Very long-term Voice Handicap Index Voice Outcomes after Montgomery Thyroplasty: A cross-sectional study

G. Desuter1,2 | E. Zapater3 | S. Van der Vorst4 | S. Henrard5 | J.T. van Lith-Bijl1,6 | P.P. van Benthem2 | E.V. Sjögren2

1Otolaryngology, Head & Neck Surgery Department, Voice & Swallowing Clinic, Cliniques universitaires Saint-Luc, Université catholique de Louvain, Brussels, Belgium
2Otolaryngology, Head & Neck Surgery Department, LUMC, University of Leiden, Leiden, The Netherlands
3Otolaryngology, Head & Neck Surgery Department, Valencia Medical School, University General Hospital, Valencia, Spain
4Otolaryngology, Head & Neck Surgery Department, Hôpital universitaire UCL Namur, Mont-Godinne, Université catholique de Louvain, Yvoir, Belgium
5Institute of Health and Society (IRSS), Université catholique de Louvain, Brussels, Belgium
6Otolaryngology Department, Flevoziekenhuis, Almere, The Netherlands

Correspondence
G. Desuter, Otolaryngology, Head & Neck Surgery Department, Voice & Swallowing Clinic, Cliniques universitaires St-Luc, Université catholique de Louvain, Brussels, Belgium.
Emails: Gauthier.desuter@uclouvain.be; gdesuter@post.harvard.edu

Objective: The aim of this multicentric cross-sectional study was to examine the permanency of Montgomery thyroplasty (MTIS) results from a patient’s perspective.

Design: The study consisted of collecting Voice Handicap Index (VHI-30) questionnaires from patients who had previously been operated with MTIS between 2 and 12 years before. Very long-term (>2 years) postoperative data were compared with the previously acquired preoperative and early postoperative VHI results. Influence of factors such as age, gender, size/side of the prosthesis and length of the follow-up were also analysed.

Setting: Multicentric study involving three tertiary European voice centres.

Participants: Forty-nine unilateral vocal fold paralysis (UVFP) patients, treated by MTIS, were included in the study.

Main outcome measures: The Voice Handicap Index-30 score.

Results & Conclusions: The median VHI was significantly different over time-points (Friedman’s test \( P < .001 \)), with a significant difference between preoperative and early postoperative time-points (median VHI: 70 vs 21, respectively; \( P < .001 \)) and between preoperative and very long-term postoperative time-points (median VHI: 70 vs 16, respectively; \( P < .001 \)). The median VHI did not differ for the early and very long-term postoperative time-points (median VHI: 21 vs 16; \( P = .470 \)).

Age differences, gender differences and size/side differences of the prostheses, centres where surgery took place and length of the follow-up showed no significant influence. Medialisation thyroplasty (MT) overall and MTIS, in particular, should be considered as a possible standard of care for UVFP when permanency of voice results is sought.

INTRODUCTION

Unilateral vocal fold paralysis (UVFP) can lead to a breathy voice, phonatory dyspnoea and, in some cases, dysphagia. Many treatments have been advocated in the past for this debilitating condition. Other than voice therapy, four different surgical procedures have been proposed as treatment for UVFP: medialisation thyroplasty (MT), injection laryngoplasty (IL), arytenoid adduction or pexy (AA) and laryngeal reinnervation (LR). These techniques can be combined. For all four interventions, satisfactory short and long-term postoperative results have been shown.

The difference between short- or early- and long-term postoperative results, regarding UVFP surgery, however, has not been clearly defined. A recent literature review revealed that the term “short-term” has been used for follow-up periods up to 14 months after surgery, whereas “long-term” has been used already at 12 months...
after surgery, creating some semantic confusion. For more clarity, we defined very long-term results, as results that were obtained, at least, 2 years after surgery.

All the surgical techniques mentioned above have their advantages and limitations. Among them, MT presents a relatively low technical challenge. This is even more so for MT using the Montgomery Thyroplasty Implant System (MTIS) for which a short learning curve, good postoperative results and a low rate of adverse events have been shown. MT is also reputed to be a one-time procedure assuring long-term results. Many authors consider MT as the gold standard for permanent treatment of UVFP. Concerns remain, however, about the permanency of the results of MT due to possible vocal fold atrophy over time.

Only four studies address very long-term results of MT as defined by this study. None of these studies investigate MT performed with the MTIS. One of these studies is a case series of 5 patients, in two studies, voice results in terms of acoustics and aerodynamics parameters are evaluated, the last study regards voice results in terms of voice-related quality of life parameter. This last study concluded that “patients that were more distant from surgery had lower V-QROL scores than those who had more recently been treated.” In other words, the only very long-term study investigating voice results from a patients’ perspective demonstrated a fading of voice results in terms of voice-related quality of life in the course of time.

To assess very long-term voice results for patients undergoing a MT with the MTIS, we launched a multicentric cross-sectional study collecting Voice Handicap Index questionnaires (VHI-30) from patients operated at least 2 years before. These very long-term postoperative data were compared with the previously acquired preoperative and the short-term postoperative VHI results.

Influence of factors such as age, gender, size/side of the prosthesis and length follow-up were also analysed.

2 MATERIAL AND METHOD

2.1 Ethical considerations

The study protocol has been approved by the Ethical Committees of the University of Louvain affiliated institutions (file 2016/13SEP/394) and the by the Comision de Investigacion/Consortio Hospital General Universitario de Valencia (file 240217).

Patients from 3 different treatment centres, practicing the MTIS and meeting the inclusion criteria, were included.

To be included in the protocol, patients had to have undergone a MTIS—with no associated procedure—as surgical treatment for a UVFP, at least 2 years before inclusion. The UVFP had to be of neurogenic origin as defined by the ELS guidelines. There was no length of time limit for the follow-up. Patients had to be aged between 16 years and 80 years at the time of the MTIS. All patient’s files had to include a pre-op VHI-30 questionnaire and an early post-op VHI-30 that had been performed less than 12 months before and less than 14 months after the MTIS, respectively.

Fourteen months was chosen as this was found to be the cut-off between short and long-term post-op according to the literature. In case of multiple postoperative early VHI-30 assessments, the earliest data were considered for the study. The VHI-30 must have been validated and published for the language of use.

A careful electronic medical record (EMR) review excluded deceased patients and patients that had to undergo further voice surgeries after the MTIS.

This study is a cross-sectional, survey based, multicentric study filed on NIH’s ClinicalTrials.gov under the number NCT02969993 (first received November 18th 2016).

The study consisted of collecting VHI-30 questionnaires from patients who had been previously been operated with MTIS at least 2 years before. The questionnaires were obtained in two different ways. In case of centres 1 and 3, VHI-30 questionnaires were sent out by mail accompanied by an introduction letter and an informed consent that had to be returned. The patient certified having filled in the VHI-30 personally, with no assistance whatsoever. Furthermore, patients were asked to disclose possible further voice surgeries, new disease or conditions that could affect their voice quality. It was also possible for relatives to communicate about the death of the patient by returning the mail.

In case of centre 2, patients were invited by phone, to come to the hospital to fill in the VHI-30 along with an informed consent. Questions about possible further voice-related surgeries or conditions that could affect their voice quality were checked by phone. Patients were isolated alone in a room to personally fill in the VHI-30 questionnaire.

Deaths reported by relatives and patients presenting with post-MTIS surgeries, diseases or conditions that could affect voice quality, were excluded and not considered for the study.

All 3 centres entered their data in one Excel data bank. The data included anonymised identification of the patient, date of birth, gender, side and size of the prosthesis, date of the MTIS procedure, date and value of preoperative VHI-30, date and value of early postoperative VHI-30 and date and value of very long-term postoperative VHI-30. Inclusion and exclusion data were also checked for each centre.

Once data were obtained, very long-term (>2 years) postoperative data were compared with the previously acquired preoperative and early postoperative VHI results. Influence of factors: age, gender, size/side of the prosthesis, centre where surgery has

Keypoints

- Montgomery thyroplasty offers good results over a long period of time.
- Gender, age and prostheses size/side do not influence very long term results.
- Montgomery thyroplasty is a good standard of care when long term results are sought.
been performed, and length of VHI-30 follow-up was also analysed.

Continuous variables were summarised using medians, interquartile ranges and ranges. To analyse the evolution of VHI in time (repeated measurements: preoperative, early and very long-term postoperative), Friedman’s rank sum test, a nonparametric alternative to the parametric test one-way repeated measures ANOVA, was used. A pairwise comparison using Nemenyi multiple comparison test was then applied to identify significant differences between time period groups. Variables associated with the decrease in VHI over time were assessed using random effects-expectation maximisation (RE-EM) tree, a mixed effects model for longitudinal data, to take into account repeated measurements. Time period and patient identifier were inserted as random effects to take into account repeated measures for each patient. The centre was assessed as a fixed effect in the model because of the low number of categories (3 centres).

3 | RESULTS

Eighty-two (82) patients were considered for the study, as they had undergone a thyroplasty using MTIS for UVFP, as a sole procedure, that had been performed at least 2 years earlier. The number of deceased patients according to the data available in their EMR was 13, 1 and 0 for centres 1, 2 and 3, respectively. In none of the cases, the cause of death was related to the MTIS. The EMR review revealed one patient that underwent a complimentary injection laryngoplasty (IL) after MTIS because of unsatisfactory voice result. This additional procedure was performed within 2 years postoperatively. Therefore, in total, 15 of the initial 82 patients were excluded from the study.

The 67 remaining patients were asked to participate in the study. The VHI-30 score along with an accompanying letter and an informed consent form, to be returned, was sent to 33 patients from centre 1 and 16 patients from centre 3. Eighteen patients from centre 2 were invited by phone to fill in the VHI-30 questionnaire at the hospital. The overall response rate was 78% (81% for centre 1, 89% for centre 2 and 56% for centre 3).

Relatives informed authors of the death of 2 patients from centre 1. One patient from centre 1 informed authors about the occurrence of a voice impairing disease (the recurrence of metastatic thyroid papillary carcinoma for which he was treated with external radiotherapy). These patients were categorised as non-responders and excluded from the study. Finally, 49 patients were included in the study (24 from centre 1, 16 from centre 2 and 9 from centre 3).

Table 1 shows the patients characteristics of the cohort.

| TABLE 1 | Patients’ characteristics at the time of Montgomery Thyroplasty Implant System (MTIS) (n = 49) |
|-----------------------------|-----------------------------------------------|
| **Cohort characteristics** | **Median [P25; P75] (min-max) or n (%)**       |
| Age at time of surgery (y)  | 52.9 [42.3; 61.8] (16.3-74.5)                  |
| Gender ratio                | 34 (69.4) females                              |
|                            | 15 (30.6) males                                |
| **Prosthesis characteristics** |                                               |
| Side: left/right ratio      | 32 (65.3) left                                 |
|                            | 17 (34.7) right                                |
| Median Size of prosthesis   | 9 [8; 10] (6-12)                               |
| Size: large*/medium-small ratio | 34 (69.4) large*                              |
|                            | 15 (30.6) medium-small                        |
| **Number of patients by centre** |                                               |
| Centre 1                    | 24 (49.0)                                      |
| Centre 2                    | 16 (32.6)                                      |
| Centre 3                    | 9 (18.4)                                       |
| **Time intervals**          |                                               |
| Time between date of pre-op VHI assessment and date of surgery, in months | 3 [1; 3] (0-12) |
| Time between date early post-op VHI assessment and date of surgery, in months | 1 [1; 2] (0-14) |
| Time between date very long term post-op VHI and date of surgery, in months | 55 [42; 66] (24-142) |

VHI, Voice Handicap Index.

*Large size defined as ≥10 for males and ≥9 for females.
The median time between the preoperative VHI-30 and the surgical procedure was 3 months. The median latency for early postoperative VHI-30 was 1 month (0-14 months), and the median latency for very long-term postoperative VHI-30 was 55 months or 4.5 years (2-11.8 years).

The median [P25; P75] VHI score was 70 (59; 84) before the MTIS. It decreased to 21 [9; 37] and 16 [9; 30] in the early and very long-term postoperative period, respectively. The median VHI was significantly different over the 3 time-points (Friedman’s test $P < .001$) with a significant difference between pre-op and early post-op (median VHI: 70 vs 21, respectively; $P < .001$) and between pre-op and very long-term post-op time-points (median VHI: 70 vs 16, respectively; $P < .001$). The median VHI did not differ significantly between early and very long-term post-op time-points (median VHI: 21 vs 16; $P = .470$).

Figure 1 displays the linear graph (A) and boxplots (B) showing the evolution of VHI-30 scores over time in all patients.

The cohort was grouped by their latency period, that is, the period between the preoperative VHI-30 and the surgical procedure was 3 months. The median latency for early postoperative VHI-30 was 1 month (0-14 months), and the median latency for very long-term postoperative VHI-30 was scored. Two types of grouping were performed. The first grouping compared three latencies in years (from 2 to 4 years, from 4 to 8, longer than 8 years). The second grouping compared three latencies in months offering three comparable groups in terms of the number of patients ($<40$ months, 40-59 months and $\geq60$ months of latency).

Table 2 shows the difference in VHI-30 between different timepoints for the three different groups of latencies calculated with both grouping techniques. Results indicate no statistical difference of VHI-30 between early and very long-term postoperative assessment (of 8 years or more). This indicates a strong stability of voice results over time.

Four variables, possibly influencing these results, were analysed through the RE-EM tree technique. Results for age differences, gender differences and size/side differences of the prosthesis are displayed in Figure 2. None of these variables showed a significant effect on previously mentioned results.

A possible “centre” effect was also statistically ruled-out.

Table 3 displays a boxplot comparing VHI-30 results by centre.

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**Table 2** Voice Handicap Index decrease according to the time since the surgery (N = 49). Latency times in years (A). Latency times in months (B)

| Latency time | A | B |
|--------------|---|---|
|              | <48 months (4 y) (n = 19) | 48-95 months (4-8 y) (n = 22) | $\geq$96 months (8 y) (n = 8) | P-value |
| Pre-op       | 69.0 [56.5; 82.0] (42.0; 110.0) | 66.0 [52.3; 81.0] (28.0; 116.0) | 72.0 [68.0; 78.0] (61.0; 94.0) | .724 |
| Early post-op| 24.0 [9.0; 50.0] (0.0; 92.0) | 17.0 [8.3; 27.5] (1.0; 57.0) | 26.0 [20.8; 30.3] (17.0; 55.0) | .232 |
| Late post-op | 20.0 [11.0; 27.5] (1.0; 68.0) | 12.5 [4.8; 20.3] (0.0; 37.0) | 23.5 [16.8; 32.8] (8.0; 45.0) | .101 |
| Difference pre-op and early post-op | $-35.0 [-60.0; -23.0] (-102.0; 21.0)$ | $-44.0 [-57.8; -38.3] (-110.0; -6.0)$ | $-48.0 [-51.8; -43.8] (-56.0; -13.0)$ | .565 |
| Difference pre-op and very long-term post-op | $-49.0 [-62.0; -41.0] (-82.0; -3.0)$ | $-53.0 [-78.5; -36.5] (-116.0; -1.0)$ | $-52.0 [-55.3; -43.8] (-58.0; -23.0)$ | .791 |
| Difference early and very long-term post-op | $-5.0 [-23.5; 3.0] (-70.0; 21.0)$ | $-4.0 [-14.0; 4.5] (-40.0; 25.0)$ | $-5.0 [-9.3; 1.0] (-13.0; 10.0)$ | .959 |

| Latency time | A | B |
|--------------|---|---|
|              | <40 months (n = 15) | 40-59 months (n = 21) | $\geq$60 months (n = 17) | P-value |
| Pre-op       | 68.5 [53.5; 74.8] (42.0; 103.0) | 71.0 [58.0; 82.3] (28.0; 116.0) | 68.0 [61.0; 81.0] (49.0; 114.0) | .850 |
| Early post-op| 22.5 [11.8; 54.3] (1.0; 92.0) | 14.0 [7.5; 33.5] (0.0; 75.0) | 25.0 [20.0; 32.0] (3.0; 57.0) | .329 |
| Late post-op | 21.0 [15.8; 24.8] (5.0; 68.0) | 12.0 [0.0; 15.8] (4.8; 48.0) | 19.0 [12.0; 30.0] (0.0; 45.0) | .089 |
| Difference pre-op and early post-op | $-32.5 [-54.0; -18.5] (-102.0; 21.0)$ | $-47.5 [-60.0; -34.3] (-110.0; -20.0)$ | $-47.0 [-51.0; -40.0] (-94.0; -6.0)$ | .246 |
| Difference pre-op and very long-term post-op | $-45.5 [-51.5; -35.8] (-82.0; -3.0)$ | $-56.5 [-68.8; -43.3] (-116.0; -1.0)$ | $-53.0 [-56.0; -43.0] (-84.0; -23.0)$ | .279 |
| Difference early and very long-term post-op | $-3.5 [-20.5; 13.0] (-70.0; 21.0)$ | $-5.5 [-15.5; 2.0] (-40.0; 25.0)$ | $-4.0 [-13.0; 0.0] (-32.0; 19.0)$ | .981 |
DISCUSSION

Unilateral vocal fold paralysis has been defined in a consensus paper by Rosen et al.\(^1\) as unilateral vocal fold immobility of neurogenic origin. MT is considered to be a “permanent” treatment of UVFP by the majority of authors. However, there is a lack of data to support this permanency. After meticulous review of the literature, Siu et al.\(^2\) even postulated a progressive fading of MT’s results due to a possible continued vocal fold atrophy over the years. Hogikyan’s et al.\(^3\) results also seem to support this hypothesis in terms of voice-related quality of life.

The results of this study, however, strongly support the hypothesis that from the patient’s perspective, MT, in this case performed with the MTIS, offers a stable voice improvement over the years. MTIS results did not deteriorate over time and were independent of patient’s age and gender, prosthesis size and side. The postulated effect of muscle atrophy does not appear to be an issue. Whether this remarkably stable benefit can be called permanent remains a somewhat semantic debate.

This is the largest study assessing very long-term voice results of MTIS from the patient’s perspective. Ryu et al.\(^4\) conducted a retrospective study on 40 patients operated for MT with self-carved silicone implants in 2012. The long-term follow-up was performed using acoustic (Jitter, Shimmer) and aerodynamic measures (Mean Airflow Rate and Maximum Phonation Time). Their results were similar, showing stable early and very long-term (up to 5 years) postoperative results. They concluded their study by suggesting the launch of further very long-term studies on other implants and other voice outcome indicators.

Although VHI-30 is largely recognised as a valid self-evaluation tool,\(^5\) correlation between the subjective VHI-30 and objective acoustic and aerodynamic measures is poor.\(^6\) Therefore, this patient-centred approach represents a different way of very long-term assessment. Considering Ryu’s results and the results in this study, a 5-year permanency of MT results has now been established using two different research methods (cross-sectional vs retrospective), two different voice assessment approaches (VHI-30 vs acoustic and aerodynamic measures) and with two different types of implants (MTIS and self-carved silicone). Furthermore, this study demonstrates that variables such as age of the patient at the time of surgery, gender and prosthesis characteristics (size and side) do not influence the permanency of these results.

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The permanency of MT results is of particular interest when it comes to cost minimisation analysis and treatment decision-making. A recent Canadian study by Tam et al.\(^7\) compared the costs of MTIS vs repeated injection laryngoplasty (IL) with hydroxyapatite.

FIGURE 2 Boxplots comparing preoperative, early postoperative and late postoperative VHI-30 results for various variable grouping of the cohort. A, age of patients at the time of Montgomery Thyroplasty Implant System (MTIS), B, gender of patients, C, small and medium (S/M), or large (L) Montgomery prosthesis used. A large prosthesis is defined as being ≥size 9 for female patients and ≥size 10 for male patients. A, results by age of the patient at the age of Montgomery Thyroplasty Implant System (MTIS), B, results by gender. C, results by size of prosthesis.

FIGURE 3 Boxplots comparing preoperative, early postoperative and late postoperative VHI-30 results by centre.
concluded that, for a similar early (<2 years) effectiveness, IL will offer a cost saving of 596 CA$. However, the hydroxyapatite has a lifespan on average of 18 months.\textsuperscript{19} With the MT’s results now showing effectivity of at least 5 years, the cost/benefit analysis could switch in favour of MT, especially for patients with a life expectancy of more than 2 years. Further prospective studies should focus on individual life expectancy as a surgical decision-making determinant.

Some bias and limitations of our study should be taken into consideration. To gather enough patients meeting the inclusion criteria, a multicentric approach was chosen. The way the VHI-30 questionnaires were collected differed for one centre. Centre 2 invited patients by phone rather than by mail. Centre 2’s VHI-30 was also filled in within the clinic setting rather than at patients’ homes. This modification of data collection was considered more appropriate to the cultural and sociological background of this particular group of patients. Authors acknowledge a possible data collection bias, although no statistical differences in very long-term VHI-30 assessments were noted between centres.

Furthermore, although the MTIS procedure is known as an easily reproducible stepwise surgical approach, operative variances in techniques and variations in operative experience between centres might have influenced results. However, one complimentary injection laryngoplasty for unsatisfactory post-MTIS voice result out of 50 surgeries (2%) represents a lower failure rate than the MT failure rates that are published in the literature.\textsuperscript{20,21} Therefore, we believe that technical variability did not have a significant impact on our results.

Finally, as centres 1 and 2 had a response rate above the 80%, and centre 3 a response rate of 56%, this difference could also represent a possible bias. We do not have an explanation for this difference in responder’s rate except for the fact that some of this centre’s patients had been operated by a surgeon who left the institution. Some patients of centre 3 might have been less motivated by a request for participation signed by an unknown surgeon. Nevertheless, despite this caveat, the overall response rate (78%) was 10% higher than the response rate of Hogikyan et al. (68%)\textsuperscript{12} and was thus considered valid for interpretation.

5 | CONCLUSIONS

This study shows that MT performed with the MTIS offers permanency of voice improvement from the patient’s perspective. Age, gender, side of procedure and size of MTIS implants do not influence very long-term results in terms of VHI-30. Therefore, MT overall and MTIS, in particular, should be considered as a possible standard of care for UVFP when permanency of voice results is sought.

CONFLICT OF INTEREST

Author G.D. has act as proctor for Bess Inc., Berlin, in 2015-17. Author E.Z. has organised a congress partially sponsored by Bess Inc., Berlin in 2017. All other authors have no conflict of interest to declare.

ORCID

G. Desuter http://orcid.org/0000-0002-5303-5878

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How to cite this article: Desuter G, Zapater E, Van der Vorst S, et al. Very long-term Voice Handicap Index Voice Outcomes after Montgomery Thyroplasty: A cross-sectional study. Clin Otolaryngol. 2018;43:1097–1103. https://doi.org/10.1111/coa.13113