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Long-term outcomes of bilateral medialisation thyroplasty in patients with vocal fold atrophy with or without sulcus

Emke MJM van den Broek[1,2], Bas J Heijnen[1], Jens C van der Valk[1], Martine Hendriksma[1], Antonius PM Langeveld[1], Peter Paul G van Benthem[1] and Elisabeth V Sjögren[1]

[1]Department of Otorhinolaryngology/Head and Neck Surgery, Leiden University Medical Center, Leiden, The Netherlands and [2]Department of Otorhinolaryngology/Head and Neck Surgery, University Medical Center, Utrecht, The Netherlands

Abstract

Objective. Evaluate long-term voice outcome after bilateral medialisation thyroplasty in glottic insufficiency due to vocal fold atrophy with or without sulcus.

Methods. Patients after medialisation thyroplasty for vocal fold atrophy with or without sulcus were identified. Long-term post-operative subjective voice outcomes (> 1 year) using Voice Handicap Index-30, subjective ratings on voice aspects and study-specific questionnaire were compared to pre-operative and shorter-term (1 year) values.

Results. Thirty-six patients were identified, of which 26 were included (16 atrophy, 10 sulcus) with median follow up of 6.7 years. Mean Voice Handicap Index score at > 1 year (40.0) showed clinically relevant (≥ 15 for groups) and statistically significant improvement compared to pre-operative score (58.1) and remained stable compared to post-operative score (35.7) at one year. Ten patients (56 per cent) reported clinically relevant improvement (≥ 10) after more than five years.

Conclusion. Long-term improvement in subjective voice outcomes is attainable in a significant proportion of patients undergoing bilateral medialisation thyroplasty for atrophy with or without sulcus.

Introduction

Patients suffering from non-paralytic glottic insufficiency with or without sulcus have complaints of deteriorated voice quality, increased effort to speak, and reduced vocal load, leading to a negative effect on health-related quality of life and functional health status.[1,2] Several treatment options for non-paralytic glottic insufficiency caused by vocal fold atrophy with and without sulcus are known from the literature and our own clinical experience.[3–6] Treatment options can be grossly categorised three ways: (1) procedures improving glottic closure such as vocal fold injection with different materials or laryngeal framework surgery in the form of (bilateral) medialisation thyroplasty; (2) in case of sulcus, procedures improving mucosal wave by removing or replacing scar tissue such as microlaryngeal phonosurgery involving the subepithelial space with or without grafting; and (3) vocal fold injection using techniques from regenerative medicine. The different options also can be used in combination.

Regarding laryngeal framework surgery, the most used material for bilateral medialisation with mobile vocal folds is Gore-Tex (GORE-TEX® Soft Tissue Patch, Gore Medical, Flagstaff, Arizona) because it is not absorbed and is considered the most permanent treatment option for improving glottic closure. To our knowledge, available literature consists of only a few studies that have reported on long-term results for medialisation thyroplasty in this patient population.[4,7,8] In this study, we evaluate the results in our own cohort in order to further investigate the longevity of bilateral medialisation thyroplasty in voice outcome. These results will contribute to the challenging task of identifying the optimal, evidence-based treatment for patients with atrophy or atrophy with sulcus and will serve to support patients' counselling in this specific patient group.

Methods

Patients

Patients with non-paralytic glottic insufficiency who underwent bilateral medialisation thyroplasty with Gore-Tex implantation between October 2012 and January 2020 under local anaesthesia were retrospectively identified and asked to participate in this cohort study. For further description of the surgical technique, we refer to our previous publication on this subject.[6] All patients received speech language therapy, including

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Corresponding author:
Emke M.J.M. van den Broek;
Email: E.M.J.vandenBroek-7@umcutrecht.nl

resonant voice therapy and vocal hygiene advice, in their first post-operative year. To be included, surgery should have been performed at least one year earlier. The study was approved by the local medical ethical committee of the Leiden University Medical Center (N21.013).

Data collection

As a part of routine clinical care in our centre, multidimensional voice outcome data were collected according to a standard protocol at three time points: pre-operatively and at 3 and 12 months post-operatively. As part of this protocol, patients' perceived voice handicap is evaluated by the Voice Handicap Index-30 and supplemented by four subjective ratings on voice aspects that were used for this study. For the long-term follow up in this study (> 1 year post-operative) subjective data were collected with the use of a digital survey, including a repeat of the routine Voice Handicap Index-30 questionnaire and four subjective ratings on voice aspects supplemented by a study-specific questionnaire.

Voice Handicap Index

Patient self-assessment was performed using the Dutch validated version of the Voice Handicap Index-30.[9] The Voice Handicap Index-30 is considered a reliable and valid method to assess the effect of voice impairments and gives a score between 0 and 120 points. The questionnaire comprises 30 items, with a grading from 0 to 4 points (0 = never and 4 = always).[10] A score of 15 points or more in Voice Handicap Index-30 was used to identify patients with voice problems in daily life.[9,11] A change in pre- and post-operative score of 10 points or more in the individual patient and 15 points or more for a group was considered clinically relevant.[11]

Patient rating of voice aspects

In addition, patients were asked to rate their voice on four domains: (1) quality of voice, (2) effort of voicing, (3) possibility or limitation in voicing, (4) voice influence on life. These subjective ratings were based on a 10-point scale. In this numeric rating scale, 1 is considered very poor, 10 outstanding, 6 and above is considered a pass, 5 and below a fail.[12]

Study-specific questionnaire

In order to gain more details about the long-term effect of surgery, a study-specific questionnaire was used to gain more in-depth information. The questionnaire contained five questions. (1) Has your voice remained stable after the last check-up at the outpatient clinic, 1 year post-operatively? (Yes/No) (if no, go to question 2, if yes, go to question 4). (2) After how many months/years after the last check-up, did your voice start to change? How many months/years? (3) Try to describe as precisely as possible what has changed after this period (in general, quality, effort, vocal load). (4) Is your voice stable now? (Yes/No). (5) Is your voice better than before surgery? (Yes/No).

Statistical analysis

All data were analysed using SPSS (IBM SPSS Statistics for Windows, Version 21.0, released 2012; IBM Corp, Armonk, NY, USA). Demographic details were presented as median and range or as proportions using percentages. The effect of time on voice parameter was assessed with the linear mixed model and was adjusted for diagnosis (atrophy versus atrophy with sulcus) and for duration of follow up (1–5 years, > 5–7.5 years, > 7.5 years). The linear mixed model was chosen because it applies a correction for missing data. For all statistical tests, a p-value < 0.05 was considered significant.

Table 1. Patient characteristics

Characteristics	Total = 26 (100%)
Median age (range)	60 (20–77)
Gender, *n* (%)	
– Male	7 (26.9)
– Female	19 (73.1)
Aetiology, *n* (%)	
– Atrophy	16 (61.5)
– Atrophy with sulcus	10 (38.5)
Years since operation, median (range)	6.7 (2.4–9.0)
Revision surgery, *n* (%)	4 (15.4)

Results

Patient characteristics

Patients' characteristics are presented in Table 1. Thirty-six patients were retrospectively identified. Ten patients were excluded: five patients could not be reached (e.g. patient died, incorrect address), no consent was obtained for four patients, for one patient consent was obtained, but with no availability of any of the voice data. In total 26 patients were included. There were some cases of missing data (one-year Voice Handicap Index score $n = 2$, one-year and long-term Voice Handicap Index score $n = 1$, long-term Voice Handicap Index score and study-specific questionnaire $n = 2$). These patients were therefore excluded in the descriptive statistics of the various modalities. In the analysis of the effect of time on voice the missing data were corrected using the linear mixed model.

Voice Handicap Index

The mean Voice Handicap Index score was 58.1 pre-operatively, 35.7 at one year follow up and 40.0 at more than one year follow up. Improvement from pre-operative to one year (Δ 22.4), and from pre-operative to more than one year (Δ 18.1) was clinically relevant (≥ 15 points, as defined for groups) and statistically significant ($p < 0.001$) for both time frames. The change in Voice Handicap Index from one year to more than one year (Δ 4.3) was neither clinically relevant nor statistically significant ($p = 0.328$). Improvement in Voice Handicap Index was similar in patients with atrophy only and with sulcus ($p = 0.908$) (Table 2).

Table 3 shows the Voice Handicap Index change grouped according to the length of follow up: 1–5 years, > 5–7.5 years and > 7.5 years. These results are in line with the results in Table 2, except for the group of 1–5 years. In this group the Voice Handicap Index score at more than one year was 50, which, although lower than the pre-operative score, did not reach the threshold for statistical significance or clinical relevance. Looking at individual patients, in the two groups with

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Table 2. Voice Handicap Index results overall and atrophy or sulcus

Voice Handicap Index results	Pre-operative Mean (95% CI)	Post-operative 1 year Mean (95% CI)	Post-operative > 1 year Mean (95% CI)
Total ($n = 25$)	58.1 (50.1–66.0)	35.7 (27.4–43.9)	40.0 (31.9–48.2)
Atrophy ($n = 16$)	57.7 (48.6–66.8)	35.3 (26.1–44.4)	39.7 (30.3–49.0)
Sulcus ($n = 9$)	58.4 (47.0–69.8)	36.0 (24.3–47.8)	40.4 (29.0–51.9)

* p-value < 0.05 was considered significant.

Table 3. Voice Handicap Index results stratified in length of follow up

Follow up	Pre-operative Mean (95% CI)	Post-operative 1 year Mean (95% CI)	Post-operative > 1 year Mean (95% CI)
Follow up 1–5 yr ($n = 7$)	63.7 (48.2–79.2)	35.9 (20.3–51.4)	50.0 (34.5–65.5)
Follow up >5–7.5 yr ($n = 9$)	53.8 (41.7–65.9)	26.6 (13.8–39.5)	26.0 (13.1–38.8)
Follow up >7.5 yr ($n = 9$)	57.7 (43.8–71.5)	45.5 (31.3–59.6)	45.1 (30.9–59.3)

* p-value < 0.05 was considered significant.

the longest follow up (> 5 years, $n = 18$) there were 10 patients (56 per cent) with a long-term clinical improvement in Voice Handicap Index of ≥ 10 points as defined for individuals. Three patients had a clinical improvement that did not reach the threshold for clinical relevance and three patients had a deterioration compared to pre-operative values, of which only one was clinically relevant (data not shown).

Patient rating of voice aspects

Pre-operative ratings of voice aspects were available in 26 patient and long-term ratings for 24 patients. Ratings for the different time points are shown in Table 4. Ratings pre-operatively ranged from 4.0 to 5.0, which could be considered unsatisfactory. The one year post-operative rating and the best post-operative rating ranged from 6.0 to 7.5. At more than one year the ratings could be considered satisfactory, ranging from 5.5 to 6.0.

Table 4. Voice rating, numeric rating scale 1–10 (1 = poor, 10 = outstanding)

	Rating (0–10)	median (IQR)
Quality	pre-operative ($n = 26$)	4.0 (2)
	post-operative 1 year ($n = 23$)	7.0 (3)
	post-operative best ($n = 24$)	7.0 (2)
	post-operative > 1 year ($n = 24$)	6.0 (4)
Effort	pre-operative ($n = 26$)	4.0 (3)
	post-operative 1 year ($n = 23$)	7.0 (3)
	post-operative best ($n = 24$)	7.0 (2)
	post-operative > 1 year ($n = 24$)	5.5 (5)
Possibility	pre-operative ($n = 26$)	4.5 (3)
	post-operative 1 year ($n = 23$)	6.0 (3)
	post-operative best ($n = 24$)	7.0 (3)
	post-operative > 1 year ($n = 24$)	6.0 (5)
Influence	pre-operative ($n = 26$)	5.0 (4)
	post-operative 1 year ($n = 23$)	7.0 (4)
	post-operative best ($n = 24$)	7.5 (5)
	post-operative > 1 year ($n = 24$)	6.0 (5)

Study-specific questionnaire

Two of the 26 patients had not answered the questionnaire and were excluded from further analysis ($n = 24$). Fifteen patients rated their present voice as being better than their pre-operative voice (62.5 per cent). Regarding stability of the voice, 10 patients (42 per cent) reported no voice change since the last follow up at one year post-operatively. Fourteen (58 per cent) of the patients did report voice deterioration after the one-year follow up, consisting mostly of voice fatigue and hoarseness, and occurring at different time points between one and nine years after surgery (median three years). Of these 14 patients, 6 patients rated their voice as stable at present and 8 patients rated their voice as unstable at present.

Discussion

In this study we evaluated the long-term results (more than one year) of bilateral medialisation thyroplasty in patients with atrophy with and without sulcus. We also compared these long-term data to data collected routinely before the procedure and at one year after the procedure.

The average long-term post-operative Voice Handicap Index scores in our cohort showed enduring improvement that was clinically relevant and statistically significant both in patients with and without sulcus. This is in accord with our earlier studies in which we also found no difference between the results of patients with atrophy and atrophy with sulcus.[5,6]

For individual patients with more than five years of follow up ($n = 18$), 56 per cent still reported a clinically relevant improvement compared with the pre-operative state. This shows that on average, stable and long-term Voice Handicap Index improvement after bilateral medialisation can be achieved and that this long-term improvement is applicable to about half of the patients. As has been reported earlier, the Voice Handicap Index scores from this study also show that although voices improve they do not normalise and that some voice burden still is to be expected.[6]

When stratifying for length of follow up, this same general effect was seen in the groups with longer follow-up lengths of > 5–7.5 years and > 7.5 years, but not in the follow-up period of 1–5 years. In this group, after having shown an initial significant improvement at one year, the Voice Handicap Index score deteriorated in the long-term follow up to scores that were in range of the pre-operative values. The underlying cause for this observation in the youngest follow-up group remains unclear. Possible explanations could be sought in a change in the case mix, an unconscious change in operative technique, or just chance in this small number of patients. However, these speculations can neither be proven nor disproven by the current data. An additional challenge when working with Gore-Tex® is the risk of change in implant volume or position due to the compression of the malleable material over time. It has been speculated that this may require some degree of overcorrection.[13] However, this effect would be present in all groups and would not be expected to have affected

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one group specifically. Nevertheless, we have started a pilot study to capture these possible volume and position changes on serial post-operative magnetic resonance imaging with the aim to better predict the optimal amount of overcorrection during surgery.

The subjective ratings were designed to mirror the grading system in Dutch schools, with 1 being the poorest score, 10 being the best score and 6 being the lowest 'passing score'. Using this approach, the pre-operative voice scores (range 4–5) can be considered unsatisfactory whereas the scores at one year (range 6–7.5) can be considered satisfactory or in some cases even good. Although the long-term scores showed a decline (range 5.5–6), they can still be considered around the satisfactory threshold and therefore better than the pre-operative scores. Although two out of three patients reported some voice deterioration in the long-term follow up in the study-specific questionnaire, most patients (62.5 per cent) rated their present voice as being better than their pre-operative voice. In summary, the subjective voice parameters used in this study (Voice Handicap Index scores, subjective ratings and the specific questionnaire) show the same trend: significant voice outcome improvement after surgery that remains stable in the first year and then shows some deterioration in the long term, although voices remain satisfactory on average.

Only a limited number of studies report on subjective, long-term voice outcome (more than one year) after medialisation thyroplasty in patients with atrophy with or without sulcus.[4,7,8] The study by Overton et al., which is the only study with follow up longer than 1.5 years, included patients with glottic insufficiency of the mobile vocal folds (total $n = 75$, atrophy $n = 14$, scar $n = 18$). The long-term follow up was divided into 1.5–3 years (total $n = 23$, atrophy $n = 4$, scar $n = 4$), 3–5 years (total $n = 13$, atrophy $n = 3$, scar $n = 2$) and 5–10 years (total $n = 12$, atrophy $n = 1$, scar $n = 3$). Although significant improvements were maintained in the long term for the study group as a whole, this did not apply to the atrophy and scar subgroups. For atrophy, the initially significant improvements in voice-related quality of life and Glottal Function Index were not maintained after more than one year follow up. For scar, no statistically significant improvement was seen at any of the tested time points.[7] In the study by Welham et al., dedicated specifically to patients with sulcus or scar, significant improvement in long-term Voice Handicap Index-30 scores after medialisation thyroplasty was noted ($n = 9$).[4] Reported in graph form, the Voice Handicap Index scores can be estimated at around 60 points pre-operatively and 30 points at 18 months.[4] Finally, Dominguez et al. reported significant improvement in long-term subjective outcomes (Voice Handicap Index-10 and Glottal Function Index) after medialisation thyroplasty in a mixed cohort of patients ($n = 20$, 20 per cent atrophy, 30 per cent paresis, and 50 per cent atrophy and paresis). In this study the Voice Handicap Index-10 decreased from 30.5 to 15.0 at 16.3 months (normal value English version Voice Handicap Index-10, ≤ 11[14]).[8]

In view of the above, we conclude that several studies, including our own study, show that (bilateral) medialisation thyroplasty can offer significant, long-term voice improvement in patients with atrophy and sulcus, but that not everyone will benefit.[4,8] This individual variation is supported by the large variations around the mean of outcomes in most studies. Also, because voices do not generally normalise, there is a persisting voice burden and possibly the need for revision surgery, additional treatment, or both. This raises the question: how satisfying are the long-term results of laryngeal framework surgery compared to other techniques, taking into regard the surgical procedure, surgical time and patient burden?

As mentioned in our introduction there are grossly three groups of operative techniques to treat vocal fold atrophy with or without sulcus. Firstly, there are the procedures to improve glottic closure: vocal fold injection and laryngeal framework surgery. In addition to the results of laryngeal framework surgery that have already been discussed, long-term results after vocal fold injection techniques have also been reported ranging from one to five years.[4,8,15–17] In their study from 2011, using hyaluronic acid, micronised acellular dermal matrix or calcium hydroxylapatite, Welham et al. reported no significant changes in Voice Handicap Index score in patients with sulcus or scar or both ($n = 9$) at any time up to 1.5 years post injection, with scores remaining close to pre-treatment values.[4] This could partially have been due to the short life-span of two of the substances used for injection (hyaluronic acid or micronised acellular dermal matrix). Dominguez et al. compared their results after medialisation thyroplasty, as discussed previously, to those of vocal fold injection with autologous fat in a mixed cohort of patients ($n = 15$, 35.7 per cent atrophy, 14.3 per cent paresis, 50 per cent atrophy and paresis). The results of vocal fold injection showed a significant improvement in Voice Handicap Index-10 at three months, but then a decrease with a score close to the pre-operative level at 19 months (pre-treatment 27.8, post-treatment 23.5).[8] In a recent study, Lahav et al. found long-lasting improvement up to three years for vocal fold injection with autologous fat in a mixed patient group (50 per cent unilateral vocal fold paralysis and 50 per cent atrophy or scar).[17] The results show an average decrease in Voice Handicap Index-30 for the whole group from 73.5 pre-operatively to 52.8 at 3 months with further decreases in time ending at 44.9 at 3 years. This trend was seen in both the unilateral vocal fold paralysis and the atrophy or scar group. Finally, Cantarella et al. and Zelenik et al. both reported long-lasting improvement after vocal fold injection with autologous fat or calcium hydroxylapatite, but the relevance of their studies for our purpose is difficult to assess due to very small proportions of patients with atrophy or scar without stratifications of the results.[15,16] In summary, we conclude that extent of long-term benefit of vocal fold injection in this patient group is still unclear, with the two largest studies in this field showing conflicting results.[8,17] Again, the large outcome variations around the mean also suggest that results will vary individually.

Secondly there is microlaryngeal phonosurgery for scar and sulcus involving the subepithelial space. The longest follow up reported for this type of surgery is 1.5 and 3 years from two studies, both using fascia temporalis implantation in patients with vocal fold scar or sulcus.[4,18] In the study by Welham et al., which also reported results for vocal fold injection and laryngeal framework surgery, only the best post-operative Voice Handicap Index, which was not attained until 18 months after the procedure, showed significant improvement compared to pre-treatment values. Reported in graph form, the Voice Handicap Index scores can be estimated at around 60 points pre-operatively and just below 30 points at 18 months. Given that the ultimate result at 18 months for graft implantation was equivalent to that of their laryngeal framework surgery group, but that the recovery trajectory was slower, Welham et al. concluded that their data did not support graft implantation as a primary treatment modality for patients with vocal fold scar or sulcus.[4] Tsunoda et al.

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used mean phonation time and laryngostroboscopic findings to report on voice outcome, with post-operative mean phonation time being significantly improved up to three years after graft implantation.[18] Because the study lacks subjective (self-evaluation) voice outcomes, it is difficult to compare their results with our findings.

- Long-term subjective improvement in voice outcome is attainable after bilateral thyroplasty with Gore-Tex for atrophy with or without sulcus
- Voices will not normalize and not every patient will benefit
- Results seem comparable to other treatment options such as vocal fold injection and microlaryngeal phonosurgery
- Additional research is needed with larger series and longer follow up for all treatment modalities

Lastly, in recent years, more and larger in-vivo studies in the field of regenerative medicine have been published. The largest series to date, with an average follow-up time of one year, reported on injection of basic fibroblast growth factor in 100 patients with atrophy, scar or sulcus.[19] Improvements in Voice Handicap Index-10 were statistically significant in all groups (atrophy 22.7 to 12.2; scar 24.7 to 12.5; sulcus 24.4 to 17.7), but an intergroup comparison showed that improvement in the atrophy group was significantly higher than in the scar or sulcus groups. Nevertheless, both the atrophy group and the scar group can be considered to reach nearly normal values (normal value English version Voice Handicap Index-10 is ≤ 11).[14] As in other studies, the variation in the post-procedure scores was large, ranging from 6.4 to 9 points for the different subgroups. The longest follow up reported until now is 2–3 years.[20,21] Although the series are small (19 and 6 patients, respectively), the results are promising. The largest series, 19 patients (9 atrophy, 8 sulcus and 2 unilateral vocal fold paralysis), showed significant improvement up to 36 months in perceptual Grade Roughness Breathiness Asthenia Strain score, mean phonation time, and endoscopic findings (minimal glottal area and minimum distance between focal folds).[20] Unfortunately, subjective voice outcomes were not included in this study. The study by Sueyoshi et al. did include subjective voice outcome, in addition to acoustic, aerodynamic and endoscopic outcomes. The Voice Handicap Index-10 showed not only significant improvement, but also close to normal Voice Handicap Index-10 scores at two years (data estimated from graph), indicating high patient satisfaction.[21] These three studies therefore carefully suggest that with regenerative surgery it might be possible to obtain long-lasting nearly normal voice outcomes.

Our study is subject to a number of limitations. The retrospective study design and a portion of non-responders (10 of 36 patients) may have led to non-response bias, which could mean either over- or underestimation of our results. However, because our data are in line with data from the literature, we judge this bias to be small. Although there were also some missing data under the responders, these were limited and corrected. In this study we used different subjective voice parameters, and in line with our study on trial vocal fold injection, we noticed only a partial overlap in these subjective voice parameters.[22] Therefor the question remains if the Voice Handicap Index, the main outcome measurement instrument used in this study, is valid and precise enough for this specific population of patients and what outcome measurement instrument would be the best alternative. We therefore again stress the need for further research on the most appropriate voice-outcome measurement instruments in this group of patients. Developing a predictive model to forecast long-term outcomes can be of supplemental value to the decision-making process for these procedures.

Conclusion

Our study shows that long-term improvements in subjective voice outcomes are attainable in a significant proportion of patients undergoing bilateral medialisation thyroplasty with Gore-Tex® for atrophy with or without sulcus, although voices will not normalise and not every patient will benefit. The results are comparable to other treatment options such as vocal fold injection, microlaryngeal phonosurgery and regenerative medicine procedures since residual voice handicap and large variations in outcomes are seen in all of the small number of studies in this area, although the sparse data available so far suggest that the residual voice handicap may be limited after regenerative procedures. The benefit of medialisation thyroplasty currently seems to be that results are attained quicker than after microlaryngeal phonosurgery and that there is more of evidence available of a long-lasting effect than for vocal fold injection in this patient population. We do however stress the need for larger series with longer follow up for all these treatment modalities.

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