

# Use of the montgomery implant system in medialization thyroplasty: postoperative vocal outcomes

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**Cite this article as:** Delahaut G, Lawson G, Remacle M, Ambroise J, Bachy V, Van der Vorst S. Use of the montgomery implant system in medialization thyroplasty: postoperative vocal outcomes. B-ENT XX XXXX 2021. 10.5152/B-ENT.2021.20336 [Epub Ahead of Print]

## ABSTRACT

**Objective:** Medialization thyroplasty using the Montgomery<sup>®</sup> Implant System (MTIS) is a surgical procedure for the treatment of persistent glottal gaps. In this study, we aimed to analyze postoperative vocal outcomes in patients suffering from unilateral vocal fold paralysis.

**Methods:** A retrospective study was conducted on 30 patients undergoing MTIS medialization thyroplasty for unilateral vocal fold immobility. This series was selected from 68 patients operated on by the same technique between 2009 and 2018. Patients with missing data were excluded. The surgical procedure was performed under local anesthesia and sedation with peroperative fiberoptic examination. A complete vocal assessment was undertaken pre- and postoperatively, including perceptual, aerodynamic, and acoustic parameters and a questionnaire. Short-term outcomes were analyzed.

**Results:** Postoperative assessment was performed at a median of 33 days (range eight to 216). Absolute median maximum phonation time showed an increase of 4.10 seconds (p < 0.05), whereas the voice handicap index decreased by 36 points (p < 0.05). No significant differences were found between sexes.

**Conclusion:** This retrospective study confirms the excellent immediate vocal results after medialization thyroplasty using MTIS. Further studies with prospective data are needed to evaluate the results according to sex of the patient.

Keywords: Dysphonia, laryngeal paralysis, medialization thyroplasty, montgomery implant, vocal outcomes

# Introduction

Unilateral vocal fold paralysis (UVFP) is a frequent cause of insufficient glottic closure. Patient symptoms are hoarseness and/or breathiness in voice with vocal fatigue. Complaints of dysphagia with potential aspiration are also often reported. The most common explanations include tumoral compression and surgical procedures involving lesions on the inferior laryngeal nerve or vagal trunk (1). If there is no treatable etiology and no recovery within six months, laryngeal framework surgery may be required.

Speech therapy is considered the first step in preventing supraglottic compensation. In case of failure, vocal cord augmentation and type I thyroplasty remain standard procedures to reduce the glottic gap, decrease vocal effort, and improve voice quality. Vocal fold injections of different materials have been successfully used in recent decades for small glottic gaps. The main disadvantages of these techniques are the lack of predictability in terms of voice outcomes, possible modifications to mucosal waves, and the need to repeat injections because of material resorption. In larger gaps with poorer voice quality or if injections technique fail, laryngeal framework techniques are preferred. Type 1 thyroplasty was first described by Isshiki (2) in 1976. It is now a standard technique where a rectangular window is created in the thyroid cartilage to introduce an implant and mobilize the vocal fold medially. Different kinds of implants are used around the world, such as cartilage or freeform (silicone or Gore-Tex) as well as preformed implants in silicone (Montgomery<sup>®</sup>, Phonoform<sup>®</sup>), hydroxyapatite, and titanium (2-7). However, there is a lack of comparative studies to assess the functional outcomes of these procedures.

In our institution, medialization thyroplasty is systematically performed with the Montgomery<sup>®</sup> Thyroplasty Implant System (MTIS) (5). In most patients, we do not associate this procedure

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CC BY 4.0: Copyright@Author(s), "Content of this journal is licensed under a Creative Commons Attribution 4.0 International License." with arytenoid adduction as described by other teams. We also use the MTIS for other indications of insufficient glottic closure, such as presbyphonia or after endoscopic cordectomies, and its safety and quick learning curve have been demonstrated (8). Implant testers of different sizes allow selection of the best implant size. Implants are designed for men and women; but owing to individual variability in larynx shape, some authors suspect that the implants may be poorly adapted. Indeed, Desuter et al. (9) reported poorer vocal outcomes in female patients. Literature on the MTIS and vocal outcomes nevertheless remains scarce (10, 11). In this study, we aimed to analyze vocal outcomes after MTIS procedure for UVFP, compare the results with other techniques, and evaluate the difference between sexes (12).

# **Methods**

# Population

All patients undergoing the MTIS surgical procedure between June 2009 and December 2018 were originally selected, representing 70 subjects. To avoid population disparity, we only included patients with UVFP. Exclusion criteria were other indications for MTIS and missing clinical data. Our final cohort of 30 patients was retrospectively investigated.

All the patients underwent a complete work-up, including preoperative and postoperative vocal assessments and fiberoptic and stroboscopic evaluations. Laryngeal electromyography and neck and chest computerized tomography (CT) scans were also performed in all the patients as part of the diagnostic work-up.

The surgery was carried out in our institution by three senior surgeons using the MTIS technique as described by Montgomery. The patients were anesthetized locally using lidocaine 2% with adrenaline (1/200,000) and adjuvant sedation with 1 mg midazolam and a titration of remifentanil. Anti-bioprophylaxis with cefazolin was given before incision. A cartilage window was achieved by drilling and calibrated with instruments designed for the MTIS. Fiberoptic examinations and vocal attempts were systematically conducted preoperatively to ascertain the best implant size. In a few patients, preoperative infraglottic pressure was measured and analyzed. A drain was put in place before closure and removed 24 hours after surgery. Cefuroxime was administered for five days after surgery.

## Vocal assessment

Vocal assessments included Hirano's perceptual scale (GRASB-I: grade [G], roughness [R], breathiness [B], asthenia [A], strain [S], instability [I]) (13). Aerodynamic measurements evaluated subglottic pressure, maximum phonation time

## **Main Points:**

- Reproducible and robust vocal outcomes with the Montgomery implant in unilateral vocal fold immobility
- Significant absolute maximum phonation time improvement (+4.1 seconds) and voice handicap index decrease (-36 points)
- No difference in terms of sex in the short-term outcomes in our cohort

(MPT), and phonation quotients. We also gathered acoustic data like fundamental frequency, frequency and intensity range, and the jitter, shimmer, and dysphonia severity index. The voice handicap index (VHI) was used as a self-assessment tool. In case of two successive postoperative vocal assessments, priority was systematically given to the first. Median postoperative assessment was performed after 33 (range eight to 216) days.

## **Statistical analysis**

Statistical analyses were conducted to evaluate the impact of surgery and sex on seven vocal outcomes (G, R, and B scores from the GRBAS-I scale, MPT, VHI score, phonation quotient, and jitter). Ordinal outcomes (G, R, and B scores) were modeled with cumulative logistic mixed-effects models and continuous outcomes (MPT, VHI score, phonation quotient, and jitter) with linear mixed-effects models. For continuous outcomes, we determined if log transformation was needed to meet the assumptions of the statistical model. When log transformation was required, the model's coefficients were back-transformed to compute the multiplicative effects of predictors. For ordinal outcomes, the model's coefficients were used to compute the odds ratio (OR) of predictors.

In each model, surgery and sex were introduced as fixed effects, whereas patient random effects were included to account for interpatient variability. A first-order interaction effect between surgery and sex was also incorporated into each model and removed when non-significant. All statistical analyses were conducted using "R.3.4.0." software (©The R Foundation).

## **Ethical considerations**

The study protocol was approved by the ethics committee of CHU UCL Namur- Godinne (82/2019). This retrospective study was performed with preexisting data extracted from medical files, and the exemption for informed consent was justified to avoid waking up patients or family distress.

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

# Results

## Population

Thirty patients met the criteria for the study, including 16 men and 14 women. Median age was 62 (range 33–80 years). Twenty subjects presented with left UVFP and 10 with right UVFP. The etiology of the disease was not specified. We encountered no extrusion or displacement of implants in our group, nor any major complications like hemorrhage or respiratory distress.

## **Perceptual analyses**

#### **G** score

The cumulative logistic regression model showed no significant interaction effect between sex and surgery. However, the G score was much lower after the operation as reflected by the highly significant OR of 0.01 (95% confidence interval [CI]: 0.001–0.073; p < 0.001) obtained for the operation variable. Median preoperative and postoperative results are shown in Table 1.

## Table 1. Vocal outcomes (median)

	G score	R score	B score	MPT (sec)	Phonation quotient (ml/sec)	Jitter (%)	VHI (points)
Median preoperative	2	1	2	4.8	520	4.7	66
Median postoperative	1	1	0	10.2	288	2.5	17

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Table 2. Vocal outcome comparison between authors									
	Number of patients	MPT	l (sec)	VHI§					
		Mean preoperative	Mean postoperative	Mean preoperative	Mean postoperative				
Montgomery et al. (11)	43	8.3 (men) 6.7 (women)	19.3 12.3	N/A <sup>‡</sup>	N/A				
Laccourreye et al. (10)	96	5	9.17	N/A	N/A				
Desuter et al. (9)	19	5	12.2	52	11				
Peretti et al. (16)	11	3.5	9.8	N/A	N/A				
Our group	30	4.8	10.2	65	21				

<sup>¶</sup>: MPT: maximum phonation time; <sup>§</sup>: VHI: voice handicap index; <sup>‡</sup>: N/A: not available





## **B** score

Postoperative values were significantly lower than preoperative values, resulting in a significant OR of 0.002 (95% CI: 0.00003– 0.058; p < 0.001) in the cumulative logistic regression model. However, no interaction effect was found for B score outcomes.

# R score

The regression model displayed a significant (p = 0.03) interaction effect between sex and operation; therefore, analyses were performed separately for each sex. Although a slight non-significant increase (OR = 1.39; p = 0.62) was detected in male patients, a strong and significant decrease (OR = 0.04; 95% Cl: 0.002–0.64; p < 0.05) was observed in female patients.

#### Aerodynamic measurements

## Maximum phonation time

A positive and significant increase of 4.5 seconds (95% CI: 2.5–6.6; p < 0.001) was observed for the operation variable in the linear mixed-effects regression model, but no significant interaction effect was encountered for MPT.

## **Phonation quotient**

A significant decrease in the phonation quotient was observed after surgery with a multiplicative effect of 0.56 (95% CI: 0.38– 0.84; p = 0.006) between pre- and postoperative values. No significant interaction effect was detected for this outcome.

#### **Acoustic analyses**

Surgery was associated with a jitter's significant decrease of 39% (95% CI: 12–56, p = 0.01). No significant interaction effect was found for jitter.

#### **Voice handicap index**

A decrease of 38 points was reached with surgery (CI: 25-50; p < 0.001) with the median preoperative VHI of 65 points falling to a postoperative result of 21 points. Decrease in the VHI was independent of sex.

# Discussion

Among laryngologists currently using the MTIS, only a few have published their functional outcomes with objective vocal parameters after surgery. In our series, each vocal parameter showed a significant improvement after surgery. Although we investigated only selected parameters, our results were sufficient to gauge the success of the MTIS for unilateral paralysis. Indeed, our data are comparable to those of other authors as described in Table 2.

However, separate analysis of our cohort points to a number of procedures that could be regarded as failures (Figure 1). If



Figure 2. Mean preoperative and postoperative maximum phonation time (seconds) according to sex

failure is defined as status quo or an increase in the VHI and status quo or a decrease in the MPT (the two most important parameters in our opinion), three out of 30 procedures (10%) may be considered as failures according to this nonacademic definition. Of the three patients involved, one was assessed only 10 days after surgery, which is too early to reach a conclusion. Another had a diagnosis of neuroborreliosis, which means that other parameters could well influence the vocal state. We found no explanation for the third patient.

A further issue is the difficulty of choosing a standard parameter to analyze vocal results in case of UVFP. The new European Laryngology Society consensus will help standardize the literature by ensuring that the same vocal parameters are assessed in all studies on the subject (1).

The retrospective design of our study led to considerable loss of data and necessitated exclusion of some patients. Moreover, we had different time intervals between surgery and postoperative assessment, which can result in bias. The mean interval was one month (range eight days to six months). We, therefore, present short outcomes with a median of one month; however, our data appear to show no adverse events or functional modifications after three months. Indeed, Desuter et al. (15) demonstrated very stable long-term follow-up of the MTIS on the basis of VHI; therefore, we believe it is not necessary to analyze vocal results after one year.

Evaluation of vocal parameters in terms of sex revealed no significant interaction effect after surgery. However, as shown in Figure 2, the increase in the mean preoperative MPT appears to be greater in men than in women without reaching significance. A larger population would be needed to resolve this issue. Data are still insufficient to consider redesigning the implant for female patients.

In conclusion, MTIS yields very good functional outcomes after medialization thyroplasty, comparable across different studies and similar to other types of implant. It is, therefore, a technique with reproducible results by different teams. We found the learning curve to be short, the procedure very well tolerated, and the vocal results robust. However, we encountered a few failures, reminding us that patient selection needs to be rigorous. Differences in terms of sex of the patients was insignificant in our cohort; however, definitive conclusions in this aspect can only be reached on the basis of analysis of larger cohorts in prospective multicentric studies.

Ethics Committee Approval: This study was approved by Ethics committee of CHU UCL Namur- Godinne (Approval n°82/2019).

**Informed Consent:** Verbal informed consent was obtained from the patients before surgery. Study was realised using retrospective analysis of preexisting files, no informed consent was obtained for study participation.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – G.D., S.V.; Design – G.D., S.V.; Supervision – V.B., S.V., G.L., M.R.; Materials – G.L., M.R., V.B.; Data Collection and/or Processing – G.D., J.A.; Analysis and/or Interpretation – G.D., S.V., J.A.; Literature Search – G.D.; Writing Manuscript – G.D., S.V.; Critical Review – S.V., V.B., M.R.

**Conflict of Interest:** The authors have no conflict of interest to declare.

**Financial Disclosure:** The authors declared that this study has received no financial support.

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