39.3 for AF and Type I injury, respectively). The combination of type of LOS and arytenoid motility at the 15th post-op day yielded satisfactory predictive values for the progression of transient VFP to permanent.

Conclusions Arytenoid motility at the 15th post-op day and type II LOS are associated with recovery of VFM. Type of LOS and FFL could be included in the follow-up protocols of patients with VFP to reliably predict clinical outcomes.

Luca Revelli and Pierpaolo Gallucci contributed equally to this work and share co-authorship.

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Introduction

Thyroid surgery is the leading cause of iatrogenic vocal fold paralysis (VFP) [1, 2]. Even unilateral VFP can impair voice and swallowing functions and thus deteriorate patients' quality of life, while also constituting a common cause of medical litigation [3]. The overall incidence of VFP widely varies among published studies (0.5–20.0%), while recent systematic reviews report a transient incidence of 0.6–9.6% and a permanent incidence of 0.0–2.0% [4–6]. Risk factors for VCP are usually associated with thyroid cancer surgery, revision surgery, lymph node dissection, retrosternal extension, abnormal anatomy [7–9] and thyroidectomy in children [10]. Among the variables to be considered, there are also surgeons' and centers' annual volume [11, 12].

The introduction of intraoperative nerve monitoring (IONM) facilitated identification and preservation of the inferior laryngeal nerve (RLN) function while accurately predicting early post-operative vocal fold motility [13]. IONM evaluates the electrophysiological activity of the RLN by electromyography of the vocal cords and its utilization varies among different regions and health systems [14]. In a review by Schneider et al. [15], the negative predictive value of loss of neuromonitoring signal (LOS) and early VFP for intermittent and continuous IONM ranged from 97.3–99.8% to 99.8–100%, respectively, while the positive predictive value from 37.8–80.5% to 47.6–88.2%, respectively. LOS is commonly subdivided into segmental LOS type I, with a clear point of injury, or global LOS type II, where the level of injury cannot be defined [16].

Although IONM quite accurately predicts transient VFP in the first post-operative days, the transition to a permanent (6 months–1 year post-operatively) paralysis [17] might be multifactorial and should not be assessed by IONM data alone. Prognostic factors associated with permanent VFP in thyroid surgery have not been thoroughly investigated yet, although type I injuries seem more frequently associated with no recovery [17, 18].

Predictive factors for permanent VFP differ among studies depending on instruments, such as laryngeal electromyography [19, 20] or laryngostroboscopy [21], and protocols, such as voice indexes [22], implemented. Although the results of such studies have individually identified possible predictive factors, due to the variability of methods applied or their complexity, none has gained general consensus or has been widely applied.

Conversely, accurate early prediction of post-thyroidectomy VFP would allow to inform and consult the patients on expectations of recovery and to facilitate the decision and timing of a permanent intervention in cases where recovery of vocal fold motility (VFM) is improbable [23–25]. The present study aimed to provide insights for a more tailored approach on those issues, by utilizing only accessible tools for the endocrine surgeon and ENT specialist and thus being theoretically reproducible.

Material and methods

This was a prospective cohort study describing the role of flexible fiberoptic laryngostroboscopy (FFL) and IONM in predicting outcomes of VFP following thyroid operations between April 2021 and December 2021. The study setting was the Division of Endocrine and Metabolic Surgery and the Division of Otolaryngology, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy. The records of the participating patients were prospectively collected in a dedicated de-identified database. Informed consent was obtained from all individual participants included.

The study included patients with VFP at 1st post-operative day laryngoscopy who underwent any type of thyroid operation, primary or reoperation, with normal vocal cord motility in the pre-operative FFL.

The exclusion criteria were: pre-operative laryngeal disease or vocal fold paralysis in preoperative FFL; surgery without IONM; advanced thyroid disease with nerve infiltration; refusal of participation or loss to follow-up.

The following parameters were included in the analysis: age, sex, relevant medical history, pre-operative diagnosis, type and duration of surgical procedure, IONM data, 1st post-operative day FFL, vocal fold and arytenoid motility on the 15th, 45th and 120th post-operative day. Patients were divided into two groups: those who recovered VFM at the 120th day (recovery group) and those who did not (non-recovery group).

In all operations, the applied protocol was aligned with the guidelines of the International Neural Monitoring Study Group (INMSG) [16, 26, 27]. All surgical procedures were performed by an experienced endocrine surgeon [12].

IONM and LOS: Intermittent IONM was performed with the C2 Xplore® system (Inomed Medizintechnik GmbH, Emmendingen, Germany). Regarding LOS, INMSG guidelines were followed [16, 26, 27]. LOS was defined as an amplitude decrease to < 100 μv after achieving an initial baseline of V1 $>$ 500 μV with appropriate latency and good laryngeal twitch baseline assessment. LOS was subdivided into two categories:

LOS type I segmental type I injury when a complete loss of the neuromonitoring signal proximal to a specific focal point on the RLN was identified, with preservation of neuromonitoring signals distally.

LOS type II global type II injury was diagnosed in the absence of a point of damage and on electrophysiological

demonstration a complete LOS along the entire course of the ipsilateral vagus and RLN.

For the purposes of this study, combined EMG events (CEs) were defined as adverse EMG events consisting of $> 50\%$ decrease in amplitude at initial baseline ≥ 500 μV, accompanied by $> 10\%$ increase in latency. All CEs that persisted until the end of the operation were considered for calculation of predictive values as performed in other publications [28].

The predictive value of LOS and early post-operative VFP has been extensively researched [15]. Since the present study focuses only on predictive values associated with VFM recovery, only LOS and CEs accompanied by VFP at the 1st post-operative day were accounted for.

Flexible fiberoptic laryngostroboscopy FFL was performed pre-operatively and in all cases with LOS, CEs or dysphonia at the first post-operative day. The equipment consisted of a 3.4-mm-diameter flexible fiberoptic rhinolaryngoscope with a video processor (XION GmbH Video-Nasopharyngoscope EV-NE, Germany), and the processing software was the DiVAS (XION GmbH, Germany). During FFL, all participants underwent a standardized endoscopic evaluation. The vocal folds and the arytenoid were observed at rest and during abductor and adductor tasks. Three parameters were evaluated during FFL: (1) VFM, presence of vocal fold motion during abduction and adduction maneuvers. (2) Arytenoid fixation (AF), absence of arytenoid motion during abduction and adduction maneuvers (3) Arytenoid motility (AM), Arytenoid motion during abduction and adduction maneuvers. All the FFLs were performed by two expert, independent and blinded ENT doctors (LD or MRM). All VFP cases underwent FFL examination at 15 days post-operatively and were addressed to speech therapy. Follow-up FFL examinations were performed at the 45th and 120th post-operative days.

Power study

Since AM has not been previously correlated with recovery of vocal fold function in similar protocols, the power study was performed post hoc. The parameters applied were: Exact, proportions, two independent groups. The dichotomous outcome was vocal fold motility/paralysis at 4 months. The result was a post hoc study power of 83.2% ($\alpha = 0.036$). The analysis was performed with G*Power (ver. 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany).

Statistical analysis

Distribution of variables was assessed with the Shapiro–Wilk test. Continuous variables were reported as mean (± standard deviation) or median (range, minimum–maximum value) depending on distribution. Differences between groups were assessed by Student's *t* or Mann–Whitney *U* test for parametric and nonparametric variables, respectively. Categorical variables were analyzed using Chi-square and Fisher's exact test and further post hoc analysis on adjusted residuals where appropriate. Data analysis was performed with IBM SPSS Statistics for Windows, Version 25.0 (Armonk, NY: IBM Corp). All analyses were two-tailed.

Results

From April 2021 to December 2021, 1172 thyroid operations were performed. Demographics and clinical characteristics of the initial population are summarized in Table 1. Eight patients from the initial population were not included based on the exclusion criteria: two had pre-operative VFP (one due to advanced thyroid cancer and one as a result of previous thyroid operation) and 6 procedures were performed without IONM (due to technical issues). Two additional patients experienced dysphonia without LOS or CEs: both had normal vocal fold motility and symptoms resolved during follow-up. Fifty-nine patients (5.01%) met the inclusion criteria and gave their informed consent to participate in the study. In all the included cases, VFP was unilateral. Eight patients were lost to follow-up (13.5%) and were not included in the final analysis. Five patients attended the follow-up dates until day 45th and did not return for the final evaluation, while three patients

Table 1 Population's characteristics

	Population characteristics
Number	1172
Age (*y*) mean, SD and range	50.3 ± 15 (10–85)
Sex (M/F)	365 (31.1%)/807 (68.9%)
Malignant/Benign	662 (56.5%)/510 (43.5%)
Type of procedure[a]	
TL	110 (9.4%)
TT	654 (55.8%)
TT + CND	372 (31.7%)
TT + CND + LND	11 (0.9%)
Reoperation	25 (2.13%)
Nerves at risk	2232
Vocal fold paralysis (yes/no)	59 (2.6%)/2173 (97.4%)
Transient	42 (1.9%)
Permanent[b]	9(0.4%)
Lost to follow-up	8(0.3%)

[a]*TT*, Total thyroidectomy; *TL*, Lobectomy, loboisthumusectomy, lobectomy and ipsilateral CND; *CND*, Central neck dissection (unilateral or bilateral); *LND*, Lateral neck dissection [b]Defined at 4 months post-operatively for this study

Table 2 Characteristics of patients with post-operative vocal fold paralysis included in the study

	Number of patients
Type of procedure[a]	
TT	28 (54.9%)
TT + CND	18 (35.3%)
TL	5 (9.8%)
Type of loss of signal (LOS)	
Combined events/complete LOS	8/43
Type I/Type II	14/37
Mechanism of RLN injury in type I LOS	
Traction	11
Electrocoagulation around the RLN	0
Pinching (picking up of tissues around the RLN imparting direct trauma to the nerve)	1
Unclear	2
Level of RLN injury in type I LOS	
Superior to the intersection of the RLN with the ITA[b]	8
At the intersection level of the RLN with the ITA	2
Inferior to the intersection of the RLN with the ITA	4
Arytenoid motility at the 15th post-operative day	
Mobile	28
Fixed	23
Vocal fold paralysis at 120 days	9 (17%)

[a] *TT*, Total thyroidectomy; *TL*, Lobectomy, loboisthumusectomy, lobectomy and ipsilateral CND; *CND*, Central neck dissection (unilateral or bilateral) [b] *ITA*, Inferior thyroid artery

attended only the first follow-up on the 15th day. Seven out of eight patients had a permanent residence outside the hospital's region, and in 5 out of 8 cases (62.5%), there was AM present on the 15th post-operative day.

The final sample of our study consisted of 51 patients with VFP. Included patients' characteristics are reported in Table 2. The recovery group consisted of 42 patients (82.4% of VFP), while the non-recovery group consisted of 9 patients (17.6% of VFP, 0.8% of all operated patients). Patients' characteristics and the comparative analysis are shown in Table 3. Of note, concerning FFL evaluation, there were no cases of uncertainty and/or disagreement that needed further evaluation by a third external examiner.

There was a significant difference between the two groups in type of LOS and AM on the 15th post-operative day. Type I LOS was registered in 7/42 patients in the recovery (16.7%) and 7/9 (77.8%) in the non-recovery group ($p = 0.001$). On the 15th post-op day, in the recovery group, 27 out of 42 patients (64.3%) showed AM, while only one out of 9 (11.1%) in the non-recovery group ($p = 0.007$).

CEs in this study manifested only in type II LOS, and all patients recovered VFM as shown in Table 3.

Type I LOS resulted in 9 out of 14 (64.2%) AF, while type II lesions in 14 out of 37(37.8%) ($p = 0.12$). At univariate analysis type I LOS and AF on the 15th post-operative day were significant risk factors for no VFM recovery (RR = 9.739, CI:1.3–72.3 and RR = 9.25, CI:2.2–39.3 for AF and Type I LOS, respectively). A multivariate regression analysis including the above two factors was not possible since the two variables potentially violate the non-collinearity assumption.

No patients in the non-recovery group had both type II injury and AM on the 15th post-op day. In the post hoc analysis, the combination of Type II injury and AM was significantly predictive for recovery of VFM (adj. Chi-square = 8.98, $p = 0.002735$), while the combination of Type I lesion and AF for no recovery of VFM (adj. Chi-square = 18.07, $p < 0.0001$) as shown in Table 4.

None of the 51 patients with VFP in the first post-operative day recovered VFM by the 15th post-operative day. Twenty-seven patients (52.9%) recovered VFM by the 45th post-operative day and an additional 15 patients (29.4%) by the 120th post-operative day. AM was a significant predictive factor for VFM recovery both at the 15th and at the 45th post-operative day ($p = 0.018$ and $p < 0.001$ in AM presence at the 15th post-operative and by the 45th post-operative day, respectively), while no significant difference was observed in patients recovering AM between the 15th and 45th post-operative day ($p = 0.31$), albeit in a small sample size (Figs. 1 and 2).

As shown in Table 5, type of LOS alone is an adequate factor for predicting the progression of transient to permanent VFP, with a positive predictive value of 78%, negative predictive value of 83% and a total accuracy of 82%. By incorporating in the IONM data the FFL findings on arytenoid motility at the 15th post-operative day, those values rise significantly to 100%, 89% and 91%, respectively.

Discussion

The results of the present study showed that the type of LOS and evaluation of AM on FFL can be utilized to predict recovery of VFM. Indeed, AM in the 15th post-operative day and type II LOS were associated with favorable outcomes.

The wide diffusion of IONM among endocrine centers and the application of the INMSG guidelines has enabled surgeons to predict quite accurately the status of VFM intraoperatively. When definitive, LOS has been strongly correlated with post-operative VFP on the first post-operative day and serves as an excellent negative predictive

Table 3 Included patients' characteristics and comparative analysis between groups

	Recovered VFM at 120 days (n = 42)	Not recovered VFM at 120 days (n = 9)	p
Age (y)	50.6 ± 13.1	47.5 ± 18.7	0.548
Sex (M/F)	12/30	2/7	0.693
Diabetes (Y/N)	3/39	1/8	0.552
Smoking status (Y/N)	15/27	2/7	0.699
Operation time (min) (median, range)	53 (29–151)	57 (33–145)	0.562
Vocal fold paralysis side (R/L)	19/23	5/4	0.718
Type of operation[a]	3/16/22/1	1/5/2/1	0.312
(TL, TT, TT + ND, Reoperation)			
Type of LOS	7/35	7/2	0.001
(Type I/Type II)			RR = 9.25[b]
			CI:2.2–39.3
Mechanism of RLN injury in type I LOS (14 patients)			0.73
Traction	6	5	
Electrocoagulation around the RLN	0	0	
Pinching	0	1	
Unclear	1	1	
Level of RLN injury in type I LOS			0.62
Superior to the intersection of the RLN with the ITA[c]	3	5	
At the intersection level of the RLN with the ITA	1	1	
Inferior to the intersection of the RLN with the ITA	3	1	
Adverse event type (combined event/complete LOS)	8/34	0/9	0.322
Malignant/benign	23/19	2/ 7	0.14
Arytenoid motility on 15th post-op day (mobile/fixed)	27/15	1/8	0.007
			RR = 9.739[b]
			CI:1.3–72.3

[a]*TT*, Total thyroidectomy; *TL*, Lobectomy, loboisthumusectomy, lobectomy and ipsilateral CND; *CND*, Central neck dissection (unilateral or bilateral); [b]*RR*, relative risk; *CI*, Confidence Intervals; [c]*ITA*, Inferior thyroid artery

Table 4 Combinations of predictive factors for no VFM recovery

	Recovered VFM[a] at 120 days	Not recovered VFM at 120 days	Adjusted p[e] value after post hoc analysis
Type I LOS[b] and AF[c]	3	6	< 0.001
Type I LOS and AM[d]	4	1	0.88
Type II LOS and AF	12	2	0.15
Type II LOS and AM	23	0	0.0027

[a]*VFM*, Vocal fold motility; [b]*LOS*, Loss of signal; [c]*AF*, Arytenoid fixation at 15th post-operative day; [d]*AM*, Arytenoid mobility at 15th post-operative day; [e]adjusted significance level: $p < 0.00625$

factor [15]. In addition, type II LOS has been long associated with higher rates and faster recovery of VFM during follow-up [17]. While there is an adequate number of studies correlating IONM findings with VFP in the immediate post-operative period, the factors affecting the progression from transient to permanent VFP have not been thoroughly investigated yet.

Interestingly, in the review by Schneider et al. [15], among studies included, there was a substantial variation from 20 to 92.5% of transient VFP progressing into permanent VFP, when intermittent IONM was used. In our series, recovery of transient VFP was comparable (82%), while type II LOS was also correlated with higher rates of recovery (p = 0.001).

Nonetheless, progression to permanent VFP must be a more intricate process and thus, additional prognostic factors should be considered instead of IONM data alone. In some publications, concomitant injury of the external branch of the superior laryngeal nerve (EBSLN) might affect permanent vocal fold paralysis due to the absence of alternative reinnervation pathways [29–31]. However, this subject remains controversial and requires further investigation, while routine EBSLN monitoring has not been implemented in our department yet to compare results.

In addition, more general predictive factors for VFP have been identified among studies such as: tumor size, age ≤ 50 years, surgery duration ≤ 120 min, malignancy and reoperation [21, 32, 33]. In an older review, risk factors associated with poor nerve regrowth included age, diabetes, smoking, and systemic disease [34]. The above-mentioned predictive factors did not affect progression into permanent VFP in this study. Patients' age, sex distribution, side of injury, type of operation and final histology

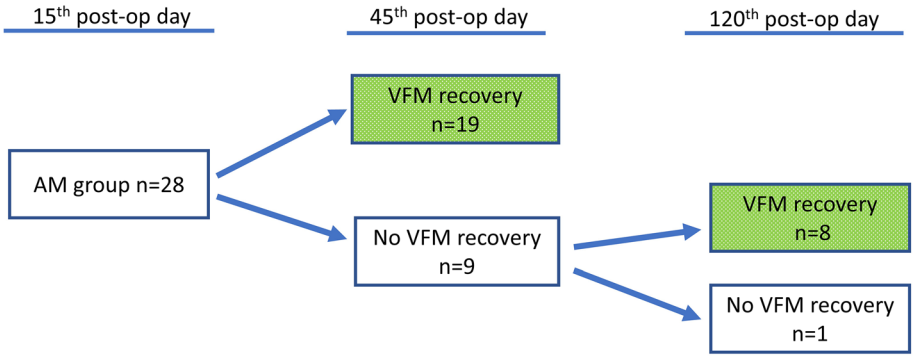

Fig. 1 In the arytenoid motility (AM) group at the 15th post-op day, consisting of 28 patients, 19 patients experienced vocal fold motility (VFM) recovery at the 45th post-op day and another eight patients at the 120th post-op day. One patient in total did not recover VFM

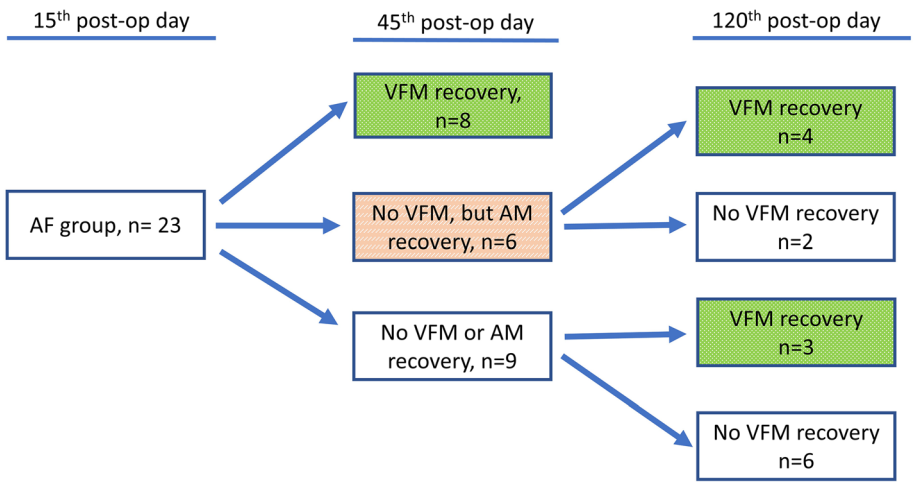

Fig. 2 In the arytenoid fixation (AF) group at the 15th post-op day, consisting of 23 patients, 8 patients experienced vocal fold motility (VFM) recovery at the 45th post-op day. Six of the patients recovered only AM at the 45th day and 9 did not recover VFM or AM. From the latter, 3 patients recovered VFM at the 120th post-op day while for the group that had recovered AM on the 45th day 4 out of 6 patients recovered VFM. Eight patients in total did not recover VFM

Table 5 Diagnostic accuracy values for progression of transient to permanent vocal fold paralysis based on intraoperative LOS type and arytenoid motility on 15th post-operative day

	Positive predictive value (%)	Negative predictive value (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
Type of LOS*	78	83	50	95	82
Type of LOS and arytenoid motility**	100	89	66	100	91

*Type I LOS was considered as a positive and Type II as negative test

**Type I LOS and arytenoid fixation was considered a positive test and type II LOS and arytenoid motility a negative test

results did not differ significantly between the two groups either (Table 3). Furthermore, smoking status, diabetes and operation time had no substantial effect on VFM recovery (Table 3).

Another predictive method that has been applied among studies is laryngeal electromyography [19, 20]. Laryngeal electromyography is able to provide an abundance of information but has a more invasive nature and is not carried out routinely in ENT examinations, while also demanding a high level of expertise to interpret the results. Therefore, electromyography examinations were not performed in this study, since they cannot be easily reproduced or easily applied in clinical practice.

A less sophisticated and more readily available tool is FFL, which findings can be used as a predictive factor. Published studies on laryngoscopy findings, predicting recovery of VFM, following thyroid operations are scarce. In a study by Reiter et al. [21], the authors identify positive mucosal waves on the paralyzed side and a minimal glottic gap < 3 mm seen at the first post-operative examination as

positive predictive factors for recovery, while Choi et al. [32] report the absence of compensatory movement of the normal side on videostroboscopy as an independent prognostic factor.

None of the above studies included [32] or managed to correlate [21] IONM results and FFL findings to predict progression of transient VFP to permanent. While, in an intriguing study by Huang et al. [22], IONM findings and perioperative voice parameters were examined to predict voice outcomes and can perhaps be applied on future ENT protocols.

In the present study, both type of LOS and evaluation of AM on the 15th post-operative day can predict to an extent permanent VFP ($p = 0.001$, RR = 9.25 and $p = 0.007$, RR = 9.739, respectively). By combining those two prognostic factors, valuable results can be yielded in predicting permanent VFP (positive predictive value: 100% and negative predictive value: 89%, Table 5).

Several limitations apply on this study. The main limitation is the small sample size of cases included. Early post-operative VFP is an infrequent event among high-volume and referral endocrine centers, while recovery of vocal fold function is common. Longer recruitment timeframes or multicentric protocols should be applied in future studies. Secondly, the follow-up of the included patients ended at four months. Based on FFL findings, displayed in Figs. 1 and 2, and by taking into account the existing literature on recovery after the first four post-operative months, one could assume that a noteworthy percentage of patients could still recover VFM. The four-month period of follow-up was decided in order to reduce potential loss to follow-up, since a large proportion of patients operated reside outside of our center's region. Despite that, 13.5% of patients were still lost at follow-up. Moreover, patients who have recovered normal voice performances are usually reluctant to undergo further follow-up, especially if they live far from the hospital. In addition, because of the need of AM evaluation, we could not rely on ENT evaluations performed outside our Institution. Future studies, with longer follow-up of at least 6 months, should be designed. Lastly, type I/II LOS was only accounted for when combined with VFP on the first post-operative day. This might render extraction processes challenging to include our data in potential future systematic reviews or metanalysis.

In conclusion, despite its limitations, the results of the present study demonstrated that IONM and FFL findings could accurately predict the natural course of VFP following thyroid operations. Consequently, clinicians might be able to better inform their patients on expectations of recovery accordingly. Similar findings could also help identify patients that would benefit from early permanent treatment, since timing of definitive intervention in cases of VFP is associated with improved quality of life [24]. Considering that only data from IONM and FFL were assessed, without including information generated from invasive procedures (i.e., laryngeal electromyography), such an approach could be easily reproducible in different clinical settings. However, taking into account the relative infrequency of VFP, further studies with larger patients' populations applying similar protocols are necessary to validate our results.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The authors declare to have read, understood and comply with the ethical requirements guidelines of SJEG. This study was approved by the Ethics Committee of Fondazione Policlinico Universitario Agostino Gemelli IRCCS (Protocol number: 23274/21).

Informed consent Informed consent was obtained from all individual participants included in the study.

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