Postlaryngectomy prosthetic voice rehabilitation themes

B.M.R. Op de Coul

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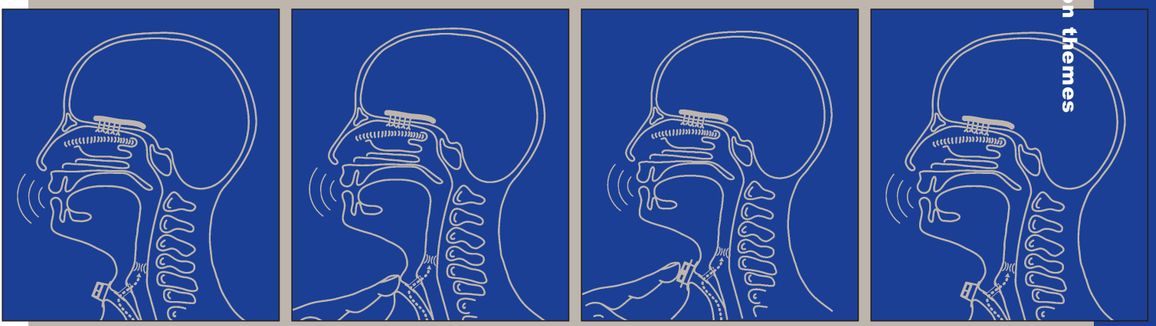
Long-term results, neoglottic imaging, quality of life, and hands-free speech



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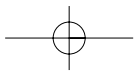

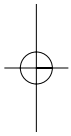

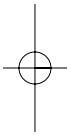

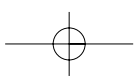

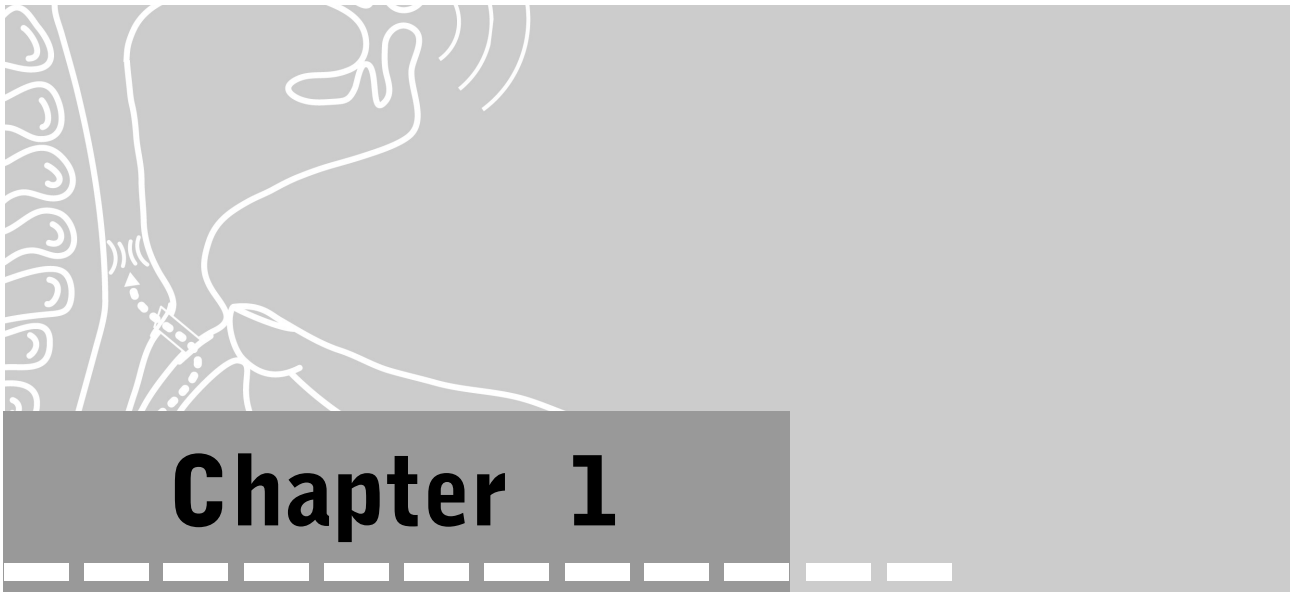

Chapter 1

General introduction

General introduction

Laryngeal cancer is the most common head and neck malignancy in the Netherlands with approximately 600 new sufferers annually. [1, 2] Fortunately, the majority of these patients can be treated with organ preservation strategies, predominantly radiotherapy or limited (CO2 laser) resection. Removal of the complete organ, i.e. total laryngectomy, is reserved for locally advanced disease [3] or recurrent disease after previous (radio)therapy. Although there are further promising developments in organ preservation protocols by combining chemotherapy with radiotherapy [4], especially in the case of a vulnerable organ such as the larynx, organ preservation is not at all synonymous with function preservation. Therefore, it can be expected that total laryngectomy will have to be carried out still quite often, if not for oncological reasons, then for functional ones. Furthermore, the side-effects of chemoradiation seriously affect the quality of life of the patient, although in a different way from total laryngectomy. Hannah et al. concluded in a recent study that chemoradiation and total laryngectomy had different effects on the quality of life of patients treated for advanced cancer of the larynx. Although these differences could be detected by functional and subscale analyses, the overall quality of life scores in the two groups were similar. [5] Wayne Koch, also discussed quality of life issues in patients after laryngectomy versus chemoradiation in a recent review. They stated that tracheoesophageal puncture enabled high-quality voice restoration in most individuals after total laryngectomy. Although none of them would have chosen to undergo total laryngectomy to treat their life-threatening condition, at least some achieved better quality of life, including better vocal function, after surgery and rehabilitation than the patients who received chemoradiation. Total laryngectomy is a far from perfect solution, but with tracheoesophageal puncture, it improved the quality and quantity of life to a group of individuals whose only treatment option was to undergo debilitating surgery in order to prolong their life. [6]

Aim of this thesis

The aim of this thesis was to improve our knowledge on factors that determine the outcome of prosthetic voice rehabilitation after total laryngectomy. Prosthetic speech was assessed in a large cohort of patients to obtain data on the long-term success rate of this rehabilitation method (chapter 2) and the occurrence and management of the side-effects. In addition, we studied the anatomy and morphology of the new 'sound source' (the neoglottis) using new methods of imaging and evaluation protocols are used (chapter 3). Quality of life was measured in relation to the anatomical changes brought about by total

laryngectomy and to the rehabilitation results. Structured questionnaires were used, which not only enabled assessment of overall and disease-specific quality of life, but also intervention-specific changes in voicing and the other functional side-effects of total laryngectomy (chapter 4). Hands-free speech with an automatic speaking valve is the closest a patient can get to normal laryngeal voicing. We evaluated a recently developed automatic speaking valve to establish whether it was possible to achieve this ultimate goal in the rehabilitation process (also chapter 4).

Total laryngectomy

Functional side effects of total laryngectomy are still important issues to study. These are the result of removal of the entire larynx (voice box) and redirection of the trachea towards the skin at the base of the neck, where a stable tracheastoma is created (see Figure 1). [7] The consequences are permanent disconnection of the upper and lower airwaysand the need for vocal (loss of the voice box), respiratory (loss of the cleaning, heating and moistening function of the nose) and smell (loss of passive nasal airflow) rehabilitation, which remain aspects of major concern in total laryngectomy patients.

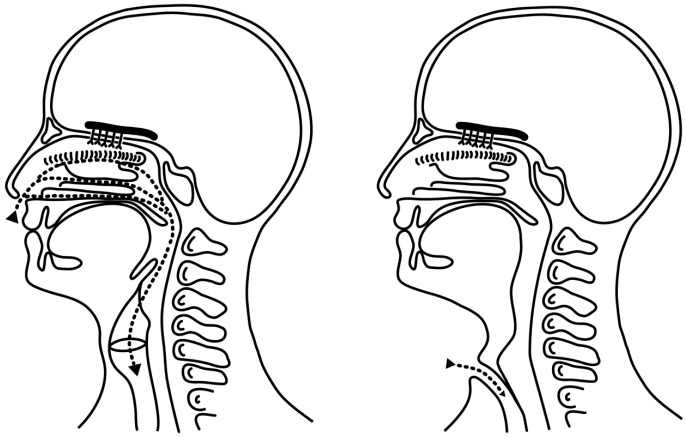

Figure 1 Patient before and after laryngectomy

Billroth performed the first laryngectomy for cancer in 1873. Since then i.e. for more than 100 years, loss of the normal voice had been considered the dominating rehabilitation problem following this procedure. Although Guttman reported tracheoesophageal shunt speech as early as in 1931, the majority of total

laryngectomy patients were using oesophageal speech and/or an artificial larynx for communication until the nineteen eighties. [8] Tracheoesophageal vocal rehabilitation methods are regarded to be more successful modes of restoring communication after total laryngectomy than oesophageal and electrolaryngeal voice techniques#. Therefore, tracheoesophageal methods can be considered as the 'golden standard' in postlaryngectomy vocal rehabilitation. Better and more consistent vocal rehabilitation results could be achieved using tracheoesophageal speech, especially since the introduction of voice prostheses, initiated by Singer and Blom. [9] In essence, a voice prosthesis is a one-way valve that is inserted into a fistula between the trachea and oesophagus. The fistula is mostly created during the total laryngectomy procedure. The one-way valve principle allows air to flow into the oesophagus and pharynx after the stoma has been closed and prevents fluids, food or saliva from entering the trachea and lungs. (see Figure 2).

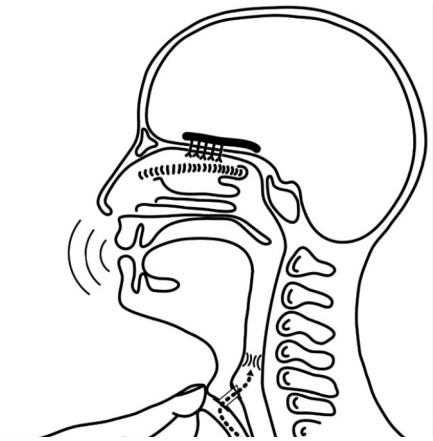

Figure 2 Digital occlusion of the tracheostoma during phonation

The use of various prostheses has become widely accepted in recent years. Two different types of prosthesis can be distinguished: non-indwelling devices [9, 10] that can be removed and replaced by the patient and indwelling voice prostheses require the intervention of a medical professional.[11-13]

Tracheoesophageal voice: the entire lung capacity is available for voicing as is also the case in normal laryngeal voicing. By closing the stoma, pulmonary air can be diverted into the pharynx through a surgically created fistula. This causes the mucosa to vibrate in the pharyngoesophageal segment, also called the pseudoglottis or neoglottis. Oesophageal voice: 60-80 ml of air is injected downwards into the oesophagus and subsequently expelled into the neoglottis to cause mucosal vibrations. Electrolaryngeal voice: vibrations produced by an electronic device are transmitted through the skin into the pharyngeal cavity and modulated in the vocal tract into intelligible speech.

In 1988, the indwelling Provox® voice prosthesis was introduced. This voice prosthesis was designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device life, simple patient maintenance and comfortable outpatient replacement.[12] As the last criterion was not optimally fulfilled, i.e. uncomfortable retrograde replacement, there was a need for further innovation, which the resulted in the second-generation device, Provox®2. It has a more comfortable anterograde replacement method, using a special disposable guide-wire.[14, 15] In chapter 2, 10 years of clinical experience are described with the consistent use of the above-mentioned two indwelling voice prostheses (Provox® and Provox®2) for vocal rehabilitation after total laryngectomy. Long-term results were analysed in a large, unselected cohort of patients and special attention was paid to the importance of adequate management of the adverse events inevitably encountered with any prosthetic rehabilitation method.

Neoglottic imaging

As mentioned above, prosthetic tracheoesophageal speech is the most successful method of vocal rehabilitation presently available. Success rates of up to 90% have been reported in recent years. [16-19] Various studiesshowed that tracheoesophageal speech gave better results than oesophageal and/or electrolaryngeal speech. [9, 20-23] Despite this progress, not all the patients acquire good tracheoesophageal speech and the reasons are not always clear. Besides possible psychological, social and educational factors, variations in surgical techniques may also influence the success of this form of alaryngeal speech and result in suboptimal anatomy and/or morphology of the new sound source,.[24-27] Imaging studies on the new sound source are essential to uncover the reasons for suboptimal voicing.

Chapter 3 evaluated several of the methods presently available for neoglottic imaging, i.e. videofluoroscopy (VF) and high-speed digital endoscopy (HS).

Videofluoroscopy, a radiographic contrast study, is the most frequently used method to investigate a new sound source. Until recently, this imaging technique was mostly performed on oesophageal speech [28-37]. Far fewer studies are available on the neoglottis in tracheoesophageal speech. [38] VF enables visual assessment of anatomical and morphological characteristics of the neoglottis at rest and during phonation and swallowing. However, application of the assessment methods published in the literature meant that it was difficult to reach consensus judgement, because no differentiation was made between anatomy and morphology.

In **chapter 3.1**, a new 'quantitative videofluoroscopy' protocol is presented to evaluate the anatomy and morphology of the neoglottis in a more standardised manner. Lateral X-ray recordings of the PE-segment were measured quantitatively using software initially designed to measure tumour volumes for radiotherapy purposes. This method leaves only one subjective parameter, i.e. tonicity of the neoglottis during phonation, whereas the remaining parameters are more or less 'objective', with clear dichotomies or numbers.

The availability of the new protocol using quantitative videofluoroscopy to analyse the anatomy and morphology of the neoglottis enabled to improve tracheoesophageal speech with the neoglottis. One technique that aims to improve voice quality in patients with hypertonic speech is myotomy (sectioning the muscle to prevent concentric contraction) of the upper oesophageal sphincter, also called the cricopharyngeal muscle. Singer et al. were the first to identify the importance of optimal tonicity of the pharyngoesophageal segment and the potential of constrictor pharyngeus myotomy to improve voice quality, in 1981.[39] Suggestions have also been made about peroperative closure or non-closure of the muscular layer. Unilateral neurectomy (sectioning the nerve branches to prevent contraction of the muscle) with or without simultaneous myotomy (to prevent hypertonicity or spasm of the neoglottis) was found to have an impact on the success of postlaryngectomy vocal rehabilitation. [27, 39, 40] The effects of surgical interventions were mostly studied by means of insufflation tests and/or radiographic contrast studies, either by plain photography or more dynamically by videofluoroscopy. [32-34, 41] **In chapter 3.2**, the quantitative videofluoroscopy protocol (described in chapter 3.1) was used to study the anatomical and morphological characteristics of the neoglottis in a consecutive series of patients, in whom the cricopharyngeus muscle/upper oesophageal sphincter was hypotonic, either after a short myotomy at the time of laryngectomy, or spontaneously as judged by peroperative palpation. Furthermore, marking the borders of the myotomized sphincter with clips enabled detailed quantitative videofluoroscopy of the relation between the neoglottic bar and the cricopharyngeus muscle.

Up till now, stroboscopy of the glottic area is the visualization method of first choice to observe these vibrations in laryngeal speech. As the neoglottis is the new sound source and thus, the substitute glottis, it would seem reasonable to apply the same diagnostic tools as those used to study mucosal vibrations in laryngeal speech. However, in alaryngeal speech, stroboscopy is complicated by the fact that the oesophageal voice and the tracheoesophageal voice are often irregular, which results in problems with triggering of the stroboscopic light.

Also, pressure from the electroglottographic electrodes placed on the neck to trigger the stroboscopy light source may cause deformation of the neoglottis. Therefore, better options theoretically are the 'frequency-independent' imaging methods of digital high-speed endoscopy (HS) [42] or videokymography [43]. These techniques make it possible to study (ir)regular vibrations by obtaining at 2000 to 4000 frames per second. The two techniques have been used in studies on pathological laryngeal voices. HS had never been used to study tracheoesophageal speech. Therefore, chapter 3.3 investigated how well this technique evaluated various characteristics of the neoglottis after total laryngectomy. HS was chosen above videokymography, because of the necessity to study the anatomy and function of the entire neoglottis. Videokymography shows single lines instead of the full frames presented by digital high-speed.

Digital high-speed imaging proved to be a useful dynamic imaging tool to gain more insight into the anatomical and morphological characteristics of the neoglottis. The next step was to evaluate whether this technique had additional clinical value compared to videofluoroscopy. Chapter 3.4 presents the results.

Quality of Life / Hands-Free Speech

One of the stigmatizing side-effects of tracheoesophageal speech is that the patient has to close the stoma with a finger to divert pulmonary air into the neoglottis to enable voicing. This means that he/she is literally always pointing towards his/her disability. Although most patients do not seem to be too uncomfortable with this 'problem', the availability of an automatic speaking valve (ASV) that enables hands-free speech, would be a valuable adjunct to put the finishing touches to the rehabilitation process. Several ASVs are available and they all have in common that they stay open during normal calm breathing, whereas they close as a result of the increased expiratory airflow when the patient starts to speak. The last chapter, chapter 4, describes a group of total laryngectomy patients who were selected to evaluate a new ASV (Provox FreeHands HME). Before the evaluation, their quality of life was assessed. Quality of life issues have become an essential aspect of head and neck cancer treatment evaluation. Especially in view of the increasing use of chemoradiation protocols it is anm obvious and relevant step to assess whether organ preservation equals function preservation.[4, 44] Furthermore, quality of life assessment is needed to put the loss of function into perspective and to evaluate the effectiveness of specific treatments and solutions after ablative surgical procedures, such as total laryngectomy, in which the sacrifice of specific functions is inherent to the treatment.

At the Netherlands Cancer Institute, several prospective clinical intervention studies were carried out on total laryngectomy patients, starting in the late nineteen eighties. At that time, no standard international validated questionnaires were available to evaluate QoL. This made it necessary to develop QoL questionnaires, dedicated to the specific problems of total laryngectomy patients. [45, 46] Over the next few years, the EORTC developed the QLQ-C30 questionnaire and several tumour-specific modules were used for e.g. lung and breast cancer.[47] According to the same guidelines of the EORTC Quality of Life Study Group, specific modules were developed for head and neck cancer (EORTC QLQ-C30 and EORTC QLQ-H&N35).[48] Although these questionnaires have resulted in a better understanding of the impact of treatment in head and neck oncology, the question remains as to whether further specialisation of the questionnaires is needed. [49-51] Recent research into the specific fields of e.g. rehabilitation of olfaction in total laryngectomy patients and functional problems after extensive ablative head and neck surgery, showed deficits in the specificity of the EORTC questionnaires and necessitated the use of additional questionnaires.[46, 52] **Chapter 4.1** found that besides the EORTC questionnaires (EORTC QLQ-C30 and EORTC QLQ-H&N35) an additional questionnaire was required to detect changes in specific voice and respiratory symptoms in this patient group. This questionnaire was included in the data analyses in the intervention study (evaluation of the new ASV) in order to detect changes in these symptoms as a result of the surgical intervention.

The ultimate goal of postlaryngectomy vocal rehabilitation should be to achieve hands-free speech using an ASV, preferably in combination with an HME, to simultaneously solve the above-mentioned respiratory problems.[53] In general, ASVs such as the Bivona I and II (Bivona Medical Technologies, Gary, Ind.), the Blom-Singer Adjustable Tracheostoma Valve (ATV; Inhealth Technologies, Carpinteria, CA), the Eska-Herrmann device and more recently, the Window valve (Adeva, Lübeck, Germany) have success rates of approximately 30% in terms of daily long-term users. [54-61] There are probably several reasons why only a limited number of patients are able to use an ASV, such as the frequently occurring troublesome fixation of the ASV to the peristomal skin, the high back-pressure needed for voicing that threatens the seal of the adhesive and/or the inadvertent spontaneous closure of the valve during physical exertion. Also, an inconvenient cough-relief mechanism, a lack of motivation and/or dexterity of the patient and a significant need for counselling by medical professionals are hurdles that need to be taken in order to successfully use an ASV. [54-61] To solve some of the problems of hands-free speech and at the same time to optimally address the respiratory problems in total laryngectomy patients, Hilgers et al. described an ASV with a fully integrated, disposable HME (Provox FreeHands HME; Atos Medical, Sweden).[53]

Their study on the development and testing of this device during short-term follow-up showed that the advanced features (obligatory HME, multi-magnet speaking and cough-relief valve systems) offered some additional benefits over existing valves. Especially the increases measured in dynamic range and phonation time was promising. However, the long-term success rate has not yet been established. Therefore, a multicentre long-term study was conducted on 79 patients who were using the Provox FreeHands HME. are addressed. **Chapter 4.2** describes the results in terms of compliance, quantitative aspects of voice quality and quality of life issues.

The results are summarized and evaluated in **Chapter 5.**

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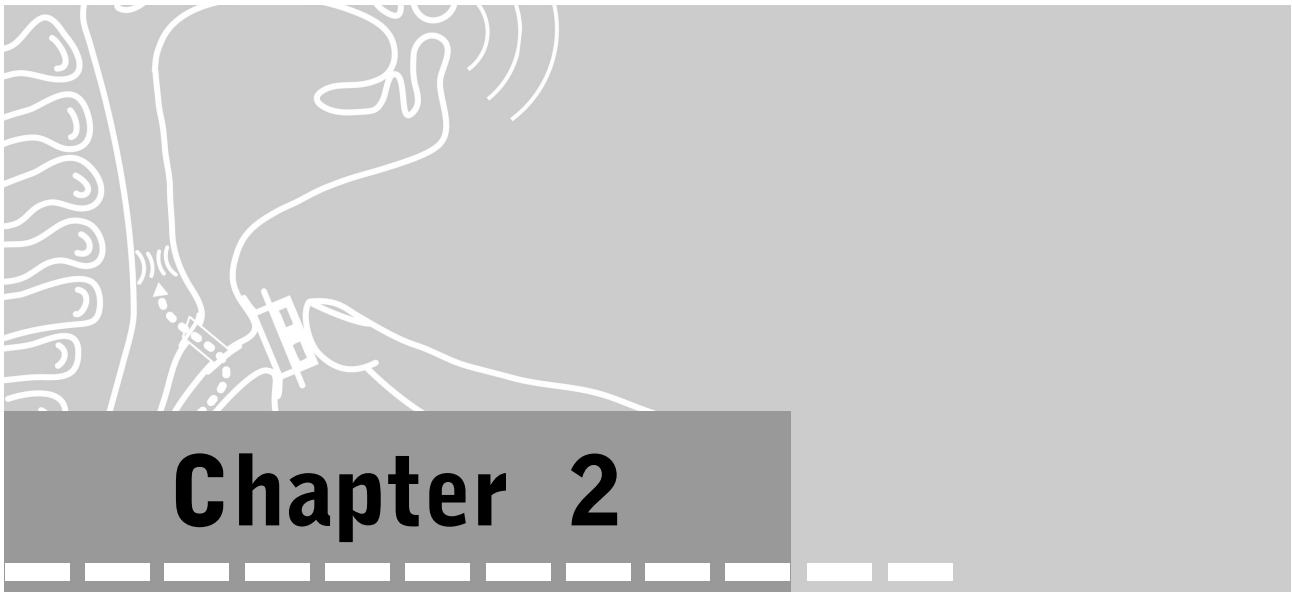
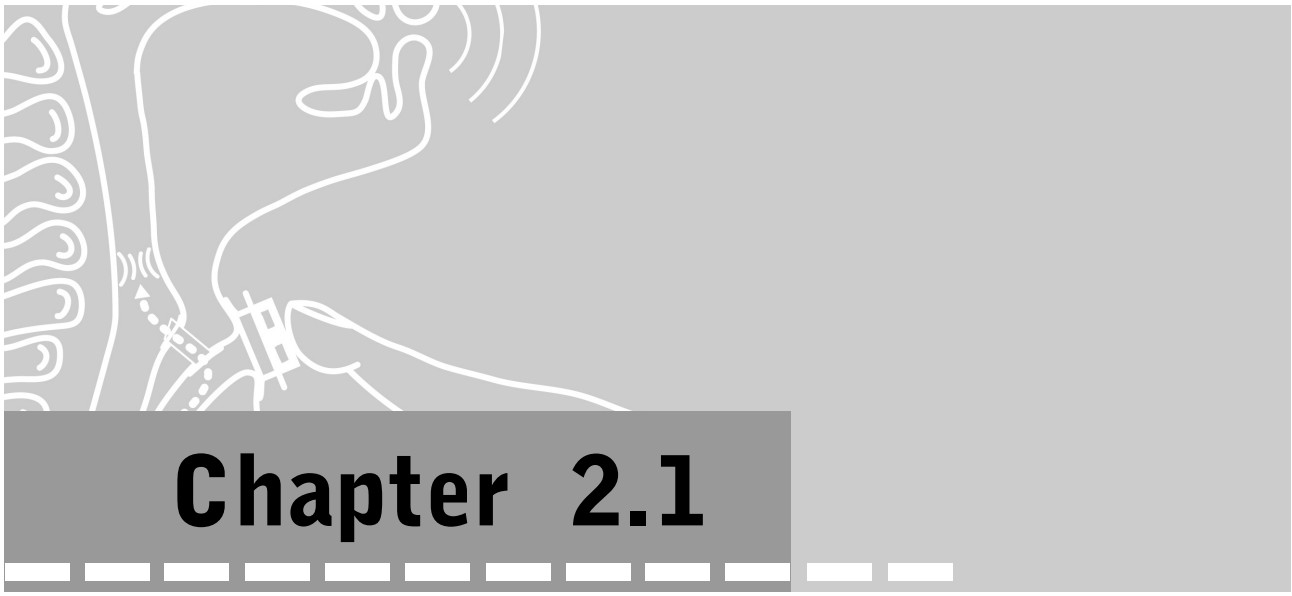


Chapter 2

Long term results



Chapter 2.1

A decade of post-laryngectomy vocal rehabilitation in 318 patients: A single institution's experience with consistent application of indwelling voice prostheses (Provox)

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Abstract

Objective: To assess long-term results with consistent use of indwelling voice prostheses (Provox®; Atos Medical AB, Hörby, Sweden) for vocal rehabilitation after total laryngectomy.
Design: Retrospective clinical analysis.
Setting: Comprehensive national cancer centre.
Patients: Three hundred eighteen patients (261 men, 57 women; mean age 62 years) from November 1988, through May 1999.
Intervention: Standard wide-field total laryngectomy (287 patients), or a total laryngectomy with a circumferential pharyngeal resection (31 patients), and 2700 prosthesis replacements. Prostheses in situ during 364,339 days (1000 patient years).
Main outcome measures: Device life. Indications for replacement (device or fistula-related), adverse events and voice quality.
Results: Median patient-device follow-up was 67 months. Mean actuarial device life for all indications for replacement was 163 days (median 89 days). Main indications for replacement were device-related, ie, leakage through the prosthesis (73%) and obstruction (4%), or fistula-related, ie, leakage around the prosthesis (13%), and hypertrophy and/or infection of the fistula (7%). Adverse events occurred in 11% of all replacements in one third of the patients, mostly solvable by a shrinkage period, or adequate sizing and/or antibiotic treatment. Definitive closure of the TE fistula tract occurred in 5% of the patients. Significant clinical factors for increased device life were no radiotherapy ($P=.03$), and age >70 years ($P<.02$). Success rate with respect to voice quality(ie,fair to excellent rating) was 88%, which was significantly influenced by extent of surgery ($P<.001$).
Conclusion: The consistent use of indwelling voice prostheses shows a high success rate of prosthetic vocal rehabilitation, in terms of the percentage of long-term users (95%), and of a fair-to-excellent voice quality (88% of the patients).

Introduction

Since Theodore Billroth in 1873 in Vienna performed the first laryngectomy for cancer, the loss of the normal voice had been considered the dominating problem following this procedure for more than 100 years. Only after Singer and Blom[1] introduced their first voice prosthesis in 1980, initiating prosthetic tracheoesophageal voice, better and more consistent results with respect to vocal rehabilitation of these patients have been achieved. Of the 3 rehabilitation methods, ie, tracheoesophageal, esophageal, and electrolaryngeal voice, the first method is considered to be the most successful mode of restoring communication after a total laryngectomy.[1-5] The use of various prostheses has become widely accepted in recent years. The following 2 different types of prostheses can be distinguished: non-indwelling devices, [1, 6] which can be removed and replaced by the patient, and indwelling voice prostheses, which have to be handled by a clinician.[7-9]

In 1988, the indwelling Provox® voice prosthesis (Atos Medical AB, Hörby, Sweden) was developed in the Department of Otolaryngology-Head and Neck Surgery, the Netherlands Cancer Institute, Amsterdam. This voice prosthesis was designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device life, simple patient maintenance and comfortable outpatient replacement.[8] Since the last criterion was not optimally fulfilled, there was a need for further innovation. This resulted in a more comfortable anterograde replacement method of the adapted, second-generation device, Provox®2, as an alternative for the more uncomfortable retrograde replacement of the original Provox prosthesis, performed using a special disposable guide-wire.[10, 11]

We herein assess the clinical experience in our institute during the last decade with the consistent use of both indwelling voice prostheses for vocal rehabilitation after total laryngectomy in a large, unselected, cohort of patients. We analyze the favorable long-term results, with special attention to the importance of adequate management of the adverse events inevitably encountered with every prosthetic rehabilitation method.

Patients and Methods

Patients

From November 1988 through May 1999, 319 patients with laryngectomy underwent rehabilitation with an indwelling Provox voice prosthesis in the Netherlands Cancer Institute. One patient from a foreign country was unavailable for follow-up after replacement during a second opinion visit. The data on the remaining 318 patients and the 3008 events with or without voice prosthesis in this 'timeframe' are the basis of this retrospective study (the relevant clinical data are summarized in **Table 1**).

We included 261men (82%) and 57 women (18%). Ages ranged from 29 to 88 years (mean, 61.9 years). The indication for total laryngectomy was a laryngeal carcinoma in 212 patients (67%), a hypopharyngeal carcinoma in 77 (24%), an oropharyngeal carcinoma in 13 (4%), a carcinoma of the cervical oesophagus in 5 (1.5%), and a thyroid carcinoma in 5 patients (1.5 %). The indication in the remaining 2 percent of the patients was intractable aspiration after irradiation for a head and neck carcinoma in 4, a tumour of the trachea in 1, and a solitary colon carcinoma metastasis invading the larynx in 1 patient.

In this series, only 37 patients (12%) never received radiotherapy. Radiation preceded the total laryngectomy in 143 patients (45%). In most cases, the indication for this surgical procedure was recurrent disease after radiotherapy, with 5 cases of chondroradionecrosis of the larynx, 6 laryngeal or hypopharyngeal primaries in a previous radiation field, and 4 cases of intractable aspiration after irradiation for a head and neck carcinoma. Postoperative radiotherapy was given to 138 patients (43%), with a mean dose of 56.7 Gy (median 60 Gy). Preoperative or postoperative radiotherapy was never considered a contraindication for primary tracheoesophageal puncture (TEP) and immediate voice prosthesis insertion. At the date of analysis (May 1999), 183 patients were still alive. The median survival since the date of operation was 7.0 years. Of the deceased patients, 60 died with recurrent disease, 6 of a secondary malignancy, and 69 of intercurrent disease.

Table 1: Clinical data, 1988 to 1999

Patients	
Study period	1988-1999
Number of patients	318
Male	261 (82%) pts
Female	57 (18%) pts
Age	29-88 years (mean 61.9 yrs)
Laryngeal carcinoma	212 (67%) pts
Hypopharyngeal carcinoma	77 (24%) pts
Oropharyngeal carcinoma	13 (4%) pts
Miscellaneous	16 (5%)
Treatment	
Total laryngectomy	287 (90%) pts
Total laryngectomy and circumferential pharyngeal resection	31 (10%) pts
Reconstructions	31 pts
Jejunal graft interposition	8 pts
gastric pull up	18 pts
radial fore arm flap	5 pts
No radiotherapy	37 (12%) pts
Radiation preceding total laryngectomy	143 (45%) pts
Post- operative radioterapy	138 (43%) pts
Vocal rehabilitation	
Primary tracheoesophageal puncture	277 (87%) pts
Secondary puncture	41 (13%) pts
Primary tonicity control PE-segment	142 pts
Neurectomy	99 pts
Myotomy	6 pts
neurectomy and myotomy	37 pts
Secondary tonicity control PE-segment	18 (6%) pts
Myotomy	16 pts
botox injection	2 pts
Periods	3008
Periods with Provox prostheses	2700
Periods without voice prosthesis	144
Periods with Groningen prosthesis	164
Follow-up	
Days with Provox device in situ	364,339 (1000 patient years)
Patients alive with voice prosthesis in situ	173 (out of 183,95%)

Surgery

The type of surgery was a total laryngectomy in 287 patients (90%), and a total laryngectomy combined with a circumferential pharyngeal resection in 31 patients (10%) (including simultaneous oesophageal resection in 18). Sixty-six patients underwent surgery before the end of 1988, when the indwelling Groningen prosthesis mainly was used. These protheses were converted to the Provox device between the end of 1988 and beginning of 1989, when indicated. Between the end of 1988 and 1999 the remaining 252 patients underwent surgery, during which time the indwelling Provox prostheses were used.
Primary TEP with immediate retrograde insertion of the voice prosthesis at the time of laryngectomy was applied in 277 patients (87%) (165 Provox, 46 Provox2, and before 1988 66 Groningen voice prostheses). Of the 41 patients (13%) undergoing secondary TEP with immediate retrograde insertion of the voice prosthesis, a Provox was inserted in 31 (Provox in 23; Provox2 in 8), whereas before 1988, a Groningen prosthesis was placed immediately during the TEP procedure in 10 patients.
Surgical procedures to influence the tonicity of the pharyngoesophageal (PE) segment during total laryngectomy were performed in 142 patients, mainly in those undergoing operation in the last 10 years. A unilateral neurectomy of the pharyngeal plexus was carried out in 136 patients (in combination with a cricopharyngeal myotomy in 37), and a cricopharyngeal myotomy only in 6 patients. The 43 myotomies were mainly performed if the surgeon deemed the upper oesophageal sphincter to be hypertonic on palpation after removal of the larynx. During follow-up, 18 patients (6%) experienced a clinical relevant hypertonicity of the PE-segment, which required treatment. Sixteen patients underwent a secondary long vertical PE myotomy (middle and inferior constrictor and cricopharyngeus muscles). In the last year, 2 patients were treated with botulinum toxin (Botox; Allergan, Nieuwegein, the Netherlands) injections for this indication.
A circumferential reconstruction of the pharynx and/or esophagus was carried out in 31 patients, using a jejunal graft interposition in 8, a gastric pull up in 18, and a radial fore arm flap in 5 patients. Because of flap necrosis, a second reconstruction procedure was necessary in 2 patients; a jejunal graft reconstruction was converted into a gastric pull-up in one patient, and a proximal gastric pull-up necrosis was reconstructed with a radial fore arm flap on top of the gastric transfer in the other.

Voice prostheses

Before 1988, the indwelling Groningen voice prosthesis was used. At the end of 1988, there was a switch to the indwelling Provox®, developed in our institute, followed by the indwelling Provox®2 in 1996, which replaced the original Provox device in most cases. The replacement of the first 2 devices requires a retrograde procedure,[7, 8] whereas the latter device is replaced in an anterograde manner.[10]
At each replacement session, a special form was used by the otolaryngologist to collect the relevant data of the indications for replacement; technical aspects, size and serial number of the prosthesis; presence of fistula problems; macroscopic signs of **Candida** growth on the prosthesis; medications; and voice quality. The indications for replacement of the prosthesis were considered to be either device or fistula related. The device-related indications included leakage through the valve, and obstruction of the prosthesis leading to an increased airflow resistance during voicing. The fistula-related indications included leakage around the prosthesis, inaccurate sizing, hypertrophy or infection of the TE-fistula, and spontaneous extrusion or loss of the voice prosthesis. In the fistula-related category, cases were also included in which the prosthesis was removed for definitive closure of the TE-fistula, eg surgical revision of the tracheostoma, a second primary tumour in the stoma region, on request of the patient, or because of a severe tracheitis.

Adverse events were defined as fistula related problems not manageable by simple prosthesis replacement, ie, leakage around the prosthesis not solvable by downsizing the device, hypertrophy and/or infection of the TE-fistula, and spontaneous extrusion or loss of the prosthesis.

Voice Quality

The assessment of the voice quality was performed at each replacement session, using the following 5-point scale rating: 5 points for excellent, 4 for good, 3 for fair, 2 for poor, and 1 for no voice. **Excellent** and **good** indicate a fluent and intelligible voice used under all social circumstances and **excellent** was used only when the patient's voice approached normalcy. **Fair** indicates a somewhat less satisfactory voice that was still used as the main method of communication. **Poor** indicates a voice with unsatisfactory quality that was not useful as a

Provox is a trademark of and manufactured by Atos Medical AB, PO Box 183, S-242 22 Hörby, Sweden.

primary communication method. To allow the use of the voice quality in multivariate statistical analysis, a mean voice quality (MVQ) score was established by calculating the sum of the individual ratings (1-5) during the whole study period, divided by the number of voice quality evaluations per patient. Mean scores were rounded (excellent ≥ 4.5; good 3.5-4.4; etc.).

Statistical methods

The main objective of the statistical analysis was to investigate the relation between several patiënt- and treatment-related factors and the lifetime of the Provox device. A Provox was replaced because of device- or fistula-related problems. Both end points were considered separately. Lifetimes not ending with the particular endpoint and ongoing lifetimes at the end of the observation period were censored. Since the number of lifetimes within patients varied from one to 114, the within-patient dependency of device lifetimes was analysed by means of a proportional hazard model including γ-distributed frailty. The model was extended by the following covariates: sex, age, myotomy (yes/no), neurectomy (yes/no), type of operation (larynx/laryngopharynx), radiotherapy (no, preoperative, or postoperative), and type of Provox device. The analyses were performed using the frailty function written for S-Plus by T.M. Therneau.[12, 13] The association of various covariables with the mean voice quality was tested by means of the Kruskall-Wallis test.

Results

This retrospective series consists of 318 patients (**Table 1**) with 3008 evaluable periods. In 1988-1989, there were 164 periods when a Groningen prosthesis replaced by a Provox device, which were excluded from further analysis. There were 144 periods without voice prosthesis, eg, shrinkage of the TE-fistula or temporary or definitive closure. Finally, there were 2700 periods with a Provox voice prosthesis in situ, at the end of which the existing voice prosthesis was either replaced by a new device, or still in situ at the end of the follow-up. The median follow-up time of the 318 patients in the observation period was 67 months. Of the 183 patients alive at the end of the follow-up (May 1999), 173 patients (95%) were still using a Provox or Provox2 voice prosthesis. In total, this series consists of 364339 days with an indwelling voice prosthesis in situ (approximately 1000 patient-years).

Most patients needed several prostheses during the 10-years observation period, with a mean of 8.5 (range, 1-55); one exceptional patient needed 114 prostheses in 10 years. The mean actuarial device lifetime over the complete period was 163 days.

Figure 1a shows the mean device life per patient for all replacement indications (in 3-months periods): in 30% of the patients devices were replaced with a mean device life of less than 3 months; in 40%, from 3 to 6 months;and in 30% longer than 6 months. The median actuarial device lifetime over the complete period was 89 days. **Figure 1b** shows the median device life per patient for all replacement indications (in 3-months periods): in 45% of the patients, devices were replaced with a median device life of less than 3 months; in 31% from 3 to 6 months; and in 24%, longer than 6 months.

Fig 1a. Mean device life per patient for all replacement indications (in 3-months periods) (2700 Provox prosthesis and 318 patients; % of patients in Y-axis)

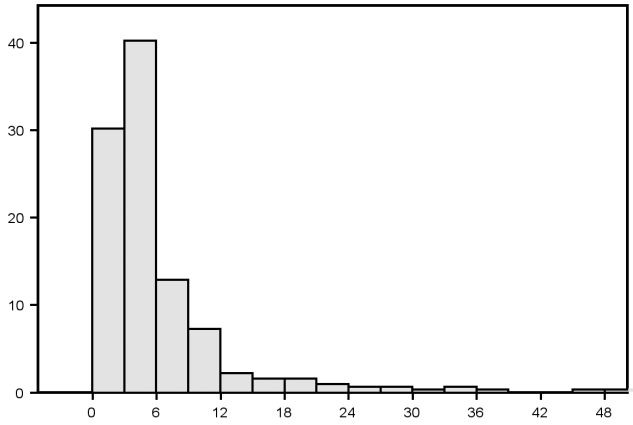


Fig 1b. Median device life per patient for all replacement indications (in 3-months periods) (2700 Provox prosthesis and 318 patients; % of patients in Y-axis)

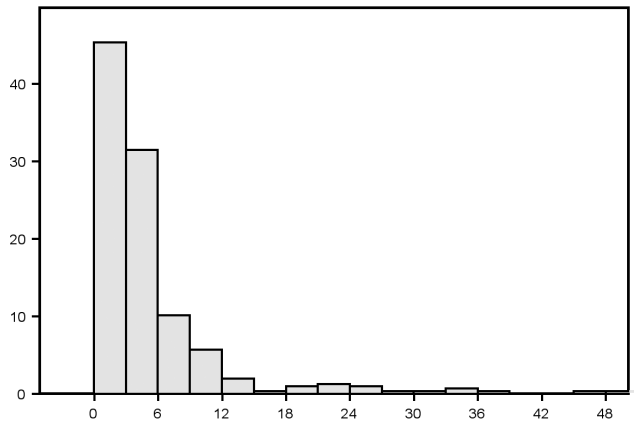


Table 2 gives an overview of the different indications for replacement of the 2700 voice prostheses used in the study period (for Provox and Provox2). At the end of the follow-up, 297 prostheses were still in use, 2396 prostheses were replaced, and in 7 replacements the indication was not known in retrospect. There appeared to be no difference in the replacement indications of the first (primarily) inserted prosthesis vs that of the following devices, ie, device- and fistula-related indications occurred in the same frequencies in the first indwelling voice prosthesis.

Table 2 Indications for replacement of the voice prosthesis (Provox and Provox2) in absolute numbers (percentages in parentheses)

	Provox	Provox2	Total
Leakage through	1213	533	1746
	(72,7)	(73,2)	(72,9)
Increased pressure	79	23	102
	(4,7)	(3,2)	(4,3)
Leakage around	218	97	315
	(13,1)	(13,3)	(13,1)
'Wrong size'	19	8	27
	(1,1)	(1,1)	(1,1)
Hypertrophy/Infection	107	55	162
	(6,4)	(7,6)	(6,7)
Spontaneous loss	11	3	14
	(0,7)	(0,4)	(0,6)
Miscellaneous	21	9	30
	(1,3)	(1,2)	(1,3)
Subtotal	1668	728	2396
Missing	7	0	7
Prothesis still in situ	138	159	297
Total	1813	887	2700

Device-related indications for replacement

The main reason for replacement was leakage of fluids through the prosthesis (1746 (73%) of 2396 replacements, in 232 patients (73%)). Improper closure of the valve occurred invariably due to Candida deposits on the device. Increased pressure, another device-related end point, was less frequently observed (102 times (4%) in 70 patients (22%)). The median time to both device-related problems was 111 days.

Time to device-related problems was longer for the Provox than for the Provox2 device. Median actuarial device-related lifetime was 120 and 92 days, respectively ($P < .001$). Radiotherapy (preoperative and postoperative) was negatively associated with time to device-related problems. In patients not undergoing irradiation, median device lifetime was 162 days compared to 111 days in patients undergoing preoperative irradiation ($P = .03$) and 102 days in patients undergoing postoperative irradiation ($P = .02$). Age also appeared to be associated with time to device-related replacement. In patients below 60 years, median device lifetime was 99 days; in patients aged 60 through 70 years, 111 days; and in patients older than 70 years, 147 days. Device-life in patients older than 70 years especially was significantly longer compared with that in the youngest group ($P < .02$). Other factors like sex, tumor type, and stage of disease were not significantly associated with time to device-related problems.

Fistula-related indications for replacement

Replacement was required for leakage around the prosthesis in 315 occasions (13% of 2396 replacements) in 133 patients (42%). Downsizing the prosthesis solved this problem in most replacements (237 times (10%) in 76 patients (24%)). Leakage around the prosthesis, not solvable by simple downsizing was observed in 81 replacements (3%) in 57 patients (18%). This adverse event was treated mostly with short-term removal of the prosthesis to allow for spontaneous shrinkage of the fistula tract. One period of shrinkage was applied to solve this problem in 41 of the 57 patients, and 12 patients 2 periods were applied. Of the remaining 4 patients, 2 had 3 and 2 had 5 episodes of removal and shrinkage. The median duration of removal of the voice prosthesis was 6 days. In the last few years, applying a purse string suture around the fistula tract often preceded the option of removal of the prosthesis and shrinkage, and this technique was used in 9 of the patients undergoing recurrent shrinkage. In an additional 4 patients collagen was injected into the fistula wall according to the technique described by Remacle.[14] Closure because of untreatable leakage around the prosthesis was ultimately necessary in 19 of these 57 patients (6% of 318 patients). In only 1 patiënt, this was a definitive procedure, whereas the remaining 18 patients underwent a new TEP procedure.

A less frequent fistula related reason for replacement was inaccurate sizing (27 times (1%) in 24 patients (7.5%)). In these cases, patients came back to the clinic because the prostheses felt uncomfortable, which was always solvable by simply upsizing or downsizing the device.

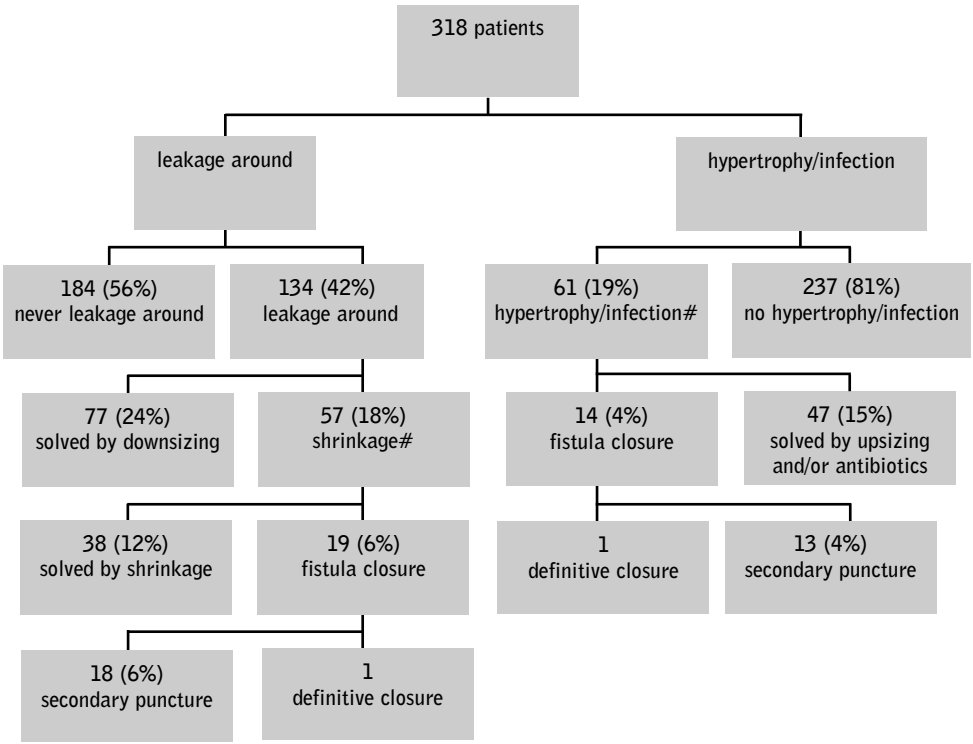
Hypertrophic scarring and/or infection of the TE fistula as indication for replacement were observed 162 times (7%) in 61 patients (19%). These adverse events were solved by upsizing the prosthesis, treatment with antibiotics,

and/or resection of granulation tissue during outpatient visit in most cases. On 15 occasions in 14 of the 61 patients, the problem could not be solved by one of these measures and removal of the prosthesis was necessary, which led to a spontaneous closure of the fistula tract. This was a definitive situation in 1 patient, whereas the remaining 13 patients underwent a new TEP procedure.
The last category of adverse events was spontaneous loss of the device, which occurred 14 times (1% of all occasions in 14 patients (4%)). There were no cases of aspiration, and in none of these cases this device loss resulted in medical complications.
Miscellaneous indications occurred 30 times (1.3%) in 27 patients (8.5%). These indications included tracheitis, stoma revision, and endoscopic dilatations.

Adverse events

Some patients experienced one or the other of these adverse events at different times during their follow-up. The 57 cases of leakage around, the 61cases of hypertrophy and/ or infection, and the 14 spontaneous losses occurred in 102 patients (32%). In 2 patients this lead to a definitive closure of the TEP. Two hundred fifty-seven replacements (11%) were considered due to adverse events,including 81 instances due to leakage around not solvable by downsizing, 162 due to hypertrophy and/or infection events, and 14 due to spontaneous losses. In **Figure 2** an overview is given of all patients with respect to fistula related adverse events.
No significant difference between Provox and Provox2 in the incidence of the various indications for replacement could be observed (**Table2**). However, the occurrence of fistula related indications for replacement with Provox2 was significantly earlier than that for Provox (57 vs 78 days after replacement; $P = .02$). The association of radiotherapy with device life regarding fistula related indications was not consistent. Altough previous radiotherapy seemed to be associated with this ($P = .05$), time to replacement after postoperative radiotherapy was not affected compared to no radiotherapy. Other factors, such as sex, age, tumor type, stage of disease, myotomy or neurectomy, showed no statistically significant association with fistula-related indications for replacement.

Figure 2 Overview of adverse events with respect to leakage around the prosthesis and hypertrophy/infection problems (# Overlap of patients with hypertrophy/infection, leakage around, and spontaneous loss (14), resulting in adverse events in 102 (32%) of the patients (in 257 (10.7%) of all replacements)



Sizing of the voice prosthesis

On 1530 occasions (65%), the size of the replacing prosthesis was the same as the one removed. A device 1 size shorter was inserted on 343 occasions (14%), 2 sizes shorter on 57 occasions (2%), and 1 or 2 sizes longer on 466 occasions (19%).

Definitive closure of the TE-fistula

During the study period, 17 patients (5%) had a definitive closure of their TE fistula. As mentioned above, 1 patient had a surgical closure because of untreatable leakage around the prosthesis. Another patient had a definitive spontaneous closure after a period of severe hypertrophy of the tissue around the fistula tract. Recurrence or second primary tumor around the TE fistula was the reason for closure in 4 patients; good communication by electrolaryngeal or esophageal speech, in 5 patients. One patient requested a permanent closure because of the necessity for frequent replacements due to uncontrollable **Candida** overgrowth. In 2 patients, a stenosis or spasm of the PE segment was the reason for closure. In 3 patients, the reason could not be identified in retrospect.

Voice-quality assessment

Voice-quality assessments were available for 268 patients (range of assessments, 1-113), allowing calculation of a Mean Voice Quality (MVQ) score. In 3% of the patients, the MVQ score was excellent; in 51%, good; and in 34%, fair. In 7% of the patients MVQ score was poor, and in 5% no voice was achieved.Owing to the small numbers, the voice results in patients who underwent a secondary myotomy (n=16) or chemical denervation of the constrictor pharyngeus muscles with Botox (n=2) were not analysed separately. The improved ratings after the treatment are included in their overall MVQ score.
MVQ scores showed to be significantly related with age; patients older than 70 years of age had a lower MVQ score (3) than patients younger than 60 years (4) and patients aged 60 to 70 years (4) ($P < .001$). The MVQ score also showed a significant relation with the extent of the surgery. Patients who underwent a total laryngectomy only had a better voice quality (MVQ, 4) compared with patients needing a circumferential pharyngeal reconstruction (MVQ, 3)
($P < .001$). Sex, radiotherapy, and tonicity control procedure showed no significant relation with the MVQ score.

Discussion

A decade of consistent application of indwelling voice prostheses (Provox) has resulted in a substantial series of patients and a wide range of informative clinical observations, confirming the high probability of successful long-term speech acquisition after total laryngectomy. Although this patient population is clinically comparable to those in many other reports on prosthetic voice rehabilitation, to our knowledge, this is the largest series in the literature. Most other studies consist of less than one hundred patients,[15-19] and only few reports describe more than one hundred patients.[20, 21] During the observation period of 10 years with a median follow-up of 67 months, which is far above the average of 2 years in most other reports, indwelling voice prostheses were in situ during 364 339 days (1000 patient-years).

The success rate of prosthetic voice is not uniformly assessed in the literature.[22] Some have based their assessment on a combination of whether the prosthesis was used at all, the quality of speech, and whether the voice prosthesis was used as a primary means of communication (initial success rate, 84%; long-term, 74%).[23] Others have used the criteria proposed at the Third International Congress on Voice Prosthesis (1988) and reported 95% with functional speech.[24] In our study, only 5% of the patients had a definitive closure of the fistula for different reasons, which means that in 95% of the cases the device stayed in situ long term. Based on a mean voice quality score, the success rate (88% fair to excellent voice) equals the better results reported by others and confirms the previously described results of this institute.[8, 25]

However high the success rate of vocal rehabilitation, as with any use of prosthetic appliances in the human body, the use of indwelling prostheses may give rise to adverse events. In the few reports in the literature carefully evaluating complications of prosthetic vocal rehabilitation, only 1 distinguished between failure of the prosthesis and fistula-related problems.[20] They used the term **prosthesis-related** complications, which included more or less the same indications as our fistula related adverse events, such as granulation or hypertrophy, widening of the fistula or leakage around the prosthesis, and loss of the voice prosthesis. Since we separated the results in device- and fistula-related indication for replacement, we shall discuss them in the same order.

Device related indications

Leakage through the prosthesis was the reason for replacement in three quarters of both replacements and patients, and was most likely to be associated with **Candida** deposits on the valve, as is reported by many others.[17-19, 26]

This was a clinical diagnosis in the beginning of the series often substantiated by microbiological cultures. Although it was not documented, we have observed some improved device lifes in individual cases by prescribing anti-fungal agents, such as nystatin and fluconazol (Diflucan), as described by others.[27, 28] The negative influence of radiation on the device life, due to possible alterations in the pharyngeal microbiology, that potentially promote **Candida** growth, as suggested previously,[25] can still be supported by the present study.
The differences found in the device lifetime of Provox and Provox2 in our retrospective study are statistically significant, and more pronounced than the findings in a recent prospective multi-institutional trial.[11] However, in that study, there was a trend toward a shorter device lifetime for Provox2. These differences are difficult to explain merely on the basis of design changes necessary to make an easy anterograde replacement of Provox2 possible. We believe that the success of the replacement system undermines the device lifetime to some extent. Because the retrograde replacement procedure is uncomfortable for many patients,[10] the alternative of the anterograde Provox2 replacement will not restrain the patient from coming to the out-patient clinic for a quick and more comfortable solution to a leaking prosthesis.[11] The fact that there is a full reimbursement for these devices in the Netherlands may also contribute to this phenomenon.
Frequent replacement as a result of valve dysfunction by **Candida** overgrowth could have dietary reasons. Busscher et al. [29] reported a prolonged device lifetime during in vitro experiments with a daily intake of buttermilk, although in vivo results, aside from some anecdotal reports by patients, are still lacking. In this retrospective study it was not possible to address this issue.

Fistula related indications and adverse events

Concerning the fistula related indications leading to replacement, leakage around the prosthesis appears to be a relatively minor problem (13% of all replacements), despite being seen at some time in the follow-up in 42% of the patients. The few studies mentioning this issue report this problem in 7% to 27% of the replacements.[17, 18, 24, 30, 31] Leakage around the device as replacement indication was not seen more frequently in the first prosthesis inserted during surgery. It could be assumed that the immediate insertion of an indwelling device during the TEP procedure, as is the custom in many European clinics for the last 20 years,[7, 21] would lead to more frequent replacements due to leakage around the device. However, it is clear from our data, that the normal subsiding of the surgical edema and consequent shortening of the fistula tract did not cause more problems in this respect in the first device.

In our experience, simple downsizing of the voice prosthesis was the solution in most of the "leakage around" cases. Therefore, it is important never to replace the voice prosthesis automatically with one of the same size, but to check the proper length first, avoiding the pistoning effect of a too long a prosthesis. As can be concluded from the results shown in **Figure 3**, one-third of the replacements required another size. In our experience, downsizing should been done too rapidly and not exceed more than 1 shaft length to prevent too much pressure on the tissues.

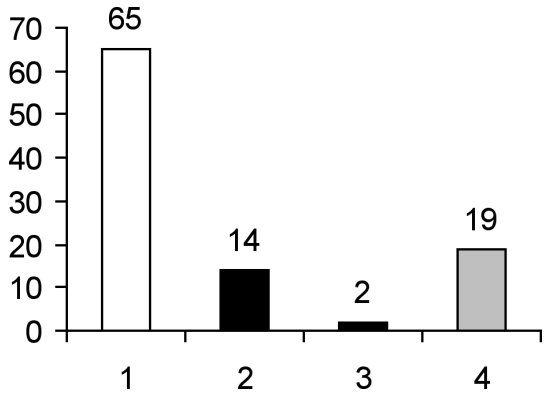


Figure 3 Size of replacing prosthesis in percentages: 1 = same size (65%), 2 = one size shorter (14%), 3 = two sizes shorter (2%), 4 = one or two sizes longer (19%)

Removal of the prosthesis to allow the fistula to shrink was reported in some studies, but an indication how long the fistula should be left alone, or whether to close the tract, was not given.[17] One shrinkage period (median, 6 days) was sufficient in most of our cases; recurrence of this problem was only seen in a few. During the shrinkage period the patient needs a nasal feeding tube and, sometimes, a cuffed trachea cannula. Little success was obtained by injection of collagen.[14] More recently, a submucosal purse-string suture around the TE fistula tract in recurrent cases precedes the shrinkage option. This is a relatively simple procedure, using an atraumatic 3x0 polyglactin 910 (Vicryl) suture, under local anaesthesia and providing an instant solution, which avoids nasogastric tube feeding and use of a cannula.

Ultimately, a surgical closure of the TE fistula because of untreatable 'leakage around' was needed in 19 patients of these 57 patients, but only in one patient no repuncture was done afterward. The surgical procedure in all cases consisted of the tracheoesophageal party wall via an incision at the cranial mucocutaneous border of the stoma, a sectioning of the fistula tract, and, without interposing grafts, closure of the esophagus in 2 layersand the trachea in 1 layer.

Although the device lifetime of the Provox2 in this series is shorter than that of the first model, the relative incidence of the indication of leakage around of Provox2 equaled that of Provox. This supports our suggestion that there is no widening of the fistula tract by the anterograde replacement of the prosthesis. Even the increased frequency of replacements did not intensify the number of cases of atrophy or hypertrophy/infection of the fistula wall. The earlier occurrence of the fistula-related adverse events with Provox2 might still be explainable by the decreased discomfort of the anterograde replacement method, which may have motivated the patient to report to the clinic earlier.

Hypertrophy, scarring and/or infection of the TE fistula (19%) were seen in a comparable percentage in our population as was atrophy (18%), discussed above. Manni and Van den Broek reported granulation and infection in 23 of their 132 patients (17.4%), and Aust and McCaffrey handled partial retraction, granulation tissue and localised cellulitis in 21% of their patients.[20, 23] Comparable in all studies was the minimal number of patients in whom the fistula had to be closed definitively.

The frequency of these adverse events could have been underestimated in our study, as our data are based on carefully and uniformly registered replacements, while hypertrophy solved by antibiotics or cauterisation only was not registered separately. However, once the TE-fistula had the tendency to granulate or retract into the mucosa during regular follow-up visits, or when the patient complained about higher pressure during speech as a result of esophageal mucosa swelling, we upsized the prosthesis to prevent actual granulation formation or infection. Because hypertrophy was registered as the indication for replacement, and actually this was not (yet) the case, this could have resulted in some overestimation.

Overlooking the fistula-related indications, 32% of our total population (representing 10.7% of all replacements) occasionally experienced an adverse event, which definitively led to fistula closure in only 2 patients (0.6%). As discussed above, these results are comparable to other studies. However, accurate sizing and an adequate approach to infection problems with the use of antibiotics and/or anti-fungal medication can prevent many adverse events. One of the problems discussed in recent years is the existence of gastroesophageal reflux disease in patients undergoing laryngectomy.

Although there seems to be a relation to postoperative wound healing problems, there is at present no clear evidence that gastroesophageal reflux disease has an influence on prosthesis- or fistula-related device lifetime. [32]

Device lifetime

As discussed before, there are many influencing factors in the assessment of the device lifetime of voice prostheses. However, interpretation of the results can be difficult, as device life times have not always been calculated in a consequent manner. Like others, in the past we have reported on mean device life.[18, 19, 23-26] However, it is probably more realistic to report on median survival times. Especially when interpreting such a high number of patients and replacements, the distribution of the data has to be taken into account. In addition, as also mentioned by others, the last valve has to be censored, since the exact lifetime of that valve is not yet known, ie,. the valve hasn't failed at the time of analysis.[17] In our study, the mean value, (163 days) is comparable to that reported by others (range 148-311 days),[18, 19, 23, 24, 26] and to the 141 days reported earlier.[25] The median value of 89 days is lower than the values reported by others (101 and 137 days) [17, 33] and probably is influenced by the shorter device life of Provox2, which has not yet been used by these authors. Since we have separated the device-related indications for replacement from the fistula-related problems, the median device life of 120 days for Provox and 92 days for Provox2 are indicative for failure of the device itself. The already-discussed success of the anterograde loading system is probably the main reason for the shorter median device life of Provox2, which is comparable to the one reported earlier.[11] As already has been mentioned, the issue of reimbursement should be taken into account. The fact that, in the Netherlands, costs of prostheses will be covered by most of the insurance companies won't stimulate an increased device lifetime either.

Voice Quality

Tracheoesophageal speech is nowadays considered as the first method of communication in laryngectomized patients, far superior to oesophageal voice, and subsequently the rating of voice quality will be of less concern, also because it is still somewhat difficult to quantify.[34] The voice quality assessment used in our institute is simple but consistent, as there is a relative intensive follow-up carried out by the same otolaryngologists, using a standard form to collect the relevant data. The 88% fair-to-excellent voice quality, found in our study, is also well in concordance with the 84% fair to good result, reported by the patients in an earlier study.[35]

Despite the consequent assessment, we have to consider the results with some reservation. Perceptual analysis is considered the golden standard, but it is rather labour intensive and not very suitable for every day practice. Compared to our rather simple subjective assessment, Delsupehe et al. described a more elaborate evaluation of prosthetic voice, analysing four objective and eight subjective voice parameters. [33] With their method, they also found that the extent of surgery, total laryngectomy vs laryngectomy combined with partial pharyngectomy, influenced the voice quality. We subscribe to the explanation that the preservation of the hypopharynx, which means a larger vibrating mucosa segment, results in a better voice.
In contrast to the device lifetime and the incidence of adverse events, the voice quality is somewhat less in the group of patients older than 70 years. This result contradicts previous findings by Hilgers and Balm, [25] although the age limit used then was 80, and the statement was also referring to device life and adverse events, which still are not different in the different age groups. Using nonindwelling prostheses, Shultz and Harrison, associated this age factor (age $>$ 60 years in their study) with the difficulty of stoma occlusion, and with a combination of hearing loss and stoma noise during speech.[22] In addition to hearing loss, a decreased ability or willingness to learn is another possible explanation.[36] A solution for the deterioration of the dexterity with age could be the use of the valved Provox HME, [37] which has been shown to improve the ease of digital stoma occlusion, and thus the voice quality. [38, 39]

Conclusions

The results of our 10-year follow-up study demonstrate that the consistent application of indwelling prostheses, such as the Provox system, can result in a high percentage of successful vocal rehabilitation. In rating successes, it is important to differentiate between device-related indications for replacements and replacements due to fistula related adverse events and to evaluate possible influencing factors. By an intensive and consequent multidisciplinary approach to problems, most of the inevitable adverse events can be solved adequately, minimizing the discomfort for laryngectomized patient using indwelling voice prostheses.

Acknowledgments.

Voice rehabilitation after total laryngectomy is very much a multidisciplinary team effort. The consistent and enthusiastic contribution over the complete study period of our senior speech therapist, Benita EGM Scholtens, has been instrumental to the positive results described in this paper. For the later years, also Corina J van As, MSc, has te be acknowledged for her clinical (speech therapy) and (phonetic) scientific contributions. Annemieke H Ackerstaff, PhD, is acknowledged for reviewing the manuscript and her major contributions to the clinical research activities in the postlaryngectomy rehabilitation program of the department.

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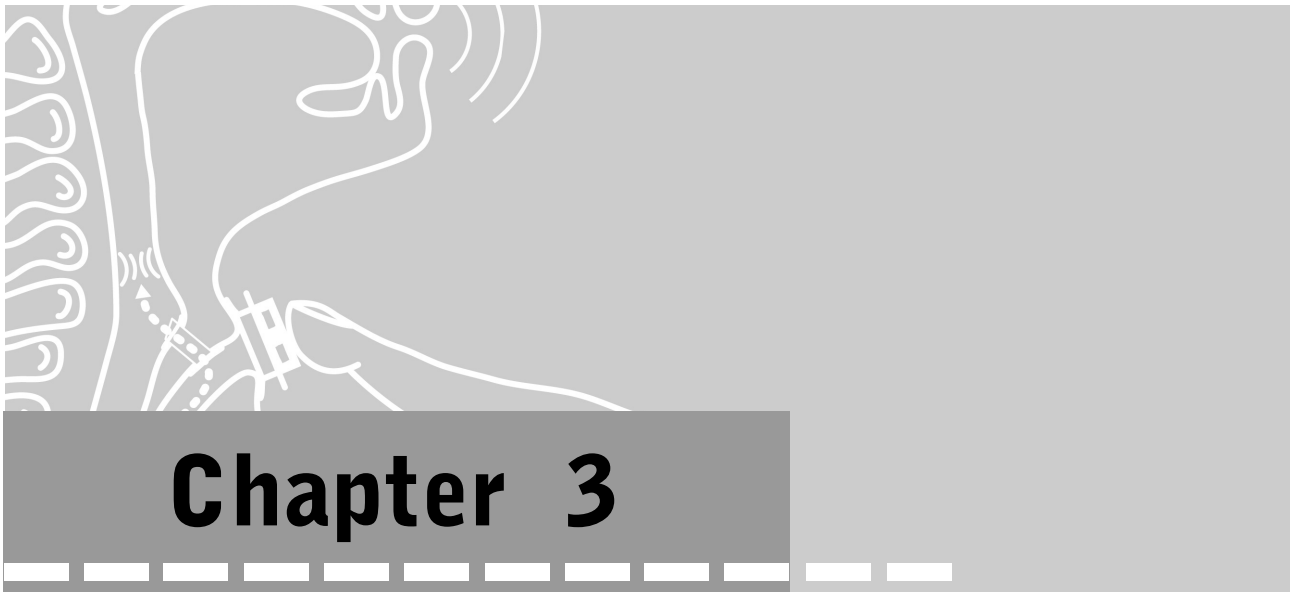
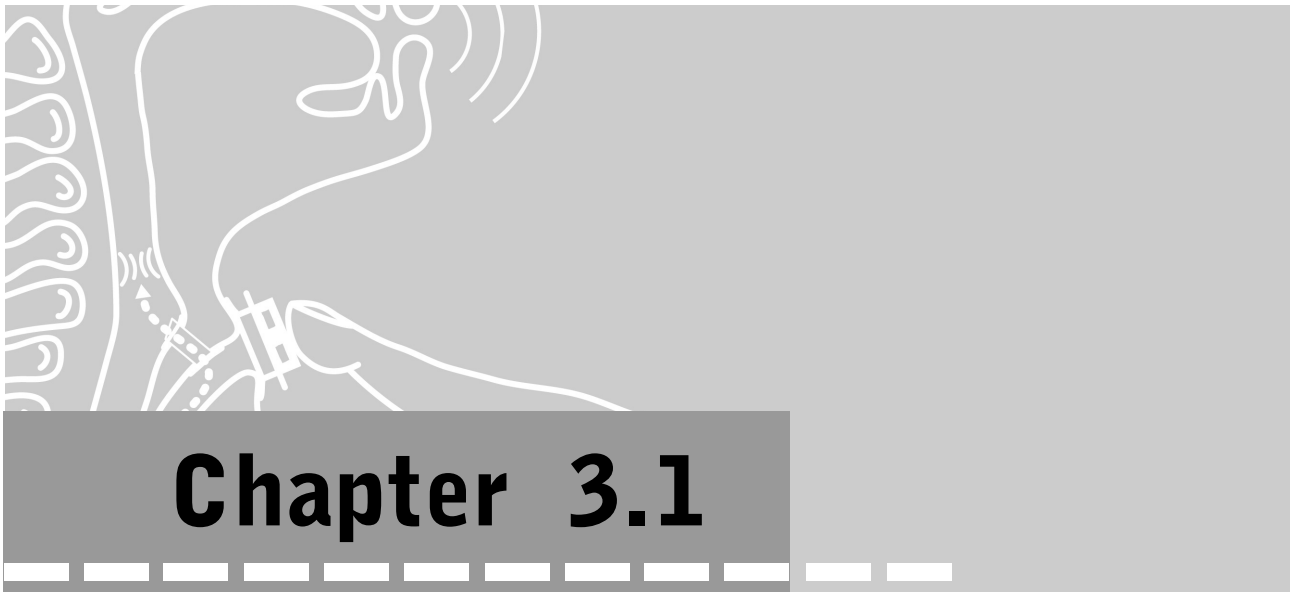


Chapter 3

Neoglottic imaging



Chapter 3.1

Quantitative videofluoroscopy: A new evaluation tool for tracheo-esophageal voice production

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Abstract

Objective: Development of a quantitative videofluoroscopy protocol, using well-defined visual parameters and quantitative measures, for the evaluation of anatomical and morphologic characteristics of the neoglottis in relation to perceptual evaluation of tracheoesophageal voice quality.
Design: A patient survey.
Setting: The Netherlands Cancer Institute, Amsterdam.
Patients: Thirty-nine laryngectomized individuals, 30 with standard total laryngectomy, and 9 with a partial or total pharynx reconstruction.
Intervention(s): Videofluoroscopy and speech recordings.
Main outcome measure(s): Well-defined visual parameters and quantitative measures based on videofluoroscopy images should improve the evaluation of neoglottic characteristics in relation to voice quality.
Results: Quantitative measures were significantly related to visual assessment outcomes. The tonicity ($P=.02$) and the presence of a neoglottic bar during phonation ($P=.03$) were significantly related to voice quality, as were several of the quantitative measures, especially the minimal distance between the neoglottic bar and the anterior esophageal wall at rest ($P< .001$) and during phonation ($P=.02$), and the index for the relative increase of the maximal subneoglottic distance from rest to phonation ($P=.01$).
Conclusions: This new quantitative videofluoroscopy protocol is a useful tool for the study of the anatomy and morphology of the neoglottis. With this protocol, characteristics relevant for tracheoesophageal voice quality, can be defined. The quantitative measures are promising for a more standardized evaluation of the neoglottis in laryngectomized individuals.

Introduction

Since the introduction of the first useful voice prosthesis two decades ago [1], tracheoesophageal voice has become a widely accepted and successful method of voice restoration after total laryngectomy. [2] The main advantage of this type of vocal rehabilitation over conventional esophageal speech is that it is pulmonary driven. Tracheoesophageal speech is proven to be closer to normal laryngeal speech than esophageal speech regarding acoustical characteristics [3-6], perceptual characteristics [7], and intelligibility.[8]

Since tracheoesophageal voice rehabilitation has become the method of choice after total laryngectomy [2], the main issue in voice rehabilitation is not any longer the ability to acquire speech.: up to 90% of the patients acquire a fair to excellent voice [9], while for esophageal speech this figure is much lower and more variable, as only 25% to 50% of these patients are able to develop functional esophageal speech [10-12]. However, one should keep in mind that tracheoesophageal voice is variable in quality. [13]

The new sound source, referred to as neoglottis, pseudoglottis, or pharyngoesophageal segment, is considered to play an important role in voice production. Throughout this paper the term **neoglottis** will be used. One of the methods frequently used for investigation of the neoglottis is videofluoroscopy. Videofluoroscopic studies have been performed far more often for esophageal voice [14-24], than for tracheoesophageal voice. [25, 26] Previous studies on esophageal voice were mainly conducted to get insight in factors influencing the acquisition of speech and were focused on discovering the site or source of vibration, causing the substitute esophageal voice. Several researchers found that sound originated at the level of the cricopharyngeus muscle. [14, 20, 27] It was also thought that it was not the mucous membrane that caused the sound, but the accumulated mucus above the neoglottis. [28] A number of researchers found that the ability to acquire esophageal speech was related to anatomical and morphologic characteristics of the neoglottis, such as dilatability of the hypopharynx and shape of the neoglottis [17], length and cervical level of the neoglottis [15], form of the neoglottis [18], extent of surgery [21], and tonicity of the pharyngoesophageal segment. [22, 24] Others could not find any relationship between good voice quality and variations in the anatomy and morphology of neoglottis. [19]Some even thought that the acquisition of voice was merely related to psychological factors. [21, 29] The age of the patient was also found to be an important factor for the ability to learn esophageal speech. [15, 16] Videofluoroscopic studies regarding tracheoesophageal speech showed that the visual characteristics of the vibratory segment of the tracheoesophageal and esophageal speakers were similar. [25, 26]

Unfortunately, both these studies lack assessment of voice quality in relation to the observed characteristics of the neoglottis.
Videofluoroscopy would gain in value if the visual assessment of anatomical and morphologic characteristics of the neoglottis were standardized and if these standards could be could be combined with quantitative measurements of the different dimensions of the neoglottis. This would make easier the establishment of a relationship between form and voice quality. Therefore, a novel assessment protocol for quantitative videofluoroscopy was developed and evaluated in relation to perceptual evaluation of voice quality.

Patients and methods

Patients

Thirty-nine patients who underwent laryngectomy, all of whom used tracheoesophageal speech by means of a Provox2 voice prosthesis (Atos Medical AB, Hörby, Sweden), were selected from a group of 173 patients with laryngectomies in follow-up in the Netherlands Cancer Institute [9 30]. Special care was taken to compose a sample of patients, in which all variations normally encountered in this group were represented. Therefore, both male and female patients, patients with a poorer voice quality, and patients with a reconstruction of their pharynx and/or esophagus were included in the study. Informed consent was obtained from all patients we asked to participate after they received written information about the purpose of the study. There were 29 males and 10 females. Ages varied from 47 to 82 years, with a mean of 67 years. The postoperative follow-up varied from 11 months to 18 years, with a mean of 6 years. Thirty patients had a standard wide-field total laryngectomy; these patients constitute the standard group. Nine patients had a pharyngeal reconstruction; these patients constitute the reconstruction group. Four patients in the reconstruction group underwent partial repair with a myocutaneous pectoralis major flap, and 5 received a total pharyngeal reconstruction (with a tubed gastric pull up in 2, a full gastric pull up in 1, and a tubed free radial forearm flap in 2 patients). In 22 patients of the standard group, an attempt was made during surgery to influence the tonicity (ie, muscular tension) of the neoglottis, by performing a myotomy of the cricopharyngeus muscle [31, 32], or a neurectomy of the pharyngeal nerve plexus. [33] In 5 patients a myotomy of the cricopharyngeus muscle combined with a neurectomy of the pharyngeal plexus was performed, while in 12 patients only a neurectomy of the pharyngeal plexus was performed. A unilateral neck dissection was carried out in 13 patients and a bilateral neck dissection in 5 patients.

Sixteen patients who underwent laryngectomy for a recurring tumor received primary radiotherapy to treat their laryngeal cancer; 21 patients received radiotherapy after their total laryngectomy; and 2 patients received no radiotherapy. **Table 1** gives an overview of the clinical information of the patients is given.

Table 1 Clinical parameters of the patient group (n=39) used in this study

Parameter		No.
Surgery	Standard total laryngectomy	30
	Reconstruction	9
Sex	Male	29
	Female	10
Tonicity control*	Myotomy+Neurectomy	5
	Neurectomy	17
	None	8
Neck dissection	None	21
	Unilateral	13
	Bilateral	5
Radiotherapy	None	2
	Primary	16
	Postoperative	21

* For the standard group (n=30)

Videofluoroscopy

The videofluoroscopy recordings were obtained with a Philips Diagnost 92 system (Philips Medical Systems, Eindhoven, the Netherlands) together with a Panasonic NV-HD650 video recorder (Matsushita Electric Industrial Co, Osaka, Japan). Videofluoroscopic recordings were made of all patients vocalizing 2 phonations of the sustained vowel /a/ at a comfortable pitch and loudness level. All x-ray film recordings were made in lateral view; patients were asked to swallow barium and phonate afterwards. A reference coin was stuck to the cheeks of the patients to enable the quantification of the different dimensions.

Speech recordings

Recordings for the perceptual evaluation were made of one fixed text that was read aloud. The recordings were made with use of the Computerized Speech Lab (CSL) (Kay Elemetrics, Lincoln Park, NJ). A standard headset microphone that came with the equipment was used,

and through the hardware of this system, with use of the CSL software, the speech data were directly recorded on a digital audio tape (DAT) by means of a Sony TCD-8 DAT recorder (Sony Electronics Inc, Park Ridge, NJ). For the perceptual evaluation, the read-aloud texts of all speakers were randomly recorded on another DAT. The text that was read by each speaker was repeated until 2.5 min had been recorded on the tape.

Visual assessment of anatomical and morphologic characteristics of the neoglottis

In the pilot phase, three judges jointly viewed all videofluoroscopy recordings using the definitions of tonicity as proposed by McIvor et al.[24] and Van Weissenbruch. [34]
These definitions include the tonicity not only during phonation, but also during swallowing and at rest. It was extremely difficult to reach consensus among the 3 judges using these definitions. A large number of our patients could not be categorized into 1 tonicity group because they did not meet all the criteria for one particular group or because they met the criteria for several groups.
Therefore, the assessment had to be adjusted considerably: the flattening of the neoglottic bar during swallowing and the appearance of a neoglottic bar at rest were judged separately from the tonicity of the neoglottis during phonation. Also, the presence or absence of regurgitation and stasis of barium contrast, as well as the level of the neoglottis relative to the cervical vertebrae, were added. With these adjustments, consensus was reached much more easily.
Apart from these more or less objective assessments, tonicity during phonation was judged subjectively using the following criteria: The tonicity of the neoglottis was judged **normotonic** when there was closure of the neoglottis, i.e., a complete or almost complete dynamic contact of the neoglottic bar with the anterior esophageal wall during phonation. The tonicity of the neoglottis was judged as **hypotonic** when there was no closure of the neoglottis during phonation and as **hypertonic** when the neoglottis was fully closed during phonation combined with considerable dilation of the esophagus below the neoglottis. **Spasm** was defined as complete closure of the neoglottis, with extreme dilation of the esophagus below the neoglottis during attempted phonation with no passage of air through the neoglottis. **Stricture** was defined as narrowing of the esophagus with no dynamic changes in any of the situations judged separately.

Quantitative measurements of the neoglottis

In addition to the visual assessment of the anatomical and morphologic characteristics, metrical measures were also used in the evaluation protocol. These quantitative measures of the neoglottis were obtained using a software program called Drawer (developed by M.B. van Herk, physicist at the Netherlands Cancer Institute/ Antoni van Leeuwenhoek Hospital, Amsterdam), which was initially designed to measure tumor volumes for the purposes of radiotherapy. Relevant frames of the neoglottis both rest and phonation were selected from the recordings (**Figure 1**), digitalized with a frame grabber, and saved as an image file. From these digitalized images, the quantitative measures were calculated. Distances were measured (in pixels) with a ruler-like tool. Areas were measured by indicating the region of interest with a paintbrush tool, after which the computer program counted the number of pixels in the region. **Figure 2** shows the neoglottis, along with indications of the measures performed. All measures in pixels were converted to millimeters or square millimeters using a coin with a known diameter.

Figure 1
On the left hand side, the videofluoroscopy image of the situation at rest and on the right hand side, the situation during phonation

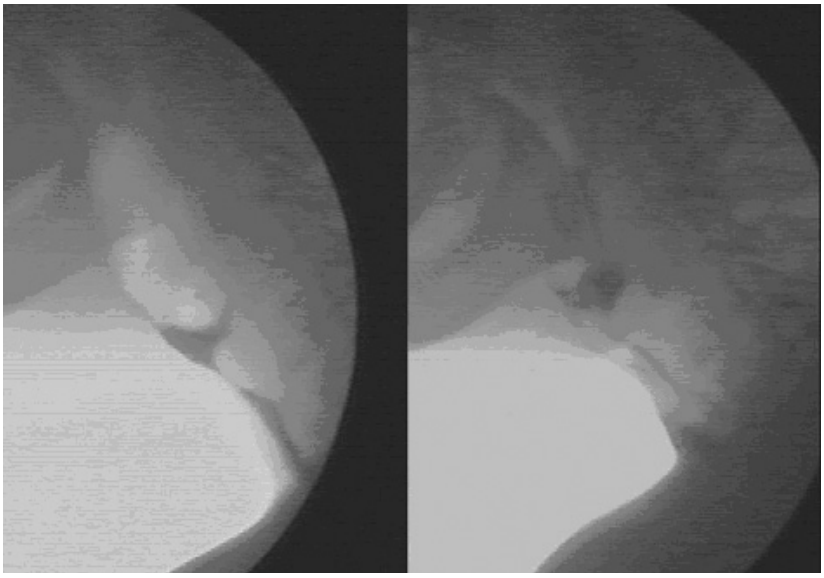
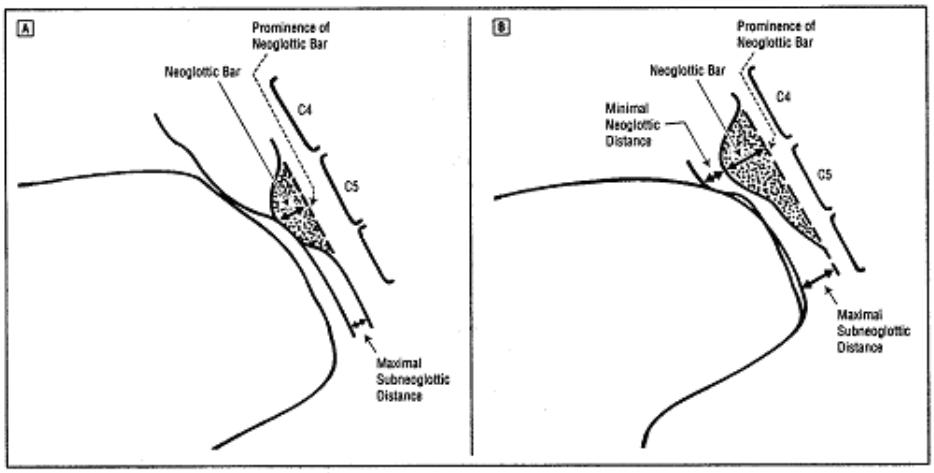


Figure 2
Schematic drawing of the videofluoroscopy image in Figure 1



Parameters measured

The minimal distance (in millimeters) was measured as the distance between the neoglottic bar and the anterior wall of the esophagus (ie, the width of the neoglottis) at rest (MINREST) and during phonation (MINPHON). The maximal subneoglottic distance (in millimeters) was measured as the maximal width of the esophagus below the neoglottis at rest (MAXREST) and during phonation (MAXPHON). The line on which the measurements were made was placed perpendicular to the posterior wall. The surface area of the neoglottic bar in lateral view (in square millimeters) was measured at rest (SURREST) and during phonation (SURPHON) in the lateral view. The prominence of the neoglottic bar toward the anterior wall (in millimeters) was measured at rest (PROMREST) and during phonation (PROMPHON). The line on which the measurement was based was placed perpendicular to the posterior wall at the most prominent point of the neoglottic bar.

In addition to these quantitative measures, the MAXPHON/MAXREST index was also calculated in order to reflect the increase of the maximal subneoglottic distance during phonation. This index is thought to give an impression of the tension of the closure of the neoglottis-tighter closure of the neoglottis may reflect a larger increase in subneoglottic distance-, although this increase may also be dependent on the rigidity of the subneoglottic tissues.

Perceptual evaluation of voice quality

Four speech and language pathologists experienced in the treatment of patients with laryngectomies were trained in the perceptual evaluation of this patient group. The evaluation involved 19 bipolar semantic 7-point scales and one overall judgment of voice quality in which the voice was judged as good, reasonable or poor. A good voice was defined as "almost similar to normal voice", a poor voice was defined as "very deviant from normal voice", and reasonable voice was defined as "somewhere in between both extremes". At the time, the results of the extended perceptual evaluation of the semantic scales were under investigation. In the present study, only the results of the overall judgment were used. The interrater reliability calculated with Cronbach α was .88. In order to compare the videofluoroscopy recordings the speakers were divided into 3 subgroups on the basis of overall voice quality. A voice was considered good or poor if at least 2 of the 4 listeners evaluated it as such. Voices that were judged good (or poor) by 1 listener and reasonable by three listeners were considered reasonable. In no instance was a voice judged good by one listener and poor by another.

Statistics

Statistical analysis was performed using the Statistical Package for Social Sciences version 7.5 (SPSS Inc, Chicago, Ill). Paired t-tests were used to compare the quantitative measures between rest and phonation, and chi-squared tests for linear-to-linear association were used to investigate the relations between voice quality, visual assessment, and clinical parameters, as well as the relations between visual assessment and voice quality. For the relation between voice quality and tonicity, an exact chi-squared test was used. Because of concerns regarding assumptions of normality for the quantitative measurements MINREST and MINPHON, non-parametric tests were used. Relations between the clinical parameters and the quantitative measurements and between the visual assessment (except for tonicity) and the quantitative measurements were investigated by means of either a t-test for independent samples or a Mann-Whitney test, depending on the distribution of the observed values. Relations between tonicity (3 subgroups) and the quantitative measurements and between voice quality (3 subgroups) and the quantitative measurements were investigated by means of analysis of variance followed by post hoc Tukey tests or by means of Kruskal-Wallis tests followed by Mann-Whitney tests with a Bonferroni correction, depending on the distribution of the observed values. In the case of obvious differences between standard deviations according to the Levine test of equality of variances, a modified t-test was used.

Results

Table 2 gives the results of the visual assessment of the anatomical and morphologic characteristics of the neoglottis for both speaker groups.

Table 2 Anatomical and morphological characteristics of the standard and reconstruction groups

Parameter	No. of patients	
	Standard (n=30)	Reconstruction (n=9)
Neoglottic bars at rest, No.		
0	7	7
1	19	2
2	4	0
Neoglottic bars during phonation, No.		
0	6	4
1	21	5
3	3	0
Regurgitation of barium during phonation		
Yes	10	4
No	20	5
Stasis of barium on neoglottic bar during phonation		
Yes	5	4
No	25	5
Flattening of the neoglottic bar during swallowing*		
Yes	15	1
No	8	1
Tonicity of neoglottic bar during phonation		
Hypotonic	9	6
Normotonic	13	2
Hypertonic	8	0
Stricture	0	1

* Only relevant in those patients in whom a neoglottis was present

At rest, 19 patients showed 1 neoglottic bar and 4 patients 2 neoglottic bars. During phonation, 21 patients showed 1 neoglottic bar and 3 patients 2 neoglottic bars. The number of patients with 2 neoglottic bars at rest (n=4) or during phonation (n=3) was too small for separate evaluation in statistical analysis. Since the voice quality of the groups with one and two neoglottic bars was thought to be comparable, these groups were taken together in further analyses. The 1 patient with stricture was left out of the analysis regarding tonicity, since no meaningful statistical analysis is possible with only one patient in a subgroup.
In the standard group, the neoglottis at rest was mostly situated around cervical vertebrae C4 and C5. During phonation, however, the neoglottis was situated somewhat higher in most speakers, with an upward shift from C4-5 to C3-4 (Table 3).

Table 3 Cervical level of the neoglottis in the standard and reconstruction groups at rest and during phonation

Cervical vertebrea/spaces	Standard (n=30)		Reconstruction (n=9)	
	Rest	Phonation	Rest	Phonation
C3		1ab,35	18	18,37
C3-4	1a,25	14,20,21b,25		
C4	1b,14,15,20,35,3,8	6a,7,8,9,15,21a,24,26,30		16
C4-5	7,8,9,21,24	10,12,22,28	16	
C5	6ab,10,12,22,30,33a	23		
C5-6	23,34	33b,36		
C6	33b,36	2ab,13		19
C6-7	2ab,13			
C7		5		17

Quantitative measurements of the neoglottis

Quantitative measurements are given in Table 4. Paired t-tests between the measures at rest and during phonation showed statistically significant differences in the 'standard' group for 2 measurements: MAXPHON was larger than MAXREST ($p<.001$), and PROMPHON was larger than PROMREST ($p< .001$). No differences were found in the reconstruction group.

Table 4 Quantitative measures of the neoglottis for the standard and the reconstruction groups

Parameter	Standard	Reconstruction
MINREST, mm	1.2 (1.4)	5.5 (4.2)
MINPHON, mm	1.5 (2.1)	4.2 (3.1)
MAXREST, mm	6.4 (3.6)†	8.1 (4.0)
MAXPHON, mm	10.6 (4.7)†	9.1 (4.6)
SIZEREST, mm^2	81 (80)	14 (23)
SIZEPHON, mm^2	88 (67)	28 (26)
PROMREST, mm	5.2 (3.8)††	1.8 (1.9)
PROMPHON, mm	8.0 (5.6)††	4.6 (5.37)
MAXPHON/MAXREST	2.05 (1.39)	0.61 (0.30)

*Values are mean (SD). MINREST indicates minimal distance at rest; MINPHON, minimal distance during phonation; MAXREST, maximal distance at rest; MAXPHON, maximal distance during phonation; SURREST, surface area of the neoglottis at rest; SURPHON, surface area of the neoglottis during phonation; PROMREST, prominence of the neoglottis at rest; and PROMPHON, prominence of the neoglottis during phonation.
†MAXPHON was significantly greater than MAXREST ($p<.001$).
‡PROMPHON was significantly greater than PROMREST ($p<.001$)

Voice quality

Voice quality could be judged for 38 out of the 39 patients, since 1 patient died before the speech sample could be obtained. Voice quality was judged as good for 13 patients, reasonable for 14, and poor for 11.

Relation between the clinical parameters and the visual assessment of the neoglottis

The neoglottic bar at rest was more often visible in the standard group than in the reconstruction group ($p=.003$). Furthermore, patients with a standard total laryngectomy more often had a normotonic or hypertonic neoglottis during phonation than the patients with a reconstructed ($p=.02$).
Within the standard group, there was no relation between visual assessment of the neoglottis and the clinical parameters myotomy, neurectomy, radiotherapy, neck dissection, age, postoperative follow-up, and sex. Relations with visual assessments were investigated only within the standard group; either the reconstruction group was too small or the parameters were invalid.

Relation between the clinical parameters and the quantitative measures of the neoglottis

The SURREST and SURPHON measurements were larger in the standard group than in the reconstruction group (SURREST, $p=.02$; SURPHON, $p=.01$), and the PROMREST measurements were smaller in the reconstruction group than in the standard group ($p<.01$). The MINREST and MINPHON measurements were smaller in the standard group (MINREST, $p=.001$; MINPHON, $p=.01$) than in the reconstruction group.
Results within the standard group also revealed a relationship between clinical parameters and quantitative measures. Whether the patient had a radical neck dissection appeared to influence some measurements of the neoglottis. The MINPHON measurement was smaller in the subgroup without neck dissection ($p=.04$), indicating that this group had a more closed neoglottis. Age was another factor that was associated with differences in the measurements; the MINREST measurement appeared smaller in the younger patient group (<70 years) ($p=.048$), indicating a narrower neoglottis in the younger patient group and a looser neoglottis in the older patient group. The clinical parameters myotomy, neurectomy, postoperative follow-up, radiotherapy, and sex were not associated with any differences in the quantitative measurements.

Relation between the clinical parameters and the voice quality

The chi-squared tests for linear-to-linear association did not reveal any relation between voice quality and the clinical parameters reconstruction, myotomy, neurectomy, radiotherapy, neck dissection, age, postoperative follow-up, and sex.

Relation between the visual assessment and the quantitative measures of the neoglottis

Relations between visual assessment and quantitative measures of the neoglottis were based on the results for all of the speaker groups, since the type of surgery was irrelevant. In the subgroup with the appearance of a neoglottic bar at rest, SURREST and SURPHON, PROMREST and PROMPHON, and MAXPHON were larger (SURREST, SURPHON, and PROMREST, $p<.001$; PROMPHON, $p=.003$; MAXPHON, $p=.03$) and MINREST was smaller ($p=.01$) than in the subgroup without the appearance of a neoglottic bar at rest.
The assessment of the appearance of a neoglottic bar during phonation showed several relationships with the quantitative measures. In the subgroup with a neoglottic bar during phonation, SURPHON and SURREST, PROMPHON and PROMREST, and MAXPHON and MAXPHON/MAXREST were larger

(SURPHON, PROMPHON, PROMREST, p< .001; SURREST, p=.01; MAXPHON, MAXREST, p=.01) and MINREST and MINPHON were smaller (p<.001) than in the subgroup without a neoglottic bar during phonation. These results indicate that the presence of a neoglottic bar during phonation was related to a shorter distance between the neoglottic bar and the anterior wall of the esophagus. Likewise, a larger subneoglottic distance during phonation was related to a larger SURPHON and a greater PROMPHON, as well as a relatively larger increase in MAXPHON. The tonicity of the neoglottic bar during phonation, when divided into the subgroups hypotonicity, normotonicity, and hypertonicity, also showed a relationship with the quantitative measures (**Table 5**), with a clear distinction between the 3 levels of tonicity.

For instance, whereas SURPHON, PROMPHON, MINREST, and MINPHON were distinctive between hypotonicity and normotonicity and between hypotonicity and hypertonicity, MAXREST and MAXPHON were distinctive between hypotonicity and hypertonicity and between normotonicity and hypertonicity.

The assessment of regurgitation of barium during phonation was also related to the quantitative measures. In the subgroup in which regurgitation of barium was observed during phonation, SURREST and SURPHON, PROMREST and PROMPHON, and MAXPHON were smaller (p=.02, p=.01, p=.02, p<.001, and p=.02, respectively) and MINREST and MINPHON were larger (MINREST, p=.003; MINPHON, p<.001) than in the subgroup in which no regurgitation of barium was observed during phonation. These results indicate that regurgitation occurred when the neoglottic bar was small or not present as well as when the neoglottis was wide.

Regarding the cervical level of the neoglottis, stasis of barium above the neoglottic bar during phonation, and flattening of the neoglottic bar during swallowing, no relations with the quantitative measures were found.

Table 5 Relations between quantitative measures and tonicity*

Quantitive measure	Overall p	Hypotonic (n=14)	Normotonic (n=15)	Hypertonic (n=8)
MINREST,†,mm	<.001	4.1 (3.4)	0.8 (1.1)	0.5 (0.9)
		p<.001	p>.99	
		p=.003		
MINPHON,†,mm	<.001	4.6 (2.3)	0.7 (1.0)	0 (0)
		p<.001	p=.39	
		p<.001		
MAXREST,††,mm	.25	7.0 (3.3)	5.0 (2.7)	9.3 (4.7)
		p=.27	p=.02	
		p=.29		
MAXPHON,††,mm	<.001	7.7 (2.6)	9.8 (4.1)	16.2 (3.9)
		p=.24	p=.001	
		p<.001		
SURREST,††,mm^2	.045	31 (38)	84 (95)	106 (72)
		p=.13	p=.77	
		p=.06		
SURPHON,††,mm^2	.001	32 (45)	97 (64)	118 (54)
		p=.009	p=.65	
		p=.003		
PROMREST,††,mm	.006	2.5 (2.6)	5.2 (3.1)	7.2 (4.6)
		p=.08	p-.33	
		p=.006		
PROMPHON,††,mm	<.001	2.7 (3.2)	9.2 (3.7)	12.9 (5.8)
		p<.001	p=.11	
		p<.001		

*Values are mean (SD). For expansions of abbreviations, see the first footnote to Table 4.
† For these nonparametric measures, the Kruskal-Wallis test and Mann-Whitney test with Bonferroni correction were used
††For these parametric measures, analysis of variance and the post hoc Tukey test were used

Relation between voice quality and visual assessment of the neoglottis

The visual assessment of the appearance of a neoglottic bar during phonation (Table 6) and the tonicity of the neoglottis during phonation (Table 7) showed significant relations with voice quality (p=.03 for appearance of a neoglottic bar; p=.02 for tonicity), such that a good voice was related to the appearance of a neoglottic bar during phonation.

Table 6 Relations between appearance of a neoglottis during phonation and voice quality*

Neoglottis during phonation	Voice Quality			
	Poor	Reasonable	Good	Total
None	4	5	0	9
1 or 2	7	9	13	29
Total	11	14	13	38

*p=.03. Values are numbers of patients

Regarding tonicity, a good voice was related to a normotonic or hypertonic neoglottis. Among the good voices, a hypotonic neoglottis was never observed. The number of speakers in this analysis was 37, since 1 speaker with stricture also fell in the poor group; this speaker was not included in statistical analysis.

Table 7 Relations between tonicity of the neoglottis during phonation and voice quality*

Tonicity	Voice Quality			
	Poor	Reasonable	Good	Total
Hypotonic	6	8	0	14
Normotonic	2	4	9	15
Hypertonic	2	2	4	8
Total	10	14	13	37

*p=.02. Values are numbers of patients

The assessment of the appearance of a neoglottis at rest, regurgitation of barium during phonation, stasis of barium on the neoglottis during phonation, and flattening of the neoglottic bar during swallowing showed no relations with voice quality.

Relation between voice quality and quantitative measures of the neoglottis

The index MAXPHON/MAXREST (p=.01), MINPHON (p<.001), and MINREST (p=.01) were different between the speaker groups (**Table 8**).

Table 8 Relations between quantitative measures and voice quality*

Parameter	Overall p	Poor (n=11)	Reasonable (n=14)	Good (n=13)
MINPHON,†,mm	.009	3.6 (3.6)	2.5 (1.8)	0.5 (1.0)
		p>.99	p=.02	
		p=.02		
MINREST,†,mm	.001	3.8 (4.0)	2.5 (2.6)	0.3 (0.7)
		p>.99	p=.02	
		p=.001		
MAXPHON/MAXREST	.005	1.4 (0.6)	1.7 (1.5)	2.9 (1.6)
		p>.99	p=.02	
		p=.006		

*Values are mean (SD). For expansions of abbreviations, see the first footnote to Table 4
†For these nonparametric measures, the Kruskal-Wallis test and Mann-Whitney test with Bonferroni correction were used

On the basis of these 3 quantitative measures, a distinction can be made between a poor and a good voice, or between a reasonable and a good voice. The MINREST and MINPHON measures were during phonation for a good voice than for a poor voice (MINREST, $p<.001$; MINPHON, $p=.02$), and better speakers showed a relatively larger increase in the MAXPHON/MAXREST ($p=.01$). For the other quantitative measures no relations with the overall judgment of voice quality were found.

Discussion

Videofluoroscopy has proven to be an important tool for the assessment of the neoglottis for both esophageal and tracheoesophageal speech. [14-26] Although videofluoroscopy is clinically valuable on the level of the individual patient, the descriptive nature of the evaluation and the lack of objective measures has hampered its wide spread use as a research tool. The present study was started in order to develop videofluoroscopy into a more objective and reproducible evaluation instrument for the analysis of anatomical and morphologic characteristics of the neoglottis. Another objective of this study was the correlation of videofluoroscopy results with voice quality in tracheoesophageal speech, which has been lacking so far.

Visual assessment of the anatomical and morphologic characteristics of the neoglottis appears to be facilitated by judging the different phases of movement of the neoglottis (at rest, during phonation, and when swallowing) separately.

With the method used by others in which this distinction was not applied, consensus judgments appeared to be less easy and efficient. [22, 24] The method presented herein leaves only one subjective parameter-tonicity of the neoglottis during phonation. The remaining parameters are more or less objective because of their use of clear dichotomies and/or numbers.

Only 3 out of 30 patients showed a double neoglottic bar during phonation, which contrasts with the findings of others, who have described this phenomenon in 5 out of 16, and 3 out of 4 patients. [25, 26] The neoglottis was located at the level of C4-5 in the majority of our patients, which is more cranial than the C5-6 level reported for the majority of patients in studies of esophageal speech. [15, 18, 29] In our study, the level tended to rise by approximately half a vertebra from rest to phonation, a phenomenon that was not observed in esophageal speech.[29] It is likely that this upward shift in tracheoesophageal voice was caused by the greater aerodynamic effect in the pulmonary driven tracheoesophageal speech.

Our method of obtaining quantitative measures was easy and straightforward, using digital images and special image evaluation software with a reference marker to allow calculation of exact distances and surface areas. The quantitative measures showed a large variability in the speaker group that was reflected in the relatively high SDs. Differences were found between rest and phonation for the maximal subneoglottic distance and the prominence of the neoglottis in the standard group, indicating a dynamic change of the neoglottis from rest to phonation.

Perceptual evaluation is still the gold standard for the evaluation of voice quality. [13] In the method applied, 4 trained judges distinguished 3 voice quality subgroups: 11 speakers with poor voices, 14 with reasonable voices, and 13 with good voice quality. Voice quality is not easily defined. In this study, a voice that was considered close to normal was called good, and a voice that was very deviant from normal was judged as poor. A voice that was not very close to normal but also not very deviant, for instance slightly bubbly, was judged as reasonable. The high interrater reliability of the perceptual evaluation shows that our subgroupings were consistent and reliable and therefore useful for comparison with the other outcome measures in this study.

Some correlations were observed between clinical parameters and quantitative measures. The differences between the standard and the reconstruction groups were not surprising because of the larger extent of surgery in the latter group. Our results suggest that the present reconstruction techniques still result in less favorable conditions of the neoglottis. Furthermore, our quantitative measures indicate that neck dissection and age have an influence.

The MINPHON measure was smaller in the group without neck dissection and the MINREST was smaller in patients under 70 years of age. These quantitative measures are correlated with good voice quality. The finding that neck dissection seems to influence the anatomy of the neoglottis has not been reported earlier for tracheoesophageal voice and needs to be studied in larger series before any conclusions can be drawn, especially since results for esophageal voice quality are conflicting. Smith **et al.** [16] found that patients with a laryngectomy only had better voice results than patients with an additional neck dissection, whereas Richardson did not find any such influence. [21]

Investigating the relationship between the results of the visual assessment and the quantitative measures was one of the main objectives of this study. Replacement of the more subjective visual assessments of the neoglottic characteristics by more objective and precise quantitative measures could allow the evaluation of videofluoroscopy recordings in a more consistent and standardized manner, with the results within and between studies could become easier comparable in the future. It is noteworthy that relations between quantitative measures and visual assessment were found for all parameters, except for flattening of the neoglottic bar during swallowing and stasis of barium above the neoglottic bar during phonation. This suggests that the majority of the visual assessments might be replaceable by these quantitative measures.

Another important part of this study was to investigate the possible relations between the neoglottis and voice quality. To the best of our knowledge, this particular study has not yet been performed for tracheoesophageal speech. Results showed that voice quality was related to the appearance of a neoglottic bar during phonation and to tonicity of the pharyngoesophageal segment. This is most obvious in the good group, members of which always had a visible neoglottic bar during phonation; none were hypotonic, but some were hypertonic. All 3 types of tonicity were seen in the poor and reasonable voice groups, which suggests that tonicity is not as clear an indicator for voice quality as might be expected. However, these results make it clear that hypotonicity is an unfavorable condition of the neoglottis regarding voice quality and should be avoided. On the other hand, hypertonicity of the neoglottis is clinically much less of a problem, since it still can be associated with a good voice and, in relevant cases, can be fixed relatively easily by surgical intervention (myotomy) [31, 32] or medical intervention (botulinum toxin type A injection (Botox; Allergan Inc, Irvine, Calif)). [35] Hypotonicity can be fixed only by exerting some digital pressure on the external neck, thereby enabling approximation of the esophageal tissues during phonation. Other forms of surgical intervention or phonosurgery of the neoglottis are not yet available for this problem. Since it is common nowadays to perform a neurectomy of the pharyngeal plexus and/or a myotomy of the pharyngeal muscles during total laryngectomy, it should be stressed that care should be taken to avoid overcorrection, which could result in hypotonicity. [31-33]

Results of the investigation of the relations between voice quality and quantitative measures were interesting. The most important factor appeared to be MINPHON-- the closer the neoglottis, the better the voice quality. This shows the relevance of closure for the sound production, something that is already well known for normal laryngeal voices. Surprisingly, this measure was not used in earlier studies regarding esophageal speech. However, some quantitative measures were performed in some studies. They were always performed during phonation, and consisted of the length of the neoglottis, [25] the prominence of the neoglottis, [18] the dilatability of the esophagus below the neoglottis, [29] and the width of the hypopharynx.[17] The only measure comparable to one of those used in our study was the "dilatability" of the esophagus, expressed by the MAXPHON/MAXREST index, which appeared to influence voice quality.[29] These authors observed a relation between the acquisition of esophageal speech and the width of the esophagus, indicating that a wider subneoglottic distance was related to a better voice. They presumed that a greater amount of air would be obtained within the lumen, providing a sufficient amount of air for voice production. In the present study, we also found that the MAXPHON/MAXREST index differed between the voice quality groups. The good speakers showed a relatively larger increase in MAXPHON compared to MAXREST. Presumably, in tracheoesophageal speech, the increase in maximal subneoglottic distance is related to the tension of the neoglottic closure together with the flexibility of the tissues of the neck. In this respect, it should be noted that tension of the neoglottis that is too high (ie, extreme hypertonicity or spasm) led to a relatively large increase in the maximal subneoglottic distance, with very poor or even absent voice. Since there was a clear correlation between the visual assessment and the quantitative measures, it seems possible to substitute for the classical visual parameters the quantitative measures MINREST and MINPHON, as well as the MAXPHON/MAXREST index. The only exception was the situation in which there was hypertonicity or spasm of the neoglottis in conjunction with fibrosis of the surrounding tissues in the neck. In such a case, hypertonicity did not lead to extreme dilatation of the subneoglottic region.

The finding that the quantitative measures show no difference between the poor and the reasonable group can be explained best by the assumption that the neoglottic characteristics leading to a poor or reasonable voice quality are diverse. Problems with saliva interference and/or regurgitation may decrease voice quality substantially, irrespective of the tonicity of the neoglottis.

In conclusion, this study shows that it is possible to analyze videofluoroscopy images in a more quantitative manner and that some objective measures can be applied to replace the descriptive parameters formerly used to assess the neoglottis. The clear correlation of the videofluoroscopy results with good voice quality and the objective nature of the proposed assessment protocol may increase the usefulness of this imaging technique for the rehabilitation of individuals with laryngectomies.

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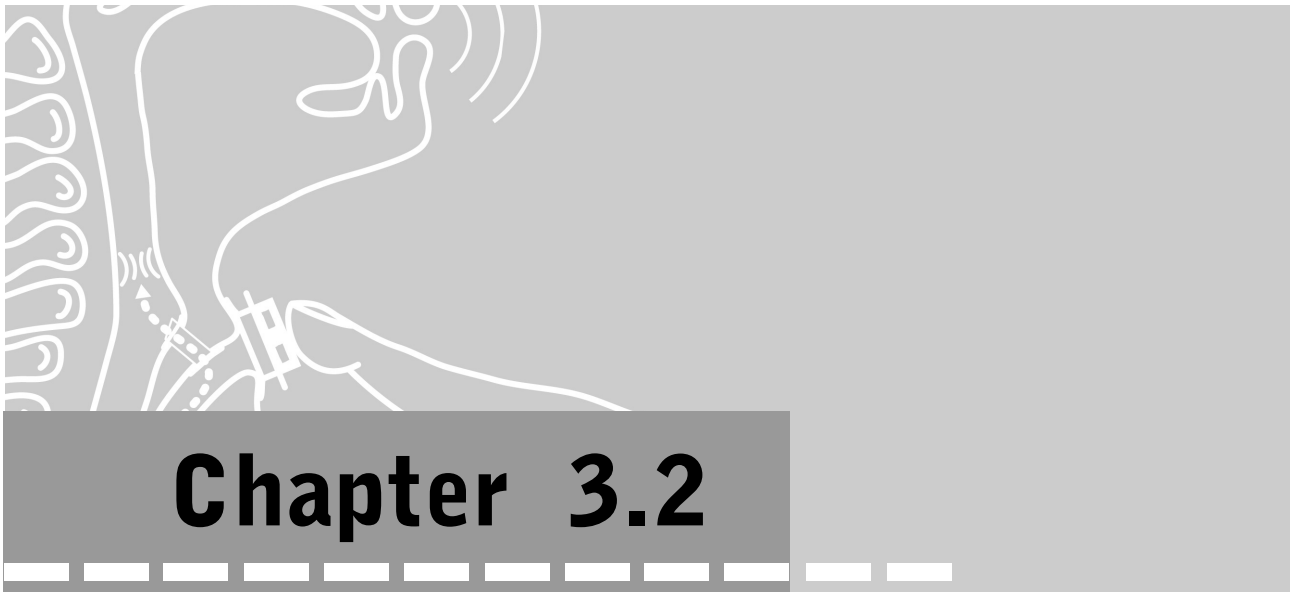

Chapter 3.2

Evaluation of the effects of primary myotomy in total laryngectomy of the neoglottis with the use of quantitative videofluoroscopy

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Abstract

Objective: To evaluate the influence of primary myotomy on characteristics of the neoglottis in patients after laryngectomy.
Design: Patient survey.
Setting: University Medical Center St. Radboud, Nijmegen, the Netherlands.
Patients: Nineteen consecutive laryngectomized patients (12 with primary lateral myotomy of the upper esophageal sphincter (marked by metal clips); 7 not requiring myotomy, (according to peroperative palpation).
Interventions: Videofluoroscopy.
Main Outcome Measures: Visual assessments and quantitative measures of the neoglottis were used to study the relations between myotomy, and anatomy and morphology of the neoglottis.
Results: Quantitative measurements showed no difference between the neoglottic characteristics of the myotomized (n=12) and non-myotomized (n=7) patients, who were all judged to have moderate (n=4) or good (n=15) voice quality. Results for the entire patient group during phonation showed only one single neoglottic bar, no hypertonicity of the neoglottis, and a significant shortening of the neoglottic bar (P= .007). Results for the myotomized group during phonation showed elevation of the caudal clip (P= .046), shortening of the myotomy (P= .011) and decreased overlap of the cranial clip and the neoglottic bar (P= .007). Furthermore, significant relations were found between the various quantitative measures of the neoglottis and those of the myotomy.
Conclusions: Quantitative videofluoroscopy enables study of the influence of myotomy on the anatomical and morphologic characteristics of the neoglottis. Our results suggest that a planned myotomy of the upper esophageal sphincter is beneficial when applying prosthetic voice rehabilitation after total laryngectomy.

Introduction

The importance of vocal rehabilitation following total laryngectomy has been recognized ever since Billroth performed the first laryngectomy due to cancer.1 Until the nineteen-eighties, the majority of laryngectomized patients used esophageal speech and/or an artificial larynx for communication. Since the introduction of voice prostheses, initiated by Singer and Blom, better and more consistent results in vocal rehabilitation were able to be achieved.[2] During the following years, several different types of voice prostheses were developed, broadening choices for patients and health care providers. [2-7]

Prosthetic tracheoesophageal speech is the most successful method of vocal rehabilitation presently available. Success rates of up to 90% have been reported in recent years. [8-11] In various studies, tracheoesophageal speech has been shown to give better results than esophageal and/or electrolarynx speech. [2, 12-15]

Despite this progress, not all patients acquire good tracheoesophageal speech. The reasons for this are not always clear. Besides possible psychological, social and educational factors, variations in surgical techniques may also influence the success of this form of alaryngeal speech. [16-19] Singer and Blom in 1981 were the first, to our knowledge, to identify the importance of an optimal tonicity of the pharyngoesophageal segment and the potential to improve the voice quality by constrictor pharyngeus myotomy.[20] Suggestions for closure or non-closure of the muscular layer have been discussed. Unilateral neurectomy and/or myotomy in the prevention of hypertonicity or spasm of the neoglottis were found to have an impact on the success of postlaryngectomy vocal rehabilitation.[19-21]

The effects of these surgical interventions were mostly studied by means of insufflation tests and/or radiographic contrast studies, either by plain photography or more dynamically by videofluoroscopy.[22-25] Using these imaging techniques, descriptions of the anatomy and morphology of the neoglottis in particular were given. In a recent study, a new 'quantitative videofluoroscopy' protocol has been presented to evaluate the anatomy and morphology of the neoglottis in a more standardized manner. [26]

In the present study, this quantitative videofluoroscopy protocol was used to study the anatomical and morphologic characteristics of the neoglottis in a consecutive series of patients, in which the cricopharyngeus muscle/upper esophageal sphincter was hypotonic, either after a short myotomy or spontaneously, as judged by intraoperative palpation. Furthermore, with marking of the borders of the myotomy-treated sphincter with clips, quantitative videofluoroscopy allowed detailed study of the relation between the neoglottic bar and the cricopharyngeus muscle.

Patients and methods

Patients

The patient group studied consisted of a consecutive series of 19 patients treated at the University Medical Center St.Radboud, during a 1-year period. All underwent a standard total laryngectomy and used tracheoesophageal speech by means of voice prostheses (Provox (Atos Medical AB, Hörby, Sweden), Nijdam (Medin, Groningen, the Netherlands) or Groningen (Medin)(these patients were part of a prospective study published earlier[7]). The indication for total laryngectomy was a laryngeal carcinoma in 18 patients (9 glottic, 9 supraglottic) and 1 hypopharyngeal carcinoma. Four patients received no radiotherapy. Eleven patients were treated for a recurrence after radiotherapy, and four patients were treated with radiotherapy postoperatively. There were 17 males and 2 women. Ages, calculated at the moment of videofluoroscopy, ranged from 39 to 78 years, with a mean of 62 years. The interval between surgery and videofluoroscopy varied from 2 to 7 years, with a mean of 5.4 years. In 15 patients the voice quality was judged as good and in 4 patients as moderate using the criteria described in a study of Van den Hoogen et al.[7]

Indication and technique of primary myotomy

After the removal of the larynx, the tonicity of the cricopharyngeus and upper esophageal musculature (referred to as **upper esophageal sphincter**) was evaluated by intraluminal palpation (by introduction of a finger). Guided by the tonicity of the upper esophageal sphincter, the surgeon decided whether to perform a primary, lateral myotomy of this musculature. In 12 patients, the upper esophageal sphincter was deemed to be hypertonic on palpation and the surgeon decided to carry out this procedure. To mark the length and position of the myotomy, a metal clip was placed at its cranial and caudal border. In the remaining patients, the surgeon considered the upper esophageal sphincter not to be hypertonic on palpation, and no myotomy was carried out. This procedure was followed by closure of the pharyngeal mucosa T-shaped in 2 layers and closure of the constrictor pharyngeus musculature.

Videofluoroscopy

Videofluoroscopy recordings were made of a sustained /a/ at comfortable loudness level and pitch, while the patient was in a lateral position (Siemens Polystar; Siemens, Erlangen Germany).

To delineate the pharyngoesophageal segment optimally, the patient was asked to swallow high density barium. This resulted in a good visualization of the mucosal surfaces of the hypopharynx, PE-segment, and oesophagus. The patient was asked to take one swallow of barium and to phonate afterwards. A metal reference scale in centimeters was taped to the patient's neck, in order to enable quantification of the different dimensions.

Quantitative videofluoroscopy protocol

Videofluoroscopy images were analyzed according to the protocol described by Van As et al.[26] In brief, this protocol consists of a standardized visual assessment form, using clear dichotomies (yes/no), anatomical landmarks (cervical vertebrae C4-5-6) and one subjective scale (hyper-normo-hypotonicity), in combination with quantitative measurements of the neoglottis, making use of the image analysis software program Drawer.(developed by M.B. van Herk, PhD, Netherlands Cancer Institute/ Antoni van Leeuwenhoek Hospital, Amsterdam)
Recordings were visually assessed for the situation at rest, during swallowing and during phonation separately by two observers, making use of consensus judgment. The neoglottis was judged as normotonic, when there was a full or almost full closure during phonation; hypotonic, when there was no closure of the neoglottis during phonation; and hypertonic when the neoglottis was fully closed during phonation combined with considerable dilation of the esophagus below the neoglottis during phonation.
For the quantitative measures, relevant frames for the situation at rest and during phonation were chosen from the videofluoroscopy recordings, using a frame grabber. In the program Drawer the relevant contours of the neoglottis (anterior and posterior esophageal wall, neoglottic bar) were outlined, and the reference points for several distances and the surface area were marked. All measurements were calculated in pixels and then transformed to millimeters by use of a scale in centimeters, which was adhered to the patients' skin as a reference. The Figure 1.a. shows a schematic drawing of the neoglottis, together with the quantitative measures performed. The following parameters were measured:
Minimal distance during phonation, the distance during phonation between the neoglottic bar and the anterior wall of the esophagus (a in **Figure 1.a**);
Minimal distance at rest, defined the same as during phonation; **Maximal subneoglottic distance during phonation**, defined as the level of maximal distance; the line on which the measurements were made was placed perpendicular to the posterior wall (b in **Figure 1.a**);

Maximal subneoglottic distance at rest, defined the same as the situation during phonation; **surface area of the neoglottic bar during phonation**, the surface of the neoglottis in lateral view, indicated by the gray area in **Figure 1.a**; **Surface area of the neoglottic bar at rest**, defined the same as for the situation during phonation;
Prominence of the neoglottic bar during phonation, the prominence of the neoglottic bar towards the anterior wall; The line on which the measurement is based is placed perpendicularly to the posterior wall at the most prominent place of the neoglottic bar(c in **Figure 1.a**);
Prominence of the neoglottic bar at rest, defined the same as for the situation at rest.

In addition to the measurements of the neoglottis, which were available for all patients (n=19), quantitative measurements were performed relative to the metal clips, placed during total laryngectomy on the cranial and caudal border of the myotomy (n=12). All measurements were performed using the upper edge of the neoglottic bar as a starting point. From this point in caudal direction, parallel to the cervical axis, distances were calculated to the cranial and caudal clip, and to the lower edge of the neoglottic bar. This resulted in the following measures: length of neoglottic bar (LNB), length of myotomy (LM), cranial clip (CRC) and caudal clip (CAC). (**Fig. 1.b**)

Figure 1a Schematic drawing of the neoglottis after total laryngectomy. a = minimal neoglottic distance, b = maximal subneoglottic distance, c = prominence of the neoglottic bar. C3-C6 =cervical vertebrae C4-C6, gray surface = two-dimensional lateral size of the neoglottic bar

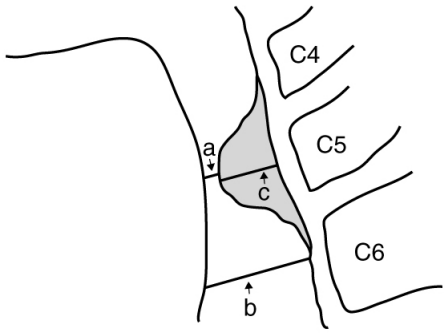
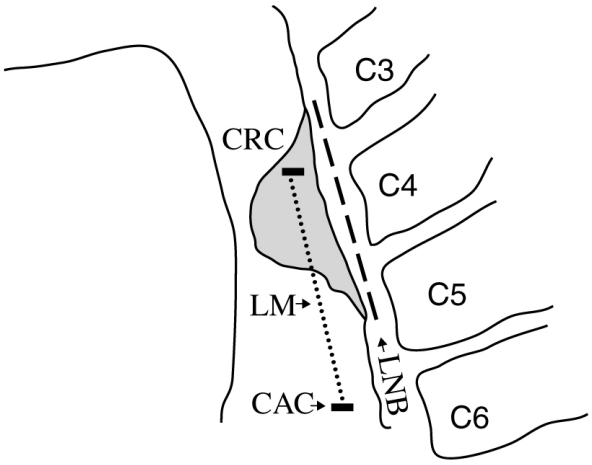


Figure 1b Schematic drawing of the neoglottis. The myotomy is marked by metal clips; CRC = cranial clip, CAC = caudal clip. LM = length of myotomy, LNB = length of neoglottic bar. C4-C6 =cervical vertebrae C4-C6, gray surface = two-dimensional lateral size of the neoglottic bar



Statistics

Paired t-tests were used to compare the quantitative measures at rest and during phonation. To investigate relations between the various quantitative measures Pearson's correlations coefficients were calculated; for minimal distance at rest, Spearman rank correlation coefficients were calculated because of to concerns regarding assumptions of normality. Differences between the quantitative measures of the myotomized and the non-myotomized group were investigated by means of t-tests for 2 independent samples; for minimal distance at rest and minimal distance during phonation, the non-parametric Mann-Whitney test was used because of concerns regarding assumptions of normality. Relations between myotomy (yes/no) and the presence of a neoglottic bar at rest (yes/no) and tonicity (normotonic/hypotonic) were calculated with exact chi-squared tests.

Results

Visual assessment of anatomical and morphologic characteristics of the neoglottis

At rest, 14 patients showed a single neoglottic bar (10 in myotomy group and 4 in the nonmyotomygroup), whereas 5 patients (2 with myotomy and 3 without myotomy) did not show a neoglottic bar.

The presence of a neoglottic bar at rest was not related to whether a myotomy had been performed (P= .305). During phonation, all patients had a single neoglottic bar. Fifteen patients were judged as having a normotonic neoglottis and 4 a hypotonic segment. Three of the patients with a hypotonic neoglottis did not have a myotomy and 1 did. This relation was also nonsignificant (P=. 117). There was no significant correlation between tonicity and voice quality (P=. 178). There was also no significant relation between myotomy and voice quality (P=. 117). The cervical levels of the neoglottic bars of individual patients at rest and during phonation are given in Table 1. At rest, the neoglottis was mostly situated between cervical vertebras 5 and 6, whereas during phonation the neoglottis was mostly located between cervical vertebras 4 and 5.

Quantitative measurements of the neoglottis

Table 2 gives the results of the quantitative measurements. The t tests between the myotomy group (n=12) and the nonmyotomy group (n=7) showed no statistically significant difference between any of the neoglottic measurements.

Quantitative measurements related to myotomy clips

All 12 patients in the myotomy group had a visible neoglottic bar during phonation. Table 3 gives the measurements related to the myotomy. The mean length of the myotomy at rest, calculated as the distance between the cranial and caudal clip, was 25.3 mm (range, 8.48-45.16 mm). At rest, the neoglottic bar was situated entirely above both myotomy clips in two patients. In the remaining ten patients, the neoglottic bar was partially (n=4) or entirely (n=6) situated between the cranial and caudal border of the myotomy. The caudal clip was always inferior to the caudal edge of the neoglottic bar. During phonation there was always an upward shift of the neoglottic bar, resulting in 3 patients having their neoglottic bar superior to the cranial clip of the myotomy. The remaining 9 patients showed some overlap between the neoglottic bar and the myotomy, although less in comparison to the situation at rest. During phonation, the caudal clip elevated about 3 times as much as the cranial clip did. Paired t tests showed that during phonation a significant shortening of the neoglottic bar (P= .007), an elevation of the caudal clip (P= .046), a shortening of length of the myotomy (P= .011) and a decreased overlap of the cranial clip and the neoglottic bar (P= .007) occurred.

Table 1 Cervical vertebrea level of the neoglottis at rest and during phonation. Numbers in this table represent patient numbers.

Cervical vertebrae	N=19	
	Rest	Phonation
C3		
C3-C4	10	10,18
C4	1,2,18	1,2,3,16
C4-C5	3,9,16	5,8,9,13,19
C5	5	4,7,11,14
C6	6,15	15
C6-C7	14,17	17
C7		

Table 2 Means and standard deviations (s.d; between brackets) of the various measures of the neoglottis in the non-myotomized and myotomized patients

Parameters	Mean (s.d.) (n=19)	Non-myotomized patients (n=7)	Myotomized patients (n=12)
MINREST, mm	1.1 (3.0)	2.6 (4.7)	.18 (.62)
MINPHON, mm	2.4 (4.1)	4.7 (5.8)	.99 (1.8)
MAXREST, mm	8.1 (4.0)	7.5 (5.0)	8.5 (3.5)
MAXPHON, mm	15.5 (6.2)	15.2 (7.1)	15.7 (5.9)
SURREST, mm^2	143.9 (114.7)	77 (81)	183 (116)
SURPHON, mm^2	168.2 (115.3)	139 (107)	185 (121)
PROMREST, mm	6.9 (5.1)	4.3 (3.7)	8.4 (5.3)
PROMPHON, mm	11.3 (5.2)	9.7 (4.3)	12.2 (5.6)
MAXPHON/MAXREST	2.1 (0.7)	2.2 (.75)	2.1 (.72)

Table 3 Measurements in rest and during phonation, related to the metal clips, placed at the cranial and caudal border of the myotomy (n=12). All distances are measured caudal from the upper level of the neoglottis (accepting this point as 0)

Parameters	Mean distance at rest in mm (s.d.)	Mean distance during phonation in mm (s.d.)
Length of neoglottic bar (LNB)*	31.9 (12.6)	23.1 (13.7)
Cranial clip (CRC)	15.3 (12.9)	14.1 (14.7)
Caudal clip (CAC)*	40.6 (14.5)	35.9 (16.0)
Length myotomy (LM)*	25.3 (12.3)	21.7 (13.0)

*Significant difference between rest and phonation ($p<.05$)

Relation between quantitative measurements of myotomy and neoglottic bar

Regarding the length of the myotomy at rest and during phonation, a negative correlation was found with the length of the neoglottic bar at rest (at rest, $r=-0.62$; $P=.030$; during phonation, $r=-0.61$; $P=.034$). This indicates that the myotomy was shorter in the more elongated neoglottic bars and vice versa.
Concerning the cranial clip of the myotomy a positive correlation was found with the surface area of the neoglottic bar at rest and during phonation (at rest, $r=0.91$; $P<.001$; during phonation, $r=0.78$; $P=.003$). This indicates that the further down the cranial border of the myotomy was from the upper edge of the neoglottic bar, the larger the surface area of the neoglottic bar.

The caudal clip of the myotomy, both at rest and during phonation, showed a positive correlation with the prominence of the neoglottic bar during phonation ($r = 0.64$; $P = .024$ and $r = 0.756$; $P = .004$) and during rest ($r = 0.64$; $P= .025$ and $r = 0.80$; $P= .002$). These results together indicate that a lower placed myotomy is related to a more prominent neoglottic bar during phonation.

Discussion

In the present study, analyzing the effects of myotomy during total laryngectomy on the neoglottis, striking observations were made. By means of the visual assessment protocol and quantitative measurements, recently described by Van As et al., a group of 12 consecutive patients with myotomies were compared with a group of 7 patients without myotomy, operated upon in the same period.[26] There was nonsignificant relationship between the presence of a neoglottic bar at rest and whether the patient had myotomy. Although 5 patients had no neoglottic bar at rest, there was always a neoglottic bar during phonation. This suggests that always performing a myotomy, except in situations, where the upper esophageal sphincter is already hypotonic on palpation, still results in the presence of a neoglottic bar during phonation. As known from other studies, the presence of a neoglottic bar is a prerequisite for good tracheoesophageal speech. [26-28] The fact that all voices were judged as good ($n=15$) to moderate ($n=4$) is in accordance with this. Although in 4 patients the neoglottis was judged to be hypotonic, but still with a clearly visible neoglottic bar, this is not in contradiction to the former observation, since Van As et al. also found a reasonable voice quality in approximately half of the patients with a (slightly) hypotonic neoglottis. [26]

Many studies have reported on the necessity of additional surgery to control the tonicity of the neoglottis in tracheoesophageal or esophageal speech. [17-20, 29-33] It is difficult to compare most of these studies, as there are reports about esophageal and tracheoesophageal speakers, and clear differences in timing of the surgical procedures, ie, primary or secondary.

Mahieu et al. prefer to perform a myotomy as a primary procedure. [30] Unwillingness of the patient to undergo another operation and difficulty of an operation in a previously operated and possibly irradiated region led to this preference. Some authors suggest to performing a unilateral myotomy at the time of surgery in order to prevent any spasm or hypertonicity.[19, 30, 34] Mahieu suggests performing 'a 4-6 cm myotomy of the inferior constrictor pharyngeal muscle, the cricopharyngeal muscle and a small section of the upper esophageal musculature' after deeming the neoglottis hypertonic. [30]

Since myotomies are carried out as a primary procedure during total laryngectomy, it is nearly impossible to objectify the impact of the myotomy on the neoglottis. In a recent study by Van Weissenbruch et al. patients were randomized for an additional tonicity treatment without judging the tonicity of the upper esophageal sphincter during the operation. [19] This study compared postlaryngectomy patients who underwent primary unilateral pharyngeal myotomy with patients who underwent pharyngeal plexus neurectomy and patients who did not undergo additional treatment at all. Theirs is one of the few studies with a control-group containing untreated patients. They found that patients who underwent primary myotomy and neurectomy were most successful in obtaining good tracheoesophageal speech.

Besides the discussion on the necessity of tonicity control after laryngectomy, there is also no consensus in the literature about the exact muscles responsible for the tonicity of the neoglottis, not to mention the optimal surgical procedure, and whether or not to close the muscular layers. [17, 19, 20, 30, 32, 35] To the best of our knowledge there has been no earlier reporting on objective data of the myotomy itself or the relationship between the myotomy and the neoglottis.

In the present study, the upper and lower border of the myotomy was marked with clips, giving an opportunity to visualize and quantify the relation between the myotomy and the neoglottic bar. With respect to the position of the neoglottic bar in relation to the myotomy during phonation, the neoglottic bar was seldom situated totally in between the myotomy clips.

If overlap was demonstrated, it was seen less during phonation. This sustains the theory that the cricopharyngeus muscle -upper esophageal sphincter- is not the most essential part of the neoglottic bar [27, 29]. According to Wetmore et al. and Codosh et al., the bulging mucosa and/or the constrictor muscles cranial to the cricopharyngeus muscle contributed mostly to the vibration and created the neoglottic bar. [27, 29] These authors also found a considerable number of patients (5 of the 16, 30%) with a double neoglottic bar, with the lower bulge not contributing to voice production. In our series, no double neoglottic bar was found, which can probably be explained by the fact that we have always myotomized the upper esophageal sphincter when there was suggestion of hypertonicity.
Also based on this latter theory, i.e. the cricopharyngeus muscle-upper esophageal sphincter- is not the most essential part of the neoglottic bar, Hirano et al. recommended a cricopharyngeus myotomy and a tracheal ring cartilaginous implantation. They suggested that, in this way, better neoglottic closure during phonation can be obtained, and subneoglottic obstruction can be prevented in order to achieve optimal neoglottic vibration.[36] Taking all these theories into account this may imply that a myotomy of the cricopharyngeus muscle/upper esophageal sphincter should be performed in every patient, unless already hypotonic of its own.

On the basis of the quantitative measurements in relation to the position of the myotomy clips, some interesting observations were made. For instance, the longer the myotomy the shorter the neoglottis is. Also, a lower placed myotomy results in a larger and more bulky and prominent neoglottic bar. Furthermore, overlap of the myotomy and neoglottic bar results in less prominence of this bar. Since a prominent neoglottic bar is beneficial for voice quality, this probably indicates that the myotomy should not be carried out more cranially than the upper esophageal sphincter itself. The often advocated long myotomy, including the constrictor pharyngeus muscles, therefore, may not be optimal.[19,30]

In conclusion, quantitative videofluoroscopy enables study of the relations between myotomy of the upper esophageal sphincter and the anatomy and morphology of the neoglottis. In a group of 19 patients, most having good tracheoesophageal voice quality, one clear neoglottic bar was always visible and none of these patients showed signs of hypertonicity. Therefore, in our opinion, a primary, lateral myotomy of the upper esophageal sphincter (unless it is already hypotonic of its own) is an essential part of surgery, when applying primary prosthetic voice rehabilitation after total laryngectomy.

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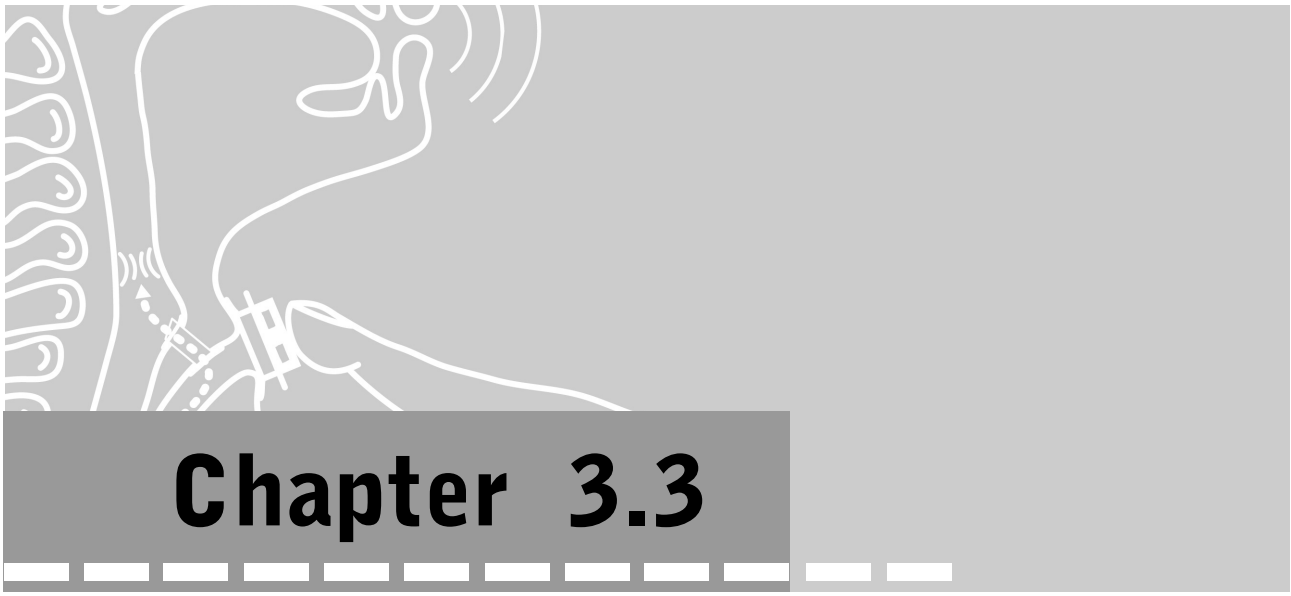

Chapter 3.3

High-speed digital imaging of neoglottic vibration after total laryngectomy

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Abstract

Objectives: To establish the applicability of digital high-speed imaging in studying neoglottic mucosal vibration after total laryngectomy and to perform a structured evaluation of the recordings by means of a standardized assessment form in order to gain insight about the anatomical and morphologic characteristics of the neoglottis.
Design: Evaluation of a new clinical tool and description of clinical disorders in a patient survey.
Setting: The Netherlands Cancer Institute, Amsterdam.
Patients: Forty-six patients who underwent laryngectomy, 36 who underwent standard total laryngectomy, and 10 who underwent a partial or total pharynx reconstruction (i.e. myocutaneous pectoralis major flap (n=4), free radial forearm flap (n=2), tubed gastric pull-up (n=3), and full gastric pull-up (n=1).
Intervention: Digital high-speed imaging, using a 90^0 rigid laryngoscope, of the neoglottic vibration in prosthetic tracheoesophageal speakers after total laryngectomy.
Main outcome measures: Digital high-speed imaging might overcome some of the problems of stroboscopy in studying irregular voices and could, therefore, be expected to give more insight into the anatomical and morphologic characteristics of the neoglottis.
Results: Digital high-speed recordings could be obtained in 44 of 46 patients. Using a structured evaluation form, a wide variability in anatomical and morphologic features could be established.
Conclusions: Digital high-speed imaging appeared to be a useful tool in studying the irregular vibrations of the neoglottis. Evaluation by the structured evaluation form gives a good idea about the wide variability in anatomical and morphologic features of the neoglottis.

Introduction

In the past two decades vocal rehabilitation of laryngectomees is performed increasingly by prosthetic tracheoesophageal (TE) voice. In several studies comparing esophageal with TE voice, it was found that TE voice is more similar to normal voice than esophageal voice.[1-3] However, comparing TE with normal voice reveals that TE voice is still considered as very deviant from normal voice.[1-4] To gain more insight in the underlying mechanism of voice production in patients who underwent total laryngectomy and into the factors that are influencing the quality of the voice, it is necessary to extend our knowledge of the anatomical and morphologic characteristics of the new voice source. This new voice source is often referred to as the pharyngo-esophageal (PE) segment, pseudoglottis, or neoglottis. Herein, the term neoglottis will be used.

In TE voice restoration, a surgical fistula is created between the trachea and the esophagus, in which a voice prosthesis is inserted. A voice prosthesis acts as a 1-way valve, allowing air from the trachea to pass into the esophagus, and preventing food and saliva from entering the lungs. By occluding the tracheostoma, pulmonary air is directed through the valve into the esophagus. On speaking, the air passing the esophagus sets the neoglottis into vibration. After standard total laryngectomy with primary closure of the pharynx, in general, constriction of the cricopharyngeus muscle narrows the neoglottis and allows formation of a vibrator for voice.[5] The variable lengths of the narrowing of the neoglottis suggest contribution from the inferior pharyngeal constrictors in some patients.[5] It can be expected that differences between TE voices are related to differences in the anatomical and morphologic characteristics of the neoglottis.[5-7]

Studies of the anatomical and morphologic characteristics of the neoglottis have been performed by videofluoroscopy, [5,7-12] stroboscopy,[12-14] and fiberoptic visualization.[12,15] In laryngeal voicing, stroboscopy is a common method used to visualize vocal fold vibration. With stroboscopy, a virtual slow-motion of the rapid vibration is acquired by subsequent light flashes that are slightly out of phase with the fundamental frequency of the vocal fold vibration. Stroboscopy is thus dependent on triggering based on the fundamental frequency extracted from the electrglottographic signal or the acoustical signal of the voice source. "Frequency-independent" visualization methods like high-speed imaging[16] or videokymography [17] are available, which were already used in studying pathological laryngeal voices.[17-21] The advantage of these frequency-independent techniques is the possibility of studying irregular vibrations by performing recordings with many (≤ 2000) frames per second. These techniques are, to the best of our knowledge, not yet used to investigate anatomical and morphologic characteristics of the neoglottis. In the present study, we investigated whether high-speed imaging is useful as a technique to investigate various characteristics of the neoglottis after total laryngectomy.

We used high-speed imaging and not videokymography since we were interested in the anatomical and morphologic features of the entire neoglottis, which can indeed be achieved by visualization in full frames but not by a single scanning line.

Patients and methods

The subjects were 46 patients who underwent laryngectomy (35 men and 11 women). Informed consent was received from all subjects. The age of the subjects varied from 46 to 82 years (mean, 67 years). All patients were using TE voice (Provox voice prosthesis; ATOS Medical AB, Hörby, Sweden).[22,23] Stoma occlusion was performed with a valved heat and moisture exchanger (ATOS Medical AB)[24] in 44 patients, and with a hands free speech valve (Inhealth Technologies, Carpinteria, Calif.)[25] in 2 patients. The postoperative follow-up was longer than 6 months in 42 patients and less than 3 weeks in 4. The median postoperative follow-up was 3 years 2 months (range, 2 weeks to almost 18 years). A standard total laryngectomy was performed in 36 patients. In 4 patients, the pharynx was reconstructed partially with a pectoralis major myocutaneous flap; and in 2 patients, a circumferential defect of the pharynx was reconstructed with of a tubed free radial forearm flap. Four patients underwent a total laryngopharyngoesophagectomy, which was reconstructed with of a full gastric pull-up procedure in 1 patient and with a tubed gastric pull-up procedure in 3 patients. A unilateral radical neck dissection was performed in 14 patients and a bilateral neck dissection in 7; in 25 patients, no neck dissection was performed at all. During surgery, a myotomy of the cricopharyngeus muscle was performed in 8 patients. A neurectomy of the pharyngeal nerve plexus was performed in 22 patients. Imaging of the neoglottis was performed with a unique digital high-speed camera system.[16] This system consisted of a personal computer (Pentium 166MHz;WIS GmbH, Nuremberg, Germany) and a camera head with a digital charge coupled device sensor chip, which has a resolution of 128 by 128 pixels at 256 gray values and a maximal spectral sensitivity in the far red and near infrared range. The recording rate was 2000 frames per second, enabling a sufficient oversampling with respect to the expected fundamental frequencies. The camera was used in combination with a 90° rigid endoscope (model 4450.57; Wolf, Knittlingen, Germany), and a cold light source (model 482; Karl Storz, Tuttlingen, Germany). The patients were asked to produce a sustained /a/ sound. As in normal indirect laryngoscopy, patients were asked to put out their tongue to reveal the cranial opening of the neoglottis. In 12 patients local anesthesia (10% lidocaine hydrochloride spray) was used during the high-speed recording examination.
During the recording process, each picture was written into a circularly organized semiconductor memory of 256 megabytes. The recording was stopped by a post-trigger signal. By this procedure, all frames recorded during the preceding 8 seconds were held in the camera memory.

Sequences containing relevant parts of phonation were stored on a computer hard disk. For permanent storage the image-sequence is copied onto a compact disk (CD-ROM). Once stored, the recording can be replayed at any delayed speed, down to single frame display, using a software program (Winplay Speedcam Version 1.10; Fraunhofer Institute for Integrated Circuits, Erlangen, Germany, available at http://www.iis.fhg.de).

An adapted version of the stroboscopic assessment form suggested by Hirano and Bless (1993) was used for visual evaluation. It consisted of 3 image quality variables and 7 temporal and morphologic characteristics of the neoglottis (**Table 1**). In a first trial session, 6 raters (1 ear, nose and throat specialist; 1 phoniatrician (M.T); 1 resident (B.M.R.O.d.C.); 1 speech therapist; 1 phonetician/speech therapist (C.J.v.A); and 1 computer scientist/image processing specialist (T.W.)), blinded for the clinical data judged the recordings independently of each other. Afterwards, the results were discussed, and a final rating form was composed (**Table 2**). In the actual rating, the recordings were, in 4 rating sessions of 2 hours each, judged by 3 raters (1 phoniatrician (M.T.); 1 resident (B.M.R.O.d.C.); and 1 phonetician/speech therapist (C.J.v.A.)) who reached consensus of opinion in all cases. For the judgments, a replay speed of 25 single frames per second was used.

Table 1 Definition of the variables used for visual assessmeent of digital high-speed recordings of the neoglottis

Variables	Definition
Assessability	Overall quality of the recording
Brightness	Balance of grey-level distribution
Focus	Degree of focusing of relevant parts
Saliva	Amount of saliva present, regarding the visibility of the neoglottis
Visibility of the origin of the neoglottis	The origin of the neoglottis was judged as being visible when the starting point of the vibration could be identified; not visible was scored when only the final part of the travelling vibration could be seen, or when the origin of the neoglottis could not be identified at all
Shape of the neoglottis or vibrating part	Contour of the lumen during the open phase of vibration
Location of the visible vibration	Predominant site of vibration; combinations of more sites were possible
Presence of mocusal wave	Differentiation of a mucosal wave from the vibration of the wall of the neoglottis or reconstructed pharynx, in analogy to the travelling wave on vocal folds
Regularity of vibration	Visual impressions of the regularity of the vibration
Closure phase	Duration of the open or closed phase of the neoglottis in relation to the complete cycle of vibration

Results

Acquiring high-speed images was possible in 44 out of 46 patients. The absence of color, the low resolution, and the light power available sometimes limited the overall quality of the recordings; however, even with these limitations it was possible to obtain useful recordings in all but 2 patients. In one patient who underwent standard total laryngectomy, the investigation was not possible due to a high gag reflex. In another patient who underwent a full gastric pull-up procedure, no useful recordings could be obtained and only dark images could be acquired due to the dispersion of the light in the wide neoglottis.
Different shapes and vibration patterns of the neoglottis were seen. Even in the patients in whom data were recorded shortly after surgery, mucosal vibrations could be identified. The only difference with patients in longer postoperative follow-up was the clearly visible presence of fibrin deposits on the sutures. During TE phonation saliva is driven upward by the expiratory airflow, which sometimes interacts with the mucosal vibration.

Table 2 Rating form as used in the final rating session to judge digital high-speed recording of 44 patients who underwent laryngectomy

Assessment form: high-speed imaging of the neoglottis **Recording number:**						
Assessability	Good	Fair	Moderate	Poor		
Brightness	Good	Fair	Moderate	Poor		
Focus	Focused	Slightly unfocused	Unfocused			
Saliva	None	A little	Moderate	Much	Obstructing	
Visibility of origin of the neoglottis	Visible	Not visible				
Shape of neoglottis	Circular	Triangular	Split side-to-side	Split anterior-posterior	Irregular	Not assessable
Location of visible vibration*	Posterior	Anterior	Left	Right	All walls	Not assessable
Presence of mucosal wave	Strong	Weak	Absent			
Regularity of vibration	Regular	Irregular	Not assessable	Not assessable		
Closure phase	Open phase predominates	Equal	Closed phase predominates			

*More locations can be present

Four figures with examples of a vibrating neoglottis are shown. In each figure, the sequence of the subsequent frames in time is from the upper left frame, in horizontal direction, to the lower right frame. In the upper part of each frame the posterior wall is situated; in the lower part, the anterior wall. Right and left are shown as in normal endoscopic investigation. An example of a circular shaped vibrating neoglottis, with a clear mucosal wave is given in **Figure 1**. The dark circular area at the right side of the first frame is the lumen of the neoglottis. The brighter semi-circular structures above and below the lumen are mucosal folds of the neoglottis. The left esophageal wall is not completely visible. During the subsequent frames the lumen enlarges and reaches a circular shape, until in frame 23 a new opening in the depth appears. From frame 14 to 20 an irregular brighter structure (mucosal wave) develops and moves towards the anterior mucosal fold.

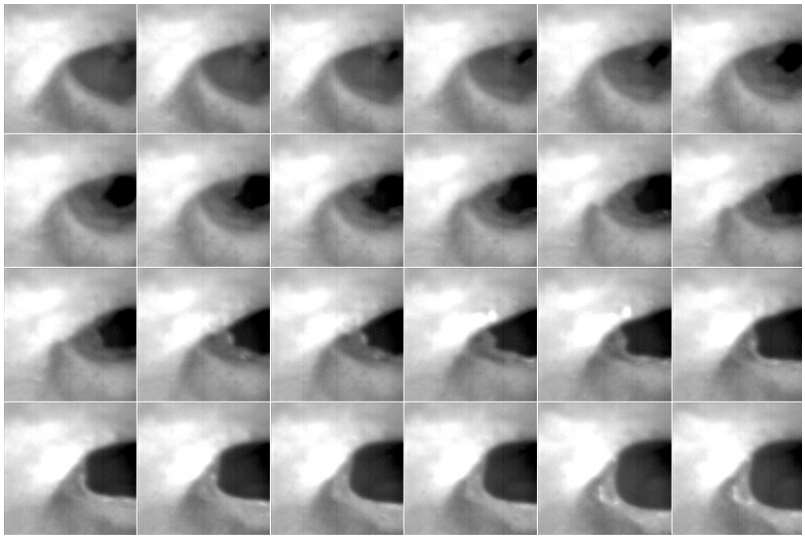

Figure 1 Neoglottis after standard total laryngectomy (male patient, age 66, 14 years postoperative). A circular shaped neoglottis with a mucosal wave developing on the anterior wall. In frame 13 in the depth the beginning of the next vibratory cycle is visible.
Besides the circular shaped neoglottis shown in Figure 1 also split, triangular, and irregular shapes were seen. In **Figure 2** an example is given of a triangular shaped neoglottis, and in **Figure 3** an example of a side-to-side split-shaped neoglottis is given

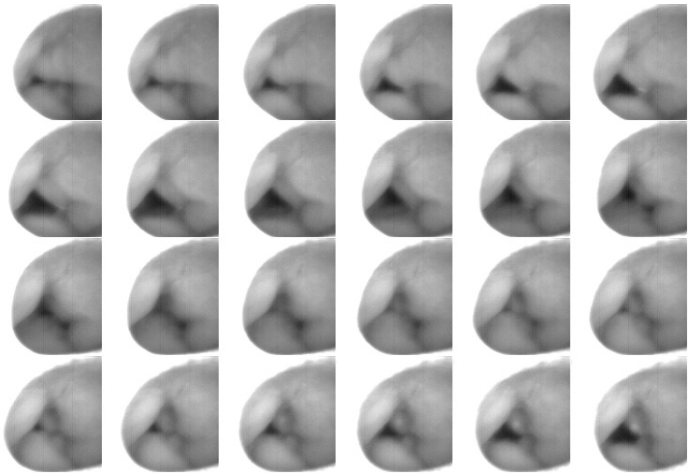

Figure 2 Neoglottis after standard total laryngectomy (female patient, age 62, 2 years postoperative). In the first frames, during the closed phase of vibration, the mucosal folds lie together in an upside-down T-shape, which alters to a triangular shape in the open phase of vibration

Figure 3 Neoglottis after standard total laryngectomy (male patient, age 66, 11 years postoperative). The neoglottis is split-shaped from left to right. The anerior wall is vibrating in an anterior-posterior direction. A little saliva is seen at the cranial edge of the neoglottis

In the patients with a circumferential pharyngeal reconstruction with a radial fore arm flap, a complete gastric pull-up, or a tubed gastric pull-up, neoglottic vibrations also could be seen. In **Figure 4** an example of a vibrating neoglottis of a patient after a total laryngopharyngoesophagectomy, with a tubed gastric pull-up reconstruction is given.

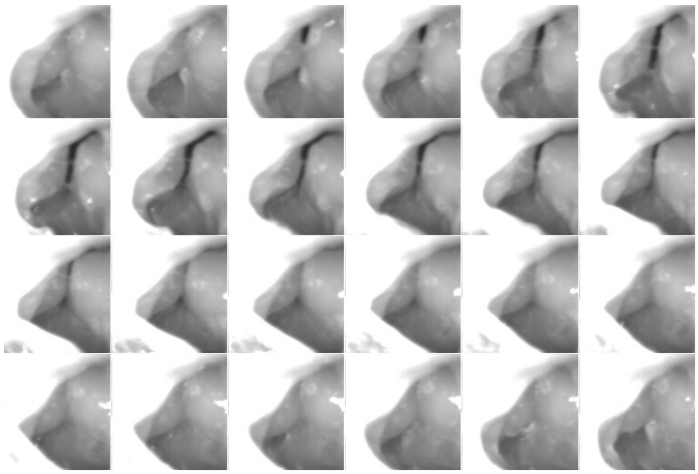

Figure 4 Neoglottis after total laryngopharyngoesophagectomy with tubed gastric pull-up reconstruction (female patient, age 49, 4 years postoperative). The neoglottis has an anterior-posterior split shape. During phonation the mucosal folds vibrate in mediolateral direction toward each other

Overall quality of recordings

All recordings were judged for quality by the following variables: assessability, brightness, and focus. When more recordings were stored for one patient, the recording with the best consensus judgements for these 3 variables was chosen for further evaluation. The results that are given herein are the results of consensus judgments for all 44 patients for whom evaluable recordings were stored. It appeared that the assessability was good in 22 recordings, fair in 9, moderate in 10, and poor in 3. Brightness was good in 34 recordings, fair in 9, and moderate in 1. The recordings were focused in 24 cases, slightly unfocused in 18, and unfocused in 2. The number of recordings that are slightly unfocused is relatively high; because of large individual differences in the level of the vibrating part, it was not always possible to adjust the focus of the endoscope before or during the phonation optimally. An overview of the results of the judgments of the overall quality of the recordings is given in Table 3.

Table 3 Results of the judgements of the overall quality of the high-speed recordings of 44 laryngectomized patients

Variable	Evaluation	No. (%) of patients*
Assessability	Good	22 (50.0)
	Fair	9 (20.5)
	Moderate	10 (22.7)
	Poor	3 (6.8)
Brightness	Good	34 (77.3)
	Fair	9 (20.5)
	Moderate	1 (2.3)
	Poor	0 (0.0)
Focus	Focused	24 (54.4)
	Slightly unfocused	18 (40.9)
	Unfocused	2 (4.5)

*Percentages may not total 100 because of rounding

Evaluation of characteristics of the neoglottis in patients who underwent standard laryngectomy

There were 35 evaluable patients who underwent a standard total laryngectomy. The results of the frequency analysis of the results of the consensus judgments are given in **Table 4**. In most patients, there was only a little to a moderate amount of saliva visible, although in a few cases it was more extensive or even obstructing the neoglottis. The origin of the neoglottis was clearly visible in approximately two thirds of the patients; in one third of the patients, it was not clearly visible, which is the case when the neoglottis seems to be situated at a deeper level, or when it is obstructed by saliva. The shape of the neoglottis was variable: irregular or left-to-right split shapes were seen most often. The location of the vibration was mostly situated at 2, 3, or more walls. There was a strong or weak mucosal wave visible in half of the patients, and no mucosal wave was seen in the remaining half. Sometimes a mucosal wavelike movement of saliva was seen, resulting in collection of saliva at the upper part of the neoglottis, which was not judged as a mucosal wave. In two thirds of the patients, an irregular vibration of the neoglottis was seen. In half of the patients, the open phase of vibration was longer than the closed phase of vibration. The closed phase was never judged as longer.

Evaluation of characteristics of the neoglottis after total laryngectomy with reconstruction of the pharynx

There were 9 evaluable patients who underwent a total laryngectomy with a partial or total reconstruction of the pharynx. A large variation in the different characteristics of the neoglottis was seen. The small patient group and subgroups prohibit drawing any meaningful conclusions. Results of the consensus judgments for the three small subgroups are given in the right side of **Table 4**.

Table 4 Results of the evaluation of the characteristics of the neoglottis in digital high-speed recordings

Variable	Judgement	Type of laryngectomy			
			With pharynx reconstruction		
		Standard Total (n=35*)	With Pectoralis Major Flap (n=4)	With Gastric Pull-up (n=3)	With Radial Forearm Flap (n=2)
Saliva	None	4 (11)	0	0	0
	A little	15 (43)	1	0	0
	Moderate	11 (31)	1	2	1
	Much	3 (9)	2	1	0
	Obstructing	2 (6)	0	0	1
Visibility of the origin of the neoglottis	Visible	24 (69)	3	3	1
	Not visible	11 (31)	1	0	1
Shape of the neoglottis	Circular	5 (14)	0	1	1
	Triangular	1 (3)	0	0	0
	Split side-to-side	11 (31)	0*	0	0
	Split a-p	2 (6)	3*	0	0
	Irregular	10 (29)	0*	2	0
	Not assessable	6 (17)	1*	0	1
Location of the visible vibration	Posterior	4 (11)	0	0	0
	Anterior	3 (9)	1	0	1
	Lateral	3 (9)	1	0	0
	2 or 3 walls	10 (29)	1	1	0
	All walls	12 (33)	1	2	1
	Not assessable	6 (9)	0	0	0
Presence of mucosal wave	Strong	12 (34)	2	1	0
	Weak	5 (14)	0	1	0
	Absent	17 (49)	2	1	2
Regularity of vibration	Regular	11 (31)	0	1	0
	Irregular	23 (66)	4	2	2
	Not assessable	1 (3)	0	0	0
Closure phase	Open	18 (51)	2	2	1
	Equal	6 (17)	1	0	0
	Closed	0 (0)	0	1	0
	Not assessable	11 (31)	1	0	1

*Percentages are given in parentheses. They may not total 100 because of rounding
*Numbers differ from original article due to typing error

Discussion

The first aim of this study was to establish the applicability of digital high-speed imaging in studying characteristics of the neoglottis in patients after total laryngectomy. From this study, it can be concluded that useful images giving realistic visual information about the vibration of the neoglottis can be collected for further evaluation. The clinical applicability of digital high-speed imaging would be improved if images would be in color, the resolution were higher, and the light power were stronger. However, already with the presently available equipment, useful recordings could be obtained in the majority of the patients studied. There are, to the best of our knowledge, no earlier reports about the use of this technique in studying the neoglottis, and, thus no studies are available for comparison. However, a few articles report on the use of stroboscopy in these voices. Damsté [13] stated that the pseudoglottis in esophageal voice, just like the vibration of the normal glottis, could be observed by the aid of a stroboscope, but that conditions must be favorable: a purely periodical vibration and a patient capable of retaining air in the esophagus sufficiently long to permit the introduction of a mirror. He succeeded in a few patients, and saw "serpentine movements" over a great depth (1-1.5 cm); the duration of the opening of the upper mucous membrane folds was only short in proportion to the duration of the closed phase. Hammarberg and Nord [12] studied 4 TE speakers using videofluoroscopy and fiberendoscopy. In one of these patients, who had short sequences of regular vibrations of the neoglottis, it was possible to register stroboscopic images. These indicated a pattern of successive closures and openings of the segment. Omori et al.[14] studied the dynamics and origin of the neoglottis in 25 TE-shunt speakers by means of videofluoroscopic, strobofiberscopic, and electromyographic studies. With stroboscopy, in 18 patients they observed regular vibration, and in 7 patients, irregular vibration of the neoglottis. In 24 patients, the direction of opening and closure of the neoglottis was anterior-posterior; in one patient it was left-right. They did not report about any problems pacing the stroboscopic light flashes in the irregular TE voices.

Although this is not confirmed by Omori et al.,[14] the statement of Damsté [13] that stroboscopy is only possible in clearly periodic voices seems reasonable. Kitzing [27] stated that a necessary condition to get the stroboscopic effect is that the vibrations be (quasi) periodic during the time of observation, and that in case of aperiodicity of the voice source a blurring of the images originates. This is also confirmed by a study performed by Woo et al.,[28] in which the role of stroboscopy as a clinical tool was studied in pathological vocal fold phonation. It appeared that 17.4% of the recordings were of poor quality. A major cause for this was the inability of the patients' voice to pace the stroboscope.

From various studies, it has become clear that, although tracheoesophageal voice seems to be more stable,[29] TE and esophageal voice are often irregular.[4,30,31] Irregularities in the acoustic or electroglottographic (EGG) signal used for pacing the stroboscope cause a mistriggering of the stroboscopic light flashes. Furthermore, when an electroglottographic signal is used in laryngectomees to trigger the stroboscopic light flashes, the pressure of the electroglottographic electrodes in the neck may cause deformation of the neoglottis. We must, therefore, conclude that methods studying the neoglottis should be independent of triggering based on the fundamental frequency. Digital high-speed imaging and videokymography might, therefore, be more suitable to give reliable information about the vibratory pattern of the neoglottis. In a recent study, Schutte et al.[18] stressed that digital high-speed imaging is a powerful method for evaluating the vocal fold vibration. However, this is still nonstandard, complex equipment, which is at the moment not readily available for everyday clinical practice. As digital technologies become rapidly available at lower costs, it can be expected that a digital high-speed system will be available for clinicians and voice laboratories at costs comparable to that of the more sophisticated stroboscopy units.

The second aim of this study was to develop an instrument to describe the characteristics of the neoglottis, and to use this instrument to evaluate the anatomical and morphologic characteristics of the neoglottis in the recordings of this patient group. In analogy to the evaluation of stroboscopic images [26] an assessment form for visual assessment was used. Although this is a subjective method to describe the characteristics of the neoglottis, the evaluation form appeared to be useful to describe the visible characteristics of the recordings, and to reach consensus of opinion among the 3 raters.
The results of the consensus judgments show a wide variability in the anatomical and morphologic characteristics of the neoglottis. This wide variation was one of the most striking observations of the study, since it was expected from the study by Omori et al. [14] that most vibrations would be in anterior-posterior direction. However, in this study the neoglottis appeared to show a wide variation in shape and location(s) of vibration, even among patients with the same type of surgical intervention. This variability in the nature of the neoglottis can be explained by patient-to-patient differences in surgical invasion and reconstruction, as stated by Qi and Weinberg,[32] who found a wide variability in the nature of the voicing source signals. The evaluation of the neoglottic vibration after reconstructive surgery shows that neoglottic mucosal vibration also takes place in these voices. The appearance of neoglottic vibration shortly after surgery shows that this vibration is immediately present when vocal rehabilitation is started.

In this ongoing research project, evaluations of videofluoroscopic images and perceptual evaluation and acoustical analysis of the voice quality will be performed in addition to digital high-speed imaging. Relations between these different measurements might give more insight in the role of the different characteristics of the neoglottis in alaryngeal voice quality.

Quantitative evaluation of the high-speed recordings of the neoglottis, providing objective measurements of shape, periodicity and fundamental frequency is currently underway and already proved on recordings of the neoglottis of a few patients.[33] Objective criteria obtained by quantitative evaluation may provide useful information about the fundamental frequency and periodicity of the voice source.

In general, digital high-speed recording is a useful tool for obtaining more insight into the anatomical and morphologic characteristics of the neoglottis. The use of a structured assessment form is suggested to perform standardized evaluation.

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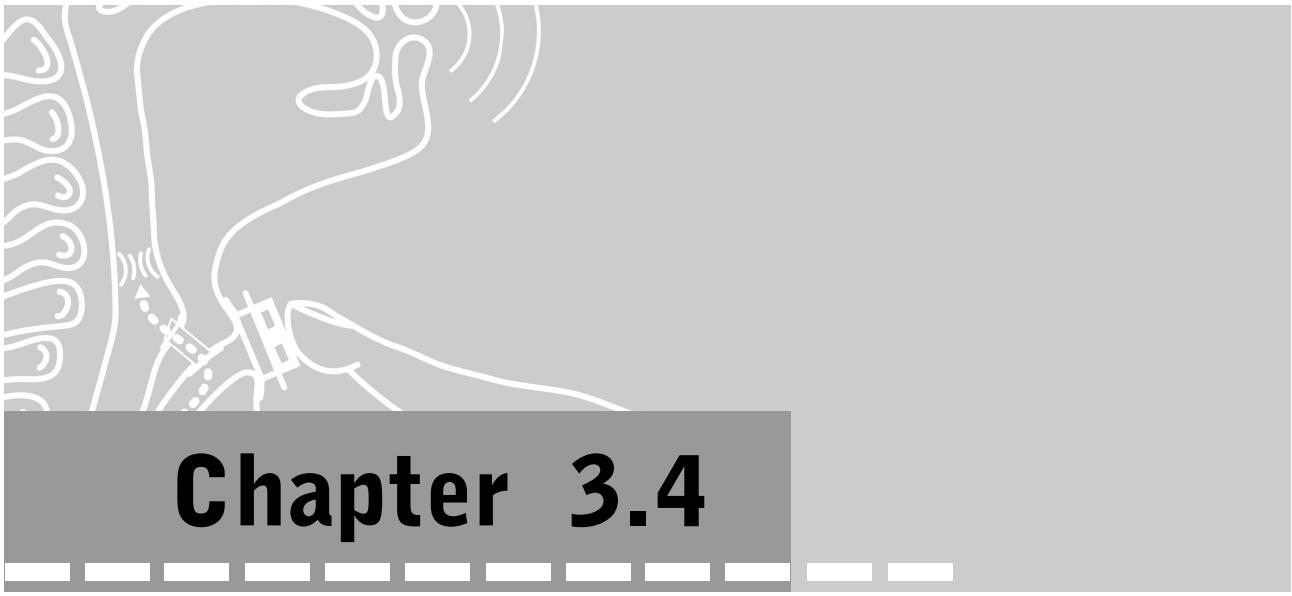

Chapter 3.4

Value of digital high-speed endoscopy in addition to videofluoroscopic imaging of the neoglottis in tracheoesophageal speech

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Abstract

Objective: to gain insight in the clinical value of using the relatively new evaluation tool digital high-speed endoscopy in addition to the widely used method of videofluoroscopy for imaging of the neoglottis in tracheoesophageal speech after total laryngectomy.
Methods: anatomical and morphologic characteristics of the neoglottis in 37 laryngectomized patients using tracheoesophageal speech have been studied by means of visual assessment of digital high-speed endoscopy recordings and by visual assessment and quantitative measures of videofluoroscopy recordings, using earlier published protocols.
Results: digital high-speed endoscopy provides information complementary to videofluoroscopy with respect to the location of the vibration, presence of a mucosal wave, regularity of the vibration, and closure of the neoglottis. The information provided by digital high-speed endoscopy is overlapping with respect to the amount of saliva (regurgitation of barium in videofluoroscopy) and visibility of the origin of the neoglottis (presence of a neoglottic bar in videofluoroscopy). Additionally, relationships between the visual assessments of the high-speed recordings and some patient characteristics were found.
Conclusion: digital high-speed endoscopy provides additional insight in neoglottic characteristics that cannot be studied with videofluoroscopy. The application of both imaging methods enhances the insight in tracheoesophageal voicing.

Introduction

Digital high-speed endoscopy (HS) is only in use at present as a research tool, although developments for clinical implementation are promising. With HS it is possible, in analogy to stroboscopy, to obtain recordings of the vibrating neoglottis in a birds-eye view. These recordings are expected to give valuable information in addition to the information obtained by videofluoroscopy (VF), which provides a lateral view. Results described by van As et al. [1] indicate that digital HS is a useful tool to study the vibratory behaviour of the neoglottis. The results showed a large variability in shapes and locations of the vibration. Several anatomical and morphologic characteristics of the neoglottis were assessed and described. Prior to the study described by Van As et al.[1] no studies have been performed using HS to study characteristics of the neoglottis. Also, nothing is known yet about the relations between anatomical and morphologic characteristics of the neoglottis as studied by means of HS and tracheoesophageal voice quality. Larsson et al.[2] investigated high-speed imaging, kymography and acoustic analysis for diplophonic voices and tremor using an analysis system developed by themselves: the high-speed toolbox. Using this system, glottal edge detections and kymograms were made of the high-speed recordings. Relations between glottal vibratory patterns and the sound waveform were found. Lundström and Hammarberg [3] used the same high-speed toolbox to study the voiced/voiceless distinction in one oesophageal and one tracheoesophageal speaker. They conclude that the high-speed recordings together with the simultaneously recorded voice signal give answers to important questions about the function of the pharyngoesophageal (PE) segment.

In view of the fact that digital HS not widely used as a clinical investigation method nowadays, the need for investigation of relationships between observations made with endoscopic HS and the more widely, already since decades, used method of VF providing a lateral view of the neoglottis, is important. Results from VF have provided important information about the new voice source after total laryngectomy. The majority of these studies have been performed in oesophageal speakers[4-17], but some also have been performed in tracheoesophageal speech [18-21].

In the present study, relationships between the anatomical and morphologic characteristics as studied by HS and those seen with VF are investigated in order to assess the possible additional value of HS. Furthermore, relationships between the anatomical and morphologic characteristics of the neoglottis as studied by means of HS and patient characteristics are assessed.

Patients and methods

Patients

The patient group studied by means of HS consisted of 46 patients selected from a group of 173 patients who had undergone laryngectomy and were at that time in follow-up at the Netherlands Cancer Institute, as described previously in detail by van As et al[1]. In summary, all voice 'varieties', normally encountered in this patient population, have been enrolled into this patient sample. Thus, also female patients and patients, who needed some type of pharyngeal reconstruction, have been included. All patients were using tracheoesophageal speech by means of a Provox®2 voice prosthesis[22]. HS recordings could be obtained from 44/46 of these patients. In one patient no recordings could be obtained due to a strong gag reflex after standard total laryngectomy, and in another (who had undergone total laryngectomy and full gastric pull-up reconstruction) no useful recordings could be obtained due to the dispersion of the light in a wide neoglottis. Of the remaining 44 patients, 5 patients who had recently undergone surgery; these 5 patients were not studied with VF. Furthermore, 2 patients refused VF, leaving 37 patients for evaluation of the relationship between HS and VF. For the relationships with the patient characteristics all 44 patients of whom HS recordings were obtained could be evaluated. **Table 1** shows the patient characteristics.

Methods

Evaluation of the VF recordings was performed using visual assessment of characteristics of the neoglottis and quantitative measures of the neoglottis. The characteristics assessed and the measurements performed, as well as the methods used, are described in detail by Van As et al.[21] In summary, the visual assessments, mostly using clear dichotomies (yes/no), consisted of the following parameters: presence of a neoglottic bar at rest and during phonation; stasis of barium above the neoglottis during phonation; regurgitation of barium during phonation; flattening of the neoglottic bar when swallowing; tonicity of the neoglottis during phonation (hypotonic, normotonic, hypertonic, stricture); and the cervical level of the neoglottis at rest and during phonation. The following quantitative measures (in millimeters) of the neoglottis are shown in **Figure 1** and were determined both at rest and during phonation: minimal (neoglottic) distance; maximal (subneoglottic) distance; surface area of the neoglottic bar; prominence of the neoglottic bar. Additionally, an index of the increase of the maximal (subneoglottic) distance from rest to phonation was calculated.

Table 1 Patient characteristics for digital high-speed imaging (column 2) and for the relationship between digital high-speed imaging and videofluoroscopy (colunm 3)

Parameter	High-speed (n=44)	High-speed versus videofluoroscopy (n=37)
Sex		
male	33	28
female	11	9
Age (years)		
range	46-82	47-82
mean	67	67
<70 years	27	23
>70 years	19	14
Postoperative (years)		
range	18 days-18	1-18
mean	6	6
<6 years	29	24
>6 years	17	15
Extent of surgery		
standard	35	29
reconstruction	9	8
Radical neck dissection		
no	24	20
uni/bilateral	20	17
Radiotherapy		
primary	20	16
postoperative	22	20
none*	2	2
Myotomy		
yes	7	5
no	28	24
Neurectomy		
yes	21	16
no	14	13

*Too small subgroup, thus not included in statistical analyses

Visual assessments of the HS recordings were performed using an evaluation protocol consisting of three assessments of the overall quality of the HS recording (assessability, brightness, and focus) and seven assessments of anatomical and morphologic characteristics of the neoglottis: amount of saliva (none, a little, moderate, much, obstructing); visibility of the origin of the neoglottis (yes, no); shape of the neoglottis (triangular, circular, split coronal, split sagital, irregular); location of the visible vibration (left, right, anterior, posterior); presence of a mucosal wave (strong, weak, absent); regularity of the vibration (regular, irregular); and closure phase (open, equal, closed). The evaluation form and the results of the visual assessments are described in by Van As et al.[1]

Only the seven assessments of the neoglottic characteristics were included in the analyses performed in this paper.An example of a frame sequence from an HS of the neoglottis is shown in **Figure 2**

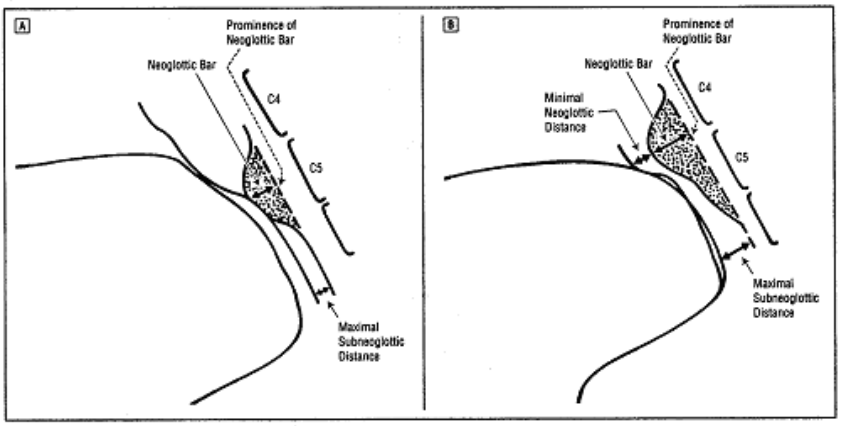

Figure 1 Schematic representation of the quantitative measures obtained during quantitative videofluoroscopy at rest (A) and during phonation (B). (from: van As CJ, et al. Arch Otolaryngol Head Neck Surg 2001;127:161-9)

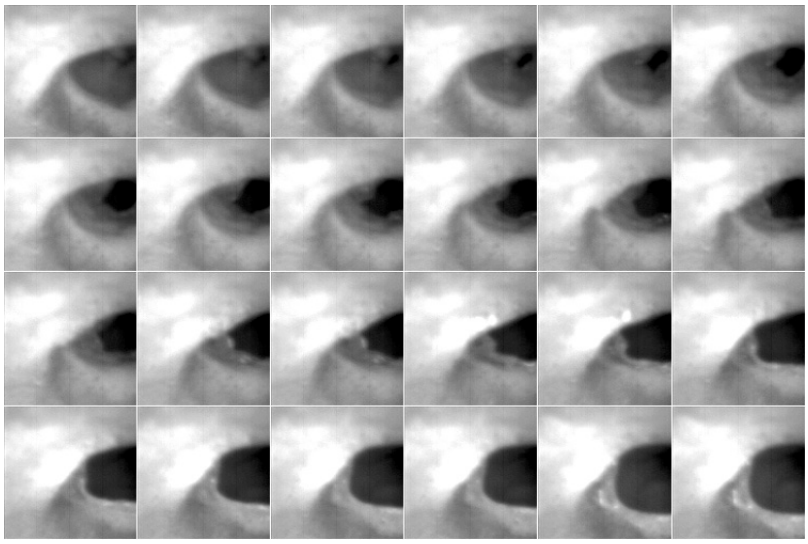

Figure 2 Sequence (from top-left to bottom-right) of subsequent frames of a digital high-speed endoscopy recording. Round shaped neoglottis.

The patient characteristics studied were: sex, age, postoperative follow-up, reconstruction, myotomy, neurectomy (of the plexus pharyngeus), radical neck dissection, and radiotherapy.

Statistical analyses

Statistical analyses were performed using the Statistical Package for Social Sciences (version 10.0; SPSS Inc. Chicago, Ill.). $P < .05$ was considered significant. The results of the visual assessments of the HS recordings are related to the results of VF (visual assessment and quantitative measures), and to the patient characteristics.

Subgroups were formed, based on the visual assessments of the HS recordings of the neoglottis. The numbers of patients in each of the subgroups mentioned below are based on the 44 patients in whom HS recordings were obtained. Not all characteristics were assessed for all 44 patients, due to the fact that not all parameters were assessable for all patients. The presence of a mucosal wave and the regularity of the vibration could be assessed in 44 patients, the location of the visible vibration in 41 patients, the shape of the neoglottis in 36 patients and the closure phase in 30 patients. For amount of saliva the subgroups formed were 'none or a little' (n=20), 'moderate' (n=15) and 'much or obstructing' (n=9); for visibility of the origin of the neoglottis the subgroups formed were 'yes' (n=31) and 'no' (n=13); for shape of the neoglottis the subgroups formed are 'circular' (n=7), 'split side-to-side (coronal)' (n=14), 'split anterior-posterior (sagital)' (n=5) and 'irregular' (n=12); the shape 'triangular' was excluded from statistical analysis as it was seen in only 1 patient.
For location of the visible vibration the subgroups formed were 'posterior wall' (n=3), 'anterior wall' (n=5), 'one lateral wall' (n=3), 'both lateral walls' (n=3), 'anterior and posterior wall' (=2), and 'all walls' (n=15); in 1 patient a combination of 'posterior and one lateral wall' was seen and in one patient a combination of 'anterior and both lateral walls' was seen (not included in statistical analysis); in 2 patients a combination of 'posterior and both lateral walls' was seen (only participated in HS part).
For the presence of a mucosal wave the subgroups formed were 'strong or weak' (n=22) and 'absent' (n=22). For the regularity of the vibration the subgroups formed were 'regular' (n=12) and 'irregular' (n=31); and for the closure phase the subgroups were 'open' (n=23) and 'equal' (n=7), the subgroup 'closed' was excluded from statistical analysis, as it contained only 1 patient.

The relations between HS imaging and the visual assessments of VF (N=37) were investigated with exact chi-squared tests for the nominal data or chi-squared tests for linear-by-linear association for the ordinal data.
For investigation of relations between HS imaging and the quantitative measures of VF, t-tests for two independent samples, or analyses of variance (ANOVA) followed by post hoc Tukey tests with Bonferroni correction were used. The increase of the maximal distance from rest to phonation (index) and the maximal distance at rest needed logarithmic transformation first.
The relations between the visual assessments of HS imaging and the patient characteristics were investigated with exact chi-squared tests for the nominal data and chi-squared tests for linear-by-linear association for the ordinal data.
In the results that are presented, only the statistically significant results are given.

Results

HS versus visual assessment of VF

Relations were found between the amount of saliva (HS) and the visibility of the origin of the neoglottis (HS) and some of the anatomical and morphologic characteristics of the neoglottis as assessed using VF. The amount of saliva (HS) showed a relationship with the presence of a neoglottic bar at rest (VF) (P=.027), to regurgitation of barium during phonation (VF) (P=.005) and to the tonicity of the neoglottis during phonation (VF) (P=.004). (Table 2)

In the patient group with a visible neoglottic bar at rest, there was more often no or a little saliva seen, while in the patient group without a visible neoglottic bar at rest there was more often a large to obstructing amount of saliva. The same trend was seen for the amount of saliva in relationship to the presence of a neoglottic bar during phonation, but this relationship was not significant (P=.084). In the group where saliva was seen (HS) often regurgitation of barium (VF) was seen as well. When a larger amount of saliva (HS) is seen, the tonicity of the neoglottis (VF) was often hypotonic.
The visibility of the origin of the neoglottis (HS) showed a relationship with the presence of a neoglottic bar during phonation (VF) (P=.036) (Table 3). In the patient group with a visible origin of the neoglottis (HS), presence of a neoglottic bar during phonation (VF) was seen more often. This shows that, although no one-to-one relation, in the majority of the cases when a neoglottic bar is seen in the lateral view with VF a neoglottis is also seen in the 'birds-eye' view obtained with HS.

Table 2 The amount of saliva seen with digital high-speed imaging (columns) and the presence of a neoglottic bar at rest, regurgitation of barium during phonation and tonicity of the neoglottis during phonation seen with videofluoroscopy (rows)

Videofluoroscopy assessment	Amount of saliva		
	none/a little	moderate	much/obstructing
Neoglottic bar at rest			
None	4	4	5
1 or 2*	15	7	2
Regurgitation			
Yes	3	6	5
No	16	5	2
Tonicity			
Hypotonic	3	7	4
Normotonic	10	3	2
Hypertonic	6	1	0

*In a few patients a double neoglottic bar was seen, this number was too small for seperate statistical analyses

Table 3 Relationship between the visibility of the originof the neoglottis seen with digital hifh-speed imaging (columns) and the presence of a neoglottic bar during phonation judged with videofluoroscopy (rows). Numbers represent number of patients, in total n=37

Videofluoroscopy assessment	Visibility of the origin of the neoglottis	
	Yes	No
Neoglottic bar during phonation		
None	3	6
1 or 2	22	6

The shape of the neoglottis (HS) was related to the presence of a neoglottic bar at rest (VF) (P=.046) (**Table 4**). As can be seen side-to-side split shapes (see the example in **Figure 3**) and irregular shapes are seen more often when there is a neoglottic bar at rest, while anterior-posterior split shapes (see the example in **Figure 3**) are seen more often when there is no visible neoglottic bar at rest.
Regarding location of the visible vibration, mucosal wave, regularity of the vibration, and closure phase, no relations were found with the results of VF.

Table 4 Relationship between the shape of the neoglottis judged with digital high-speed imaging (columns) and the presence of a neoglottic bar at rest judged with videofluoroscopy (rows). Numbers are of patients, in total n=28

Videofluoroscopy assessment	Shape of the neoglottis			
	Circular	Split side to side	Split anterior posterior	Irregular
Neoglottic bar at rest				
None	2	3	4	0
1 or 2	4	8	1	6

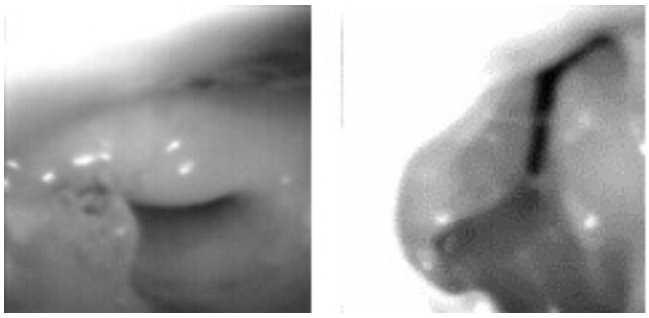

Figure 3 Example of a side-to-side split shaped neoglottis (left) and an anterior posterior shaped neoglottis (right)

HS versus quantitative measures of VF

Relations were found between the visual assessments of the amount of saliva (HS) and of the presence of a mucosal wave (HS) and some of the quantitative measures obtained from the VF recordings. **Table 5** shows the results for the amount of saliva. As can be seen from this table, the amount of saliva (HS) showed a relationship with the quantitative measures maximal distance during phonation, minimal distance at rest and the index of the maximal distance during phonation and the maximal distance at rest. The average maximal distance during phonation is larger, the minimal distance is smaller and the index is larger in the patient group with no or a little saliva compared to the patient group with a large or obstructing amount of saliva. This indicates that when there is a better neoglottic closure, the amount of saliva at or above the level of the neoglottis is smaller. Regarding the presence of a mucosal wave (HS), it was shown that the maximal subneoglottic distance during phonation was larger in the patient group in which a mucosal wave is seen compared to the patient group

in which this was not the case (P=.022; 'yes/slightly'=12.24 mm (SD 5.11 mm); 'no'=8.67 mm (SD 3.03 mm)). This may indicate that in the case with a larger subneoglottic distance, indicating tighter closure of the neoglottis, it is more likely that a mucosal wave of the mucosa overlying the muscles is present. Regarding the visibility of the origin of the neoglottis, shape of the neoglottis, location of the visible vibration, regularity of the vibration, and closure phase no relations were found with the quantitative measures.

Relations with patient characteristics (HS)

In the patient group that underwent reconstruction larger amounts of saliva were seen more often than in the patient group after standard total laryngectomy (P=.015). Also, in terms of the shape of the neoglottis a difference was found between the patient group after standard total laryngectomy and the patient group after standard total laryngectomy (P=.029). In the patient group after standard total laryngectomy side-to-side (coronal) split shapes were seen, while this shape was not seen in the patient group after reconstruction.
As the surgical differences between the patient group with a standard total laryngectomy and the patient group with a reconstruction are large, the patient characteristics sex, age, postoperative follow-up, myotomy, neurectomy, radical neck dissection and radiotherapy are studied within the patient group after standard total laryngectomy only. The reconstruction group is too small to perform statistical analysis on subgroups within it.

Regarding sex, a relation was found with the regularity of the vibration of the neoglottis (P=.024), female patients had more often a regular vibrating neoglottis than male patients. Regarding myotomy a relation was seen with the shape of the neoglottis (P=.017), in the patient group with a myotomy no side-to-side split shapes were seen, and in the group without a myotomy more often an irregular shape was seen. No relations were found with age, postoperative follow-up, neurectomy, radical neck dissection, and radiotherapy.

Table 5 Relationships between the visual assessments of the amount of saliva in digital high-speed recordings (columns 2-4) and the quantitative measures of the neoglottis performed on videoflouroscopy recordings (column 1). The p-value is given in column 2. for the measure with a significant p-value after Bonferroni correction ($p<.0056$), a Post Hoc Tukey test was performed, of which p-values are shown in the boxes attached to the arrows

Quantitive measure	p-value	Amount of saliva		
		None/a little	moderate	much/obstructing
Maximal (subneoglottic) distance during phonation	.018	11.56	9.95	5.99
Minimal (neoglottic) distance at rest	<.001	0.55	2.86	3.89
			.001	
			.007	
Index of the maximal (subneoglottic) distance during phonation and at rest	.020	2.32	2.11	1.01

Discussion

The aim of the present paper was to gain insight in the clinical value of the relatively new method of HS to investigate anatomical and morphologic characteristics of the neoglottis. VF is the method most widely used for studying neoglottic characteristics and, therefore, in the present study was used as the standard against which to compare the results of HS. In normal voice evaluation, stroboscopy is the method of choice to study the anatomical and morphologic characteristics of the vocal folds. Like stroboscopy, HS also provides a bird's-eye view of the neoglottis (while VF provides a lateral view), and could therefore be a valuable substitute for stroboscopy, which cannot be used for these voices due to the high irregularity of the neoglottic vibration [1]. Relationships between HS, as described by Van As et al. [1], and VF, as described by Van As et al.[21] were investigated, and relationships with patient characteristics were studied. Relations between both methods are investigated to gain insight in the overlap between them and the complementary value of HS.

Not surprisingly, the amount of saliva (HS) showed a relationship with regurgitation of barium (VF) and the tonicity of the neoglottis (VF). The tonicity presently can only be 'visualized' with VF; and until now, no comparable visual analogies were available yet about the visual characteristics of tonicity in a neoglottis when seen from above. However, from this study it becomes clear that regurgitation occurring in the majority of hypotonic cases is synonymous with bubbling of saliva during HS.

Also, the presence of a neoglottic bar seen during VF showed a relationship with a visible neoglottis in HS. Furthermore, when a neoglottic bar is seen at rest during VF, side-to-side split shapes and irregular shapes are seen more often, while anterior-posterior split shapes are seen more often when no neoglottic bar is seen during VF. However, VF recordings have only been made in lateral view. VF recordings in anterior-posterior view may have revealed more information about this, although such recordings are usually less clear, as the cervical vertebrae 'obscure' the image.

For the location of the vibration, presence of a mucosal wave, regularity of the vibration and closure phase, no relationships were found with VF. These assessments are thus of additional value to the assessments that can be made on VF recordings. Also, assessment of shape of the neoglottis provides an additional value since it can only be seen in bird's-eye view.

The regurgitation seen during VF might be influenced by the swallow of barium shortly before phonation, the amount of saliva judged with HS (where no barium is swallowed) may be more representative for the normal situation during phonation. However, it may also be less representative of normal voice production as the patient is requested to stick out his/her tongue out to enable the view in the esophagus to be obtained. In this respect, improvements in HS, enabling recording with a flexible fiberoptic endoscope (which is introduced transnasally and does not require the patient to stick his/her tongue out), would resolve this problem.

Only the visual assessment of the amount of saliva and the presence of a mucosal wave are related to some quantitative measures of the neoglottis during VF. In relation to hypotonicity, the quantitative measures showed that the amount of saliva is smaller when the neoglottis was closed with some tension during phonation. Interestingly, the average maximal distance during phonation was larger in the patient group showing a mucosal wave of the esophageal wall(s) during phonation. This can be explained by the tighter neoglottic closure that is seen when the maximal subneoglottic distance is larger. Most probably the muscular closure is good in this patient group and the upper mucosal layers show the mucosal wave.

The patient characteristics that were studied are sex, age, postoperative follow-up, reconstruction, myotomy, neurectomy, radical neck dissection and radiotherapy. These patient characteristics have also been studied in relationship to the VF recordings and were reported in an earlier study[21]. The finding that neoglottic characteristics studied by means of HS are less favorable in the reconstruction group is not unexpected and was also found for the VF recordings.

However, the relationship between reconstruction and the amount of saliva found in HS was not found for regurgitation during VF (which showed overlap with each other). Additionally, the relationship between reconstruction and the presence of a neoglottic bar found in VF was not found for visibility of the origin of the neoglottis in HS (found to show overlap with each other). VF also showed some influence of radical neck dissection and age within the standard total laryngectomy group that were not found for HS. The relationship found between sex and regularity of vibration during HS is a relationship that obviously could not be found for VF. Female patients show a regular vibrating neoglottis relatively more often. However, no meaningful explanations can be formulated for this difference at this time. Furthermore, myotomy was found to be related to the shape of the neoglottis. No explanation can be given for this either, but when interpreting these results it should be kept in mind that only a small subgroup of patients underwent a myotomy (n=7).

In conclusion, the relationships found between both investigation methods show that the judgment of the amount of saliva in HS and the regurgitation of barium during VF overlap somewhat, although it is thought that the judgment of the amount of saliva in HS is more representative for daily life. Another overlapping judgment is that of the visibility of the origin of the neoglottis in HS and the presenceof a neoglottic bar in VF, the latter technique being preferred as a deep location of the neoglottis can also be identified. HS can provide valuable extra information about the location of the vibration, presence of a mucosal wave, regularity of the vibration, and closure of the neoglottis. Also the fact that the methods reveal different relationships between neoglottic and patient characteristics stresses the value of using HS in addition to VF recordings. Obviously, investigation of relationships between the anatomical and morphologic characteristics studied using both imaging methods and voice quality in tracheoesophageal speech is needed to establish the relevance of the characteristics studied. Future possibilities for automated objective analyses of the HS recordings are expected to further increase the usefulness of the technique in research and clinical practice.

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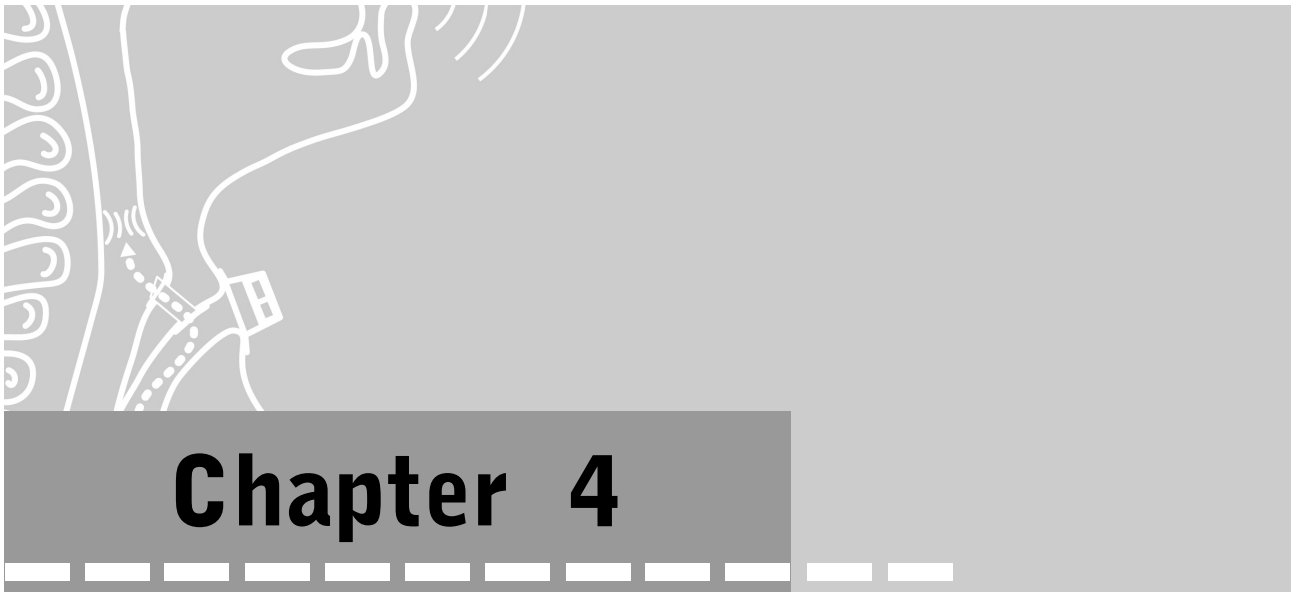

Chapter 4

Quality of life / Hands-free speech

Chapter 4.1

Quality of life assessment in laryngectomized individuals: Do we need additions to standard questionnaires in specific clinical research projects?

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Abstract

Objective: To assess, whether the EORTC questionnaires QLQ-C30 and QLQ-H&N35 give enough detailed information to study specific quality of life (QoL) related issues in laryngectomized individuals.
Design: Multi-centre, prospective clinical trial; baseline measurement with EORTC questionnaires and an additional questionnaire, focusing on specific postlaryngectomy problems.
Setting: Head and Neck Department of one Comprehensive Cancer Center and three Academic Medical Hospitals in the Netherlands.
Participants: Eighty laryngectomized individuals, selected to participate in a prospective clinical trial on hands-free tracheoesophageal speech.
Main outcomes measures: Comparison of QoL dimensions, as assessed with the standard EORTC questionnaires, with the information obtained with additional questions, aimed at discovering in more detail e.g. voice and respiratory problems in laryngectomized individuals.
Results: Based on the EORTC QoL questionnaires a good overall and voice specific QoL-level was found. However, the additional questionnaire showed that especially concerning voice and respiration more specific information was obtained. For example, despite an overall satisfaction with many aspects of the voice in more than three quarters of the patients, speaking in a noisy environment was reported by 63% of the patients as being a serious problem, and a significant relation could be established between pulmonary and voicing problems (r 0.28, $P<0.05$), something also undetectable with the EORTC questionnaires.
Conclusions: These findings underline the necessity to develop and use more specific additional questionnaires as an adjunct to the existing EORTC questionnaires, when studying specific symptoms in laryngectomized individuals, especially in order to detect intervention related changes over time.

Introduction

Quality of life (QoL) assessment has become an essential part of head and neck cancer treatment evaluation. Obviously, treatment outcomes in terms of loco-regional control, and disease free and overall survival remain key issues in the evaluation of the effectiveness of the therapy. However, especially in advanced disease the QoL after these often intensive treatments is of equal importance. This is especially true in this time of increasing use of chemo-radiation protocols, where the relevance of the assessment whether organ preservation equals function preservation is obvious. [1, 2] Furthermore, after ablative surgical procedures, such as total laryngectomy, where the sacrifice of specific functions is inherent to the treatment, quality of life assessment is needed to put the loss of function into perspective and to evaluate the effectiveness of specific treatments and solutions.

During the late eighties, at the Netherlands Cancer Institute several prospective clinical intervention studies were carried out on laryngectomized individuals. At that time standard international validated questionnaires to evaluate QoL were still lacking. This made the development of QoL questionnaires, dedicated to the specific problems of laryngectomized patients necessary. [3, 4]

In the succeeding years the EORTC has developed the QLQ-C30 questionnaire, and tumour specific modules were used for e.g. lung and breast cancer. [5] According to the same guidelines of the EORTC Quality of Life Study Group a specific module for head and neck cancer was developed. [6] Although these questionnaires have resulted in a better understanding of the impact of treatment in head and neck oncology, the question remains whether further specialization of the questionnaires would still be necessary. [7-9] Recent research in the specific fields of e.g. rehabilitation of olfaction in laryngectomized patients, and functional problems after extensive ablative head and neck surgery, showed deficits in specificity of the EORTC questionnaires and necessitated the use of additional questionnaires. [10 4]

The principal aim of the current study was to assess whether besides the EORTC questionnaires (EORTC QLQ-C30 and EORTC QLQ-H&N35) an additional questionnaire is needed to uncover changes related to specific patient groups. The data presented in this study form the baseline to a prospective intervention study with a new automatic speaking valve. [11] If the additional questionnaire proves to be necessary to detect specific voice and respiratory symptoms in this patient group, it will be included in the data analyses of the intervention study in order to enable detection of possible changes in these symptoms as a result of the intervention.

Patients and methods

The patients for this multi-centre, prospective clinical evaluation study were recruited from four comprehensive head and neck cancer centres in the Netherlands, i.e. Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital and Academic Medical Center, Amsterdam, University Medical Center St Radboud, Nijmegen, Erasmus Medical Center/Dr. Daniel den Hoed Cancer Center Rotterdam, University Hospital Maastricht. Eighty laryngectomized patients, all using prosthetic tracheoesophageal speech and looking for an (other) opportunity to acquire hands free speech, were enrolled in this study conducted for the assessment of a recently developed automatic tracheostoma valve, the Provox FreeHands HME. [11] The Protocol Review Board of the Netherlands Cancer Institute (as initiating centre) and subsequently the boards of the three other participating centres approved the study, and written informed consent was obtained from all patients before they entered the study.

Of the 80 patients, one patient withdrew after being diagnosed with a second primary tumour one week before the start of this study, resulting in 79 participants. As shown in **Table 1**, there were 71 men and 8 women, with a mean age of 65 years (range 45 to 86 years) and a median follow-up of 4.2 years (range 5 months to 17.6 years). Of the 79 patients, 53 underwent surgery for recurrent disease after radiotherapy, 22 were irradiated postoperatively, and 4 patients did not receive any radiotherapy. Although 13 patients were (to some extent) able to use oesophageal speech, all of them preferred prosthetic speech (97.5% Provox voice prosthesis (Atos Medical AB, Hörby, Sweden), 2.5% Groningen voice prosthesis (Medin, Groningen, the Netherlands)). Although the majority of the patients (N=66) had been offered the opportunity (and were trained) to use an automatic speaking valve (ASV) during their rehabilitation program, only 8 patients in this study group were daily ASV users (Blom-Singer ATV, InHealth Technologies, Carpinteria, CA, USA). Seventy-one patients were daily users of a Heat and Moisture Exchanger (HME). Most patients (89%) used the Provox HME (Atos Medical, Sweden), while 10% used the Humidifilter HME (InHealth Technologies, Carpinteria, CA, USA) and only one patient used the Stomvent HME (Atos Medical AB, Hörby, Sweden).

Table 1 Patient characteristics (N=79)

		(N=79)
Gender	Male	71
	Female	8
Age (years)	Mean	65
	Range	45-86
Follow-up (years)	Median	4.2
	Range	0.5-17.6
Radiotherapy	'Preoperative'	53
	Postoperative	22
	None	4
Preferred stoma occlusion method	ASV	8
	HME	61
	Finger	5
	Combination	5
Vocal rehabilitation	Tracheoesophageal voice	79
	Oesophageal voice	13*
	Electrolarynx	2*
	Whisper	3*

ASV=automatic speaking valve, HME=heat and moisture exchanger, *in addition to tracheoesophageal voice

Patients were interviewed at the start, at one month and at the end of the study period of 6 months by means of structured questionnaires.
Three questionnaires were used:

1. EORTC QLQ-C30, this questionnaire comprises five functional scales (physical, role, cognitive, social and emotional functioning), an overall QoL scale, three multi-items symptom scales (fatigue, nausea and vomiting, and pain) and 6 single items assessing dyspnea, appetite, sleep disturbances, constipation, diarrhoea and economic consequences of the disease. [5] All scales and item scores are linearly transformed to a scale of 0-100. A high score for the functional scales and for the overall QoL scale represents a better QoL. For the single items and for the symptom scales a higher score means a higher level of symptoms. The scores are calculated according to the EORTC QLQ scoring manual.

2. EORTC QLQ-H&N35, this questionnaire is a supplement to the QLQ-C30. [6] The module consists of questions related to the problems attributable to tumour location and treatment. It contains 7 symptom scales (pain, swallowing, senses (taste/smell) speech, social eating, social contacts, and sexuality) and 6 symptom items (teeth problems, limited mouth opening (trismus), dry mouth, sticky saliva, cough and feeling ill). It is developed in accordance with the guide-

lines given by the EORTC Quality of Life Study Group. The questions are scored in the same way as the EORTC QLQ-C30. For both questionnaires permission to apply them in this study was obtained from the EORTC centre in Brussels.

3. The third questionnaire originally was developed already in 1988 in the Netherlands Cancer Institute and was used to assess in a detailed manner the QoL in laryngectomized cancer patients [3, 4], long before the standardized EORTC questionnaires became available. Since the latter questionnaires cover many QoL domains in more general terms¸ parts of this older instrument were included in this study to obtain more detailed information. Additionally, data were collected about the socio-demographics of the patient population, and practical aspects, e.g. concerning the daily handling, of the new device. Furthermore, since this device potentially influences the voice and pulmonary status of the patients, this supplementary questionnaire was expected to provide more specific and additional information about vocal and respiratory problems after total laryngectomy that would possibly be missed with the EORTC questionnaires.

To gain more insight into the specificity of the different questionnaires, **Table 2** shows a differentiation by category of questions and questionnaire.
Data were collected in the outpatient clinics of each participating centre. The completion of the questionnaires took approximately one hour (including the subsequent explanation about the use of the ASV, and the additional voice recording, the latter two not being reported here; the QoL data will form the baseline data for the analysis of the ASV intervention study, which will be published separately). In line with earlier experience and with recent studies [1], it appeared that the majority of patients liked to have some assistance with the completion of the QoL questionnaires. Many patients preferred the items being read to them instead of completing the questionnaires all by themselves.

Table 2 Questions by category and questionnaire

	Voice	Respiratory symptoms
EORTC QLQ C-30	----------	Dyspnea
EORTC QLQ H&N35	Hoarseness Difficulty in communication	Coughing Aspiration
ADDITIONAL QUESTIONNAIRE	Type of voice rehabilitation Type of voice prosthesis Intelligibility Loudness Pitch Fluency Telephone intelligibility Intelligibility in noise Strenuousness of voice	Daily/weekly coughing Coughing during the night Daily stoma cleaning Daily/weekly sputum production Sputum production during the night

Statistical methods

As already mentioned above, the scores of the EORTC-C30 and H&N35 are calculated according to the EORTC QLQ scoring manual. [5 6] Statistical analyses included primarily descriptive analyses and cross- tabulation (if appropriate, between items of the questionnaire). Associations between items and/or scales of the 3 questionnaires used in this study were measured by Pearson's correlation coefficient. A two-tailed $P < .05$ was taken to indicate statistical significance.

Results

The results based on the EORTC QLQ-C30 showed a good QoL level in all patients. The mean values of all scales and single items are shown in Table 3. The means of the functional scales ranged between 84 and 87, whereas the global health status had a mean of 82. It is noteworthy that feelings of anxiety and depression (emotional functioning) were reported by only 6 and 9 % of the patients, respectively. Insomnia, dyspnea and fatigue were mentioned somewhat more frequently than the other symptoms. Insomnia appears to be associated with the need to clear the trachea (see below).

With regards to the scales and the items of the Head & Neck module (EORTC QLQ-H&N35), only sense, speech, sexuality and coughing do somewhat stand out (**Table 4**).
Problems with senses are mainly due to problems with smell (with only 11.4% of the patients stating of having a normal sense of smell, in contrast to 63.3% of the patients reporting a normal taste perception). Interestingly, no statistically significant correlations between senses and enjoying food and/or appetite were found. However, there were still significant problems in this respect. Swallowing of solid food was reported to be troublesome for 27% of the patients (a little) and for 11% (quite a bit to very much). A correlation test showed a statistically significant association between problems with swallowing solid food and dry mouth ($r = .43$, $P<0.001$) and sticky saliva ($r=0.31$, $P<0.01$). Teeth (denture) problems also showed to be of relevance in problems with eating ($r=.46$, $P<0.001$). Furthermore, if problems with eating occur, patients reported to have trouble enjoying their meals ($r = .50$, $P<0.001$). In addition, social eating was considered not troublesome for 56 patients (71%), while the remaining 23 patients had a little to very severe problems with social eating.

It is also noteworthy that 61 patients (77%) did not have any trouble with their appearance, while 11 patients reported to be troubled a little, 5 quite a bit and 2 patients were troubled very much in this respect. Finally, a significant correlation was calculated between age and sexuality (r 0.48, $P< 0.001$): interest in sex declines with increasing age. With respect to voice, the EORTC questionnaires give only limited information about this important aspect of laryngectomized patient's QoL. On the EORTC item, 'Have you been hoarse', 72 patients (91%) answered: not at all, while only 4 patients answered: a little, 1 quite and 2 very much. Based on the additional questionnaire, **Table 5** shows the more detailed ratings of the quality of the patients' speech. More than three-quarter of the patients was satisfied with the quality (good/fair) of their voice, i.e. intelligibility, loudness (in face to face conversations), pitch, fluency and intelligibility over the telephone. However, despite these good results, more than half of the patients (63%) had serious problems with speaking in a noisy environment. Also 11 patients (14%) reported that they considered speaking rather to very strenuous. A Pearson's correlation test showed that the more a patient is troubled by coughing and/or sputum production, the more strenuous it is to speak (r 0.28, $p<0.05$).

Table 3 Results obtained fromEORTC QLQ-C30 questionnaire

symptoms/scales/items	mean scores (s.d.)
Functional scales*	
Physical functioning	84.7 (13.6)
Role functioning	84.5 (22.0)
Emotional functioning	86.8 (19.7)
Cognitive functioning	86.1 (20.2)
Social functioning	85.4 (20.4)
Global health status	82.0 (16.3)
Symptom scales**	
Fatigue	16.2 (17.9)
Nausea and vomiting	3.8 (9.6)
Pain	5.5 (13.8)
Dyspnea	22.4 (27.1)
Insomnia	15.6 (26.6)
Appetite loss	6.3 (17.7)
Constipation	7.6 (22.6)
Diarrhoea	2.1 (8.2)
Financial difficulties	8.7 (18.3)

All scale and item scores are linearly transformed to a scale of 0-100
* A higher score for the functional scales and for the overall QoL scale represent a better QoL
** A higher score means a higher level of symptoms

Table 4 Results obtained from EORTC QLQ H&N35

EORTC QLQ H&N35**	mean scores (s.d.)
Pain	6.7 (14.9)
Swallowing	10.0 (16.8)
Sense problems	42.0 (23.7)
Speech problems	29.7 (16.7)
Social eating	10.3 (16.6)
Social contact	5.5 (10.3)
Less sexuality	27.4 (34.4)
Teeth	12.2 (24.0)
Opening mouth	6.3 (17.8)
Dry mouth	13.9 (24.2)
Sticky saliva	22.8 (28.0)
Coughing	32.9 (29.5)
Feeling ill	7.2 (19.7)
Use of painkillers	4.6 (11.6)
Nutritional supplements	2.5 (8.9)
Feeding tube	0.8 (5.3)
Weight loss	1.3 (6.4)
Weight gain	8.4 (14.6)

All scale and item scores are linearly transformed to a scale of 0-100
** A higher score means a higher level of symptoms

Based on the EORTC H&N 35 (item c45) and the additional QoL questionnaire, it was shown that in this selected group of patients, respiratory symptoms were a fairly common problem. On the question, have you been coughing (item c45), 58 patients (67%) reported having coughed during the last week (a little to very much). The additional questionnaire gives a more detailed insight in the respiratory symptoms. The weekly incidence of spontaneous coughing and sputum production can be found in Table 6. Coughing problems were more prominent during the day than during nighttime. Sputum problems were experienced by almost all patients (91%). Also during the night 24% of the patients had to clear their trachea. A statistically significant correlation (r 0.41, $p<0.001$) was found between sputum production during the night and insomnia (item c11), as already indicated above.

The majority of patients (85%) cleaned their stoma 1-4 times a day, while the remaining patients needed to do this more than 5 times a day (range 5 – 30 times a day). As already mentioned above 71 patients used an HME during the day and 56 (79%) of them used the HME also during the night. A statistically significant correlation was found between HME use and sputum production during the night (r -0.29, $p<0.05$): patients who used the HME also during the night were less troubled by nocturnal sputum production.

Table 5 Patients ratings of voice quality (N=79)

	Frequencies in %			
Voice Quality	Good	Fair	Moderate	Poor
Intelligibility	89	10	1	0
Loudness	49	41	8	2
Pitch	54	27	18	1
Fluency	87	9	4	0
Telephone intelligibility	80	14	4	2
Intelligibility in noise	9	28	30	33

Table 6 Respiratory symptoms after total laryngectomy

	Coughing		Sputum	
	Day	Night**	Day#	Night##
Not at all	34 (43%)	66 (84%)	7 (9%)	60 (76%)
1 - 2 days p.w	8 (10%)	3 (4%).	7 (9%)	8 (10%)
3 - 4 days p.w.	3 (4%)	1 (1%)	5 (6%)	1 (1%)
5 or > days p.w.	34 (43%)	9 (11%)	60 (76%)	10 (13%)

* mean 3.8 times a day; ** mean 0.4 times a night
\# mean 5.4 times a day; ## mean 0.5 times a night

Discussion

The principal aim of the current study was to assess whether besides the EORTC questionnaires (EORTC QLQ-C30 and EORTC QLQ-H&N35) an additional questionnaire is needed to uncover changes related to specific patient groups. In the present study, whether more insight can be obtained in voice and respiratory issues and their impact on quality of life (QoL) in a group of laryngectomized patients using tracheoesophageal speech, and participating in a prospective intervention study with a new ASV. [11]
Based on the EORTC QLQ-C30 questionnaires a good QoL-level was seen in all patients. Further analysis using the EORTC QLQ-H&N35 in these well-rehabilitated laryngectomized patients (i.e. successfully using a voice prosthesis and an HME), confirmed this good level, but also revealed some interesting data on more specific issues. The data reported in this paper will form the baseline for an intervention study, in which the impact of a new ASV in laryngectomized patients will be assessed. As this group of patients was highly motivated to explore a new method to acquire hand-free speech, one should realize that the positive QoL results might in part be due to selection bias.

The outcome in QoL assessment in this group of laryngectomized patients is very much in accordance with recent studies, using the EORTC (C30 and H&N35) questionnaires in head & neck oncology.[7-9] Similar outcome is found not only with studies performed in other laryngectomized patient groups, but also with studies in lower staged laryngeal cancer patients, treated with radiotherapy only. These similarities in QoL results, even between groups of patients staged and treated differently, make it unlikely that variations due to specific interventions in laryngectomized patients can be assessed. Muller et al. already stated that with regards to the assessment of voice function, both the EORTC QLQ C30 and the H&N 35 modules were not sensitive enough and require further development.[12] Also Sherman et al. suggested that additional research should focus on whether the QLQ-H&N 35 is sensitive to chemotherapy or radiation toxicity, extent of surgery, and presence of tracheoesophageal punctures or tracheotomies.[13]

The relatively low score on speech problems (29.7) in the EORTC QLQ H&N35 in the current study might be a striking example of this deficit in sensitivity. Especially in a group of laryngectomized patients, a higher score (more problems) would have been expected. However, this relatively low score in the EORTC QLQ H&N35 could be sustained by the good results in voice quality based on our own additional questionnaire (more than three quarter of the patients was satisfied with their quality of speech).

One has to keep in mind that the HME in itself can affect the speech of a laryngectomized patient in a positive way, as we have shown in the past. [14] Nevertheless, more differentiated aspects of speech, i.e. intelligibility in noise and the fact speaking could be rather strenuous as shown by our own additional questionnaire, suggest the low score in the EORTC QLQ H&N35 is somewhat misleading.

Concerning the respiratory symptoms of this patient population, a better insight in the incidence and impact of these problems was obtained with the additional questionnaire as well. Furthermore, based on the earlier developed questionnaire, an obvious improvement could be found in comparison with the results of the group of laryngectomized patients studied in the early nineties in the Netherlands Cancer Institute. [3, 15, 16] Weekly and daily incidence of spontaneous coughing, sputum production and cleaning the tracheostoma displayed lower frequencies in the current study. This is most probably due to the fact that 71 of the 79 patients used the HME on a daily basis. The improved version of the HME (Provox HME) and the fact that most patients nowadays use the HME immediately following their surgery enhances the HME compliance compared to the above-mentioned studies, and thus underscores the beneficial effect of an HME.16 The lower frequency of respiratory problems also may explain that, in contrast with earlier studies, in the present study hardly any statistically significant correlations were found between the respiratory symptoms and several daily life aspects. [3]

As mentioned before, the EORTC QLQ C30 showed that besides dyspnea and fatigue, also insomnia was more frequent than other symptoms. The significant correlation between the use of the HME and expectoration during the night and the correlation between forced expectoration and insomnia underlines the effectiveness of using the HME also during the night.

The low detection rates of anxiety and depression might be surprising and suggesting a low detection rate with the used questionnaire. However, in an earlier study using the Hospital Anxiety and Depression scale of Zigmond and Snaith, we found a similar low rates. [3] In that study according to the 14 items on that subject, patients showed an anxiety and depression level of only 5 and 7 %, respectively. Therefore, we think that the 4 items of the EORTC questionnaire are sensitive enough in this respect.

The EORTC QLQ H&N35 revealed that sense, speech, coughing and sexuality do somewhat stand out in showing higher scores than other symptom items/scales. This relative high score of sense problems in laryngectomized patients, smell in particular, is a confirmation of a problem that has been reported earlier. [4,17,18]

Although in an intervention study by Hilgers et al. restoration of olfactory acuity could be achieved in 50% of the patients, the effect on QoL yet has to be studied. [18] Again, as a result of the complexity of the assessment of olfaction itself, it will be doubtful if the standard EORTC QLQ-H&N35 will be sensitive enough to differentiate any improvement in this respect. Despite this reduction in smell and taste in the current study, it did not result in a decrease in enjoying meals. The small number of patients, which had problems in this respect, was mainly troubled by symptoms as sticky saliva, dryness of the mouth and dental problems.

The lower interest in sexuality confirms similar findings by Muller et al. [12] The significant correlation with age probably can be explained in part by the mean age of 65 years of this study group.

In conclusion, regarding the EORTC QLQ-C30 and EORTC QLQ-H&N35 many similarities in health related QoL aspects were seen compared to other studies with laryngectomized patients and laryngeal cancer patients treated with radiation only. With regard to voice function and respiratory problems the EORTC QLQ-C30 and EORTC QLQ-H&N35 questionnaires showed relatively low scores, assuming a relatively high QoL, but also a deficit in sensitivity in this group of laryngectomized patients. The use of an additional questionnaire uncovered more specific voice related problems, like difficulties in intelligibility in noise and the fact speaking could be rather strenuous. The same lack of sensitivity was found regarding respiratory symptoms. The observed lower incidence of these symptoms in comparison with earlier studies, most likely as a result of a better compliance with the use of Heat and Moisture Exchangers, exemplifies the value of this additional questionnaire.
These findings underline the necessity to use and develop more specified questionnaires, when studying specific head and neck cancer patient groups, as an adjunct to the already valuable and well-validated EORTC questionnaires.

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Chapter 4.2

Compliance, quality of life and quantitative voice quality aspects of hands-free speech

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Abstract

Objective: Long-term (6 months) assessment of compliance, aspects of voice, breathing and quality of life using a new automatic tracheostoma valve (ASV; Provox FreeHands HME).

Material and methods: Prospective clinical multi-centre trial in 79 laryngectomized patients (8 regular ASV users, 58 previously unsuccessful users, and 13 novel users). Data collection at baseline, one month and six months by means of EORTC Quality of Life questionnaires, and specific structured questionnaires concerning compliance, skin adhesion, voicing and pulmonary aspects. Objective assessment of voice parameters (maximum phonation time, maximum phonation time while counting, dymnamic loudness range, and number of pauses in a standard read-aloud text) for comparison of different stoma occlusion methods (digital occlusion via an HME and 2 different ASVs). Subjective assessment of overall voice quality.

Results: After 6 months 19% of all patients used the new ASV on a daily basis (with a mean of 5 hours a day), while 57% of the patients used this device on an irregular basis as an additional rehabilitation tool for special occasions. Two-thirds of the study group indicated to continue with the use of this new ASV after the study period. With respect to the objective parameters, statistically significant better maximum phonation times and dynamic loudness ranges were observed with the new ASV compared to the Blom-Singer ASV.Yet, digital occlusion via the Provox HME showed still the best results for all objective parameters.

Conclusion: With this new ASV it appears possible to rehabilitate patients, who previously have been unsuccessful to acquire hands-free speech. Not only was daily ASV use possible for an additional group of patients, but this new device also was appreciated by many patients as an additional rehabilitation tool for specific occasions. Despite further statistically significant improvements in aspects of voice and breathing using this novel ASV, improvement of peristomal adhesion is probably the main factor needed to further increase success rates. Nevertheless, this study shows that it makes sense to keep trying to achieve hands-free speech, even if attempts in the past have failed.

Introduction

After being introduced 25 years ago, presently prosthetic voice rehabilitation can be considered the gold standard for the restoration of oral communication after total laryngectomy.[1] Success rates can be as high as 90%, both with respect to the quality of the voice as well as the percentage of long-term users.[2] Also with respect to another major consequence of total laryngectomy, i.e. the short-circuiting of the nose and the inherent respiratory problems, considerable progress has been made in the last decade. Symptoms like coughing, and excessive phlegm production, can be reduced significantly since the introduction of heat and moisture exchangers (HME).[3] The decrease in pulmonary problems as a result of the consequent use of HMEs has not only a beneficial effect on physical and psychosocial problems, but also on voice quality.[4, 5]

A draw-back of prosthetic speech is that the patient needs to occlude the stoma with a finger. Not only does this lead to the uncomfortable occupation of one hand, but it also increases the 'visibility' of the patient's handicap, 'being pointed at in every conversation'. Therefore, the ultimate goal of postlaryngectomy rehabilitation should be the achievement of hands-free speech by using an automatic stoma valve (ASV), preferably in combination with an HME to simultaneously take care of the afore-mentioned respiratory problems. In general, ASVs like the Bivona I and II (Bivona Medical Technologies, Gary, Ind., USA), the Blom-Singer Adjustable Tracheostoma Valve (ATV; Inhealth Technologies, Carpinteria, CA, USA), the Eska-Herrmann device and, more recently, the Window valve (Adeva, Lübeck, Germany) have success rates of approximately 30% daily long-term users.6-13 That only a limited number of patients is able to use an ASV has probably several reasons, such as the frequently occurring troublesome fixation of the ASV to the peristomal skin, a high back-pressure needed for voicing threatening the seal of the adhesive, and/or the inadvertent spontaneous closure of the valve during physical exertion. Also an inconvenient cough-relief mechanism, a lack of motivation and/or dexterity of the patient, and a significant need for counseling by medical professionals are hurdles to be taken in order to successfully use an ASV.[6-13]

To overcome some of the above-mentioned problems of hands-free speech, and at the same time to optimally address the respiratory problems in laryngectomized patients, Hilgers et al. developed an ASV with a fully integrated, disposable HME (Provox FreeHands HME; Atos Medical, Hörby, Sweden).[14] The study about the development and testing of this device during short-time follow-up showed that the advanced features (obligatory HME and multi-magnet speaking and cough-relief valve systems) offer some additional benefits over existing valves.

Especially, the measured increase of dynamic loudness range and maximum phonation time was promising. The current study describes the compliance, and some quantitative aspects of voice quality and quality of life issues in 79 patients using the Provox FreeHands HME over a much longer follow-up period, i.e. 6 months.

Patients and methods

For this multi-centre, prospective clinical trial 80 laryngectomized patients were recruited from four Comprehensive Head and Neck Cancer Centres in The Netherlands, i.e. The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, and Academic Medical Centre, Amsterdam, the University Medical Centre St Radboud, Nijmegen, the Erasmus University Medical Centre/Dr. Daniel den Hoed Cancer Centre Rotterdam, and the University Hospital Maastricht. All patients were using prosthetic tracheoesophageal speech and were looking for an (other) opportunity to acquire hands-free speech. They were enrolled in this study for the assessment of a recently developed automatic tracheostoma valve (ASV), Provox FreeHands HME.[14] The Protocol Review Board of the Netherlands Cancer Institute (as initiating centre) and subsequently the boards of the three other participating centres approved the study, and written informed consent was obtained from all patients before they entered the study.

Of the original 80 patients, giving informed consent, unfortunately one patient had to withdraw after being diagnosed with a second primary tumour one week before the start of this study, resulting in 79 participants. As shown in **Table 1**, there were 71 men and 8 women, with a mean age of 65 years (range 45 to 86 years) and a median follow-up of 4.2 years (range 5 months to 17.6 years). Of the 79 patients, 53 underwent surgery for recurrent disease after radiotherapy, 22 were irradiated postoperatively, and 4 patients did not receive any radiotherapy. Although 13 patients were (to some extent) able to use oesophageal speech, all preferred prosthetic speech (97.5% Provox voice prosthesis (Atos Medical, Hörby, Sweden), and 2.5% Groningen voice prosthesis (Medin, Groningen, the Netherlands)). In this study population, 66 patients had been offered the opportunity (and were trained) to use an automatic speaking valve (ASV) during their past rehabilitation program, whereas the remaining 13 patients never had been exposed to automatic valve use. However, only 8 of the 66 'experienced' patients were 'daily' ASV users (Blom-Singer ATV), and the remaining 58 had been 'unsuccessful' in this respect.

Seventy-one patients were daily users of a Heat and Moisture Exchanger (HME). Most patients (89%) used the Provox HME (Atos Medical, Hörby, Sweden), while 10% used the Blom-Singer HME (InHealth Technologies, Carpinteria, CA, USA) and one patient used the Stomvent HME (Atos Medical, Hörby, Sweden).

Table 1 Patient characteristics (N=79)

		(N=79)
Gender	Male	71
	Female	8
Age	Mean	65 years
	Range	45-86 years
Follow-up	Median	4.2 years
	Range	5 months-17.6 years
Radiotherapy	Preoperative	53
	Postoperative	22
	None	4
Preferred stoma occlusion method	ASV	8
	HME	61
	Finger	5
	Combination HME/Finger	5
Vocal rehabilitation	Tracheoesophageal voice	79
	Oesophageal voice	13*
	Electrolarynx	2*
	Whisper	3*

ASV=automatic speaking valve; HME=heat and moisture exchanger; *in addition to tracheoesophageal voice

At baseline, all 79 participants included in this study, were informed about the FreeHands HME Automatic Speaking Valve, including the technique of voicing, the coughing mechanism, cleaning of the device, and the replacement of the HME. Also the peristomal adhesion of the baseplate, if necessary with the addition of extra silicon-glue, was explained. In order to enhance the compliance this information was given at the start of this study and, if necessary, repeated after 1 month.

The Provox FreeHands HME

This device (shown in **Figure 1**) consists of a disposable HME cassette as its indispensable core, with a re-usable multi-magnet automatic speaking valve on top. The HME can be secured to the bottom of the speaking valve to ensure proper retention in the housing of the adhesive attached to the peristomal skin and is removed by 'cracking' the cassette when it needs to be changed (at least every

24 hours). The HME is deliberately placed beneath the valve to ensure protection of the valve against mucous contamination in case the patient coughs up phlegm.

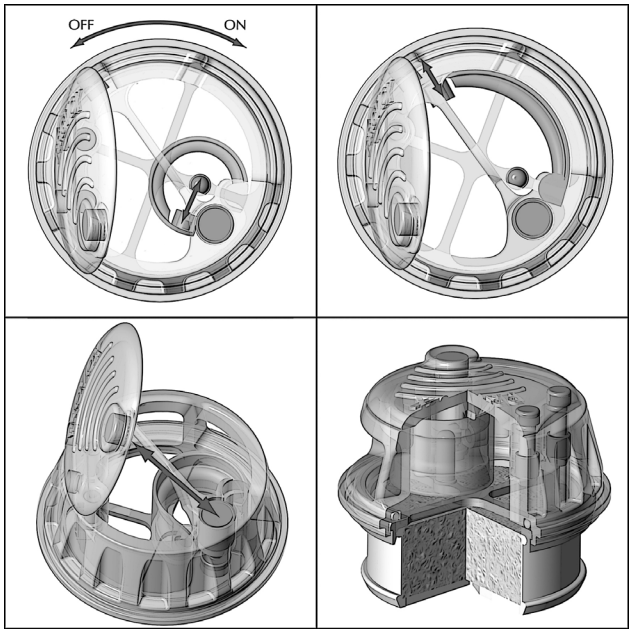


Figure 1 Provox FreeHands HME (gray arrows indicate magnetic support systems): the top-left picture shows 'on-off-mechanism', which helps to prevent inadvertent closure of the valve membrane during physical exertion (in the picture the 'on'-position is shown; turning the device into the 'off' position moves the pin onto the magnet in the valve-membrane, blocking its closure); the top-right picture shows the magnetic valve mechanism support sytem, which lowers the pressure needed for keeping the valve closed during voicing, in the mean time also lowering the pressure on the seal of the adhesive; the bottom-left picture shows: the front opening, adjustable cough-relief valve; the bottom-right picture shows the reusable automatic speaking valve with the disposable heat and moisture exchanger (HME) attached, the latter forming the indispensable 'core' of the device, also needed for the fixation of the device in the peristomal adhesive.

The re-usable automatic speaking valve contains a silicone membrane, which can occlude the side opening of the device, and has a magnet at its tip. The valve has two positions (on and off position). In the 'standard' position ('on') the membrane can move freely; in the 'activity' position ('off'; achieved by rotating the device 75^0) the membrane-magnet locks against an eccentrically placed pin, preventing closure of the membrane during physical exertion. The second function of this membrane-magnet, in combination with a second magnet near the side-opening, is to keep the membrane closed during speech, facilitating voicing with low trachea-pressure. Three types of easily exchangeable, color-coded membranes are available:

white (most flexible), green (least flexible), and blue (intermediate flexibility). Together with the Speech-Language Pathologist (SLP), the patient selects the most comfortable and efficient membrane for voicing. Furthermore, on top of the device there is a cough-relief valve, which is hinged with elastic silicone bands. This valve opens during coughing, to release the pressure built up in the trachea and to diminish the pressure on the seal and thus the untimely loosening of the adhesive. The cough-relief valve is closed by means of magnets, which enable adjustment of its opening pressure by varying the distance between the magnets. Preferably, the SLP should make this adjustment for the patient (using the provided screwdriver), so as to achieve a sufficiently high gradient between the pressures required for closure of the speaking valve and for the opening of the cough-relief valve.

For peristomal adhesion to the skin, patients can use the adhesives of the Provox HME system, or a special cannula (LaryTube; Atos Medical, Hörby, Sweden), but also other systems such as the Blom-Singer peristomal housing (Inhealth Technologies, Carpinteria, CA, USA) or Barton-Mayo stoma button (Bivona Medical Technologies, Ind., USA) were used because of the similar diameter of the valve retainer. The airflow resistance of the HME is adapted to its combination with the automatic valve, which has some airflow resistance of its own. A special container is provided for cleaning the device (overnight) with a standard denture cleaner.

Structured questionnaires

Subjective responses were collected by means of three structured questionnaires, which were completed at baseline, and after one and six months. The first questionnaire, developed already in 1988 in the Netherlands Cancer Institute, evaluates voice and pulmonary changes over time.[15, 16] To this questionnaire items were added to assess patient's experience with the Provox FreeHands HME, focusing on utility of the device, the efficacy of the valve, adhesion to the peristomal skin, and the combination of the valve with the HME filter. In case a patient had experience with the use of the Blom-Singer ATV, another supplement to the questionnaire was filled out to evaluate possible differences in functioning of the two automatic valves.
Besides this questionnaire, evaluating the compliance with the Provox Freehands HME, two other questionnaires were used to assess possible changes in quality of life (QoL) over time: the EORTC QLQ-C30, and the EORTC QLQ-H&N35, as described in an earlier study.17 Data were collected in the outpatient clinic. The completion of the questionnaires, the subsequent explanation and adjustment of the ASV, and the additional voice recordings took approximately one hour.

Voice and speech assessment

After one and six months the objective data were collected for the three stoma-occlusion methods: digital occlusion via the Provox HME, and automatic valve closure with the Provox FreeHands HME, and the Blom-Singer ATV.
The objective data collected consisted of the maximum phonation time, producing 3 times a sustained /a/ for as long as possible, of which the longest value was used in the analysis. The maximum phonation time while counting, starting from 21, was similarly recorded as well. The dynamic loudness range was obtained with the Sphynx audio sytem sound level meter (model 33-2055), whereby the maximum and minimum possible loudness values in dB, producing a sustained /a/, were recorded. A read-aloud standard text was used to establish the total number of pauses required for its completion. Speech recordings were obtained using a Sennheiser microphone and a Marantz CDR 770 audio cd recorder, and stored directly on CD-rom.
Perceived voice quality was rated by three study investigators, who all have ample experience with laryngectomized patients. They gave an overall judgment of voice quality as 'good', 'reasonable', or 'poor'. A 'good' voice was defined as 'most similar to normal voice', a 'poor' voice was defined as 'least similar to normal voice', and 'reasonable' was used for the group in between both extremes.18

Statistical analysis

Data were entered into a specially developed database of the SPSS PC+ statistical package (version 9.0). The scores of the QLQ-C30 and of the QLQ-H&N35 are transformed to a scale of 0 to 100, with a high score implying a high level of symptoms or problems (both questionnaires), or a high level of functioning or global QOL (QLQ-C30). Of the third additional questionnaire 6 voice related items were combined into a more limited set of multiple-item scales according to Likert's method of summated ratings. Where appropriate, the reliability of the scale is reported (Cronbach's alpha).
Statistical analyses included descriptive analyses and tabulations. Statistical associations were calculated by Pearson's correlation coefficient. Differences over time (baseline, 1 and 6 months) within groups were measured with paired Student's t-tests for repeated measures. For the statistical comparisons between groups, Student's t-test were employed. Also paired Student's t-tests were used to analyse differences in voice parameters between the three different stoma occlusion methods. A two-tailed $P < .05$ was taken to indicate statistical significance.

Results

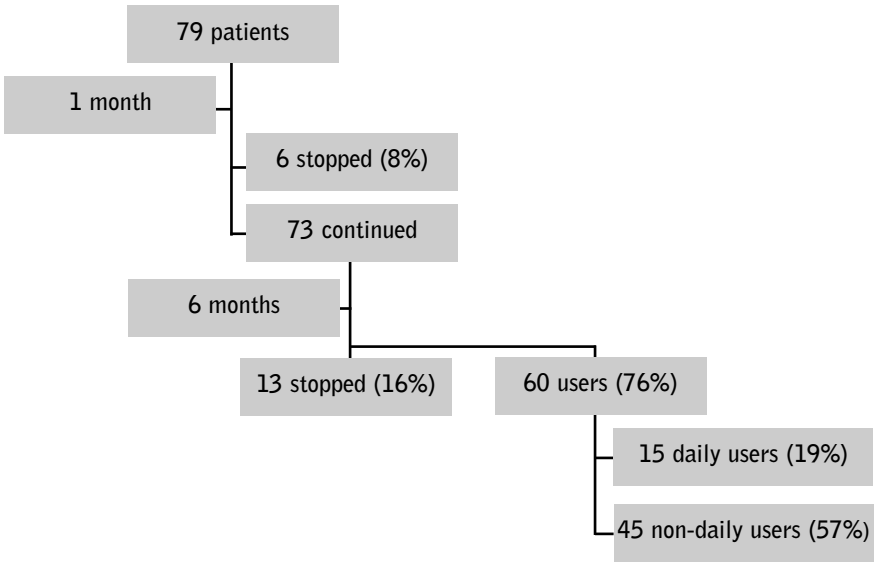
Compliance

After 1 month, 73 participants returned for the evaluation session. The other 6 patients dropped out of this study because they had trouble to communicate and/or breath normally using the FreeHands device. Although the questionnaires were sent to their home address none of these 6 patients replied. At 6-months follow-up, another 13 patients did not comply with their appointment. Again questionnaires were sent to their home address, but yet again none of the patients responded to this questionnaire. This means that 60 of the 79 patients (76%) returned to the clinic for the 6-months assessments, comprising of the questionnaires and the recordings of the various voice parameters.

Compliance rates for the FreeHands device at 1 and 6 months are shown in Table 2. During the first month of the study period, 24 of the 79 patients (33%) were using the Provox FreeHands HME on a daily basis, with a median of 4 hours a day. After 6 months this daily use reduced to 15 of the 79 patients (19%) with a median of 5 hours a day. Of the remaining 64 patients (81%), 19 (24%) stopped using the device altogether (see above), while 45 of them (57%) used the device irregularly (range 2 – 125 days, mean 35 days). Further results will mainly be based on the 60 patients who returned to the clinic and completed their 6-months' evaluation.
As indicated above, 45 patients did not use the FreeHands device on a daily basis. The main reason was the fixation of the adhesive to the peristomal skin, in a lesser degree followed by aspects such as too tiresome voicing, diminished intelligibility and increased breathing resistance, especially during physical exertion. Regarding the exchangeable, colour coded membranes that close the side opening of the valve to enable voicing, 27 patients choose the white membrane (most flexible), 31 patients the blue (intermediate flexible), and 2 patients the green (least flexible).

Table 2

Compliance



For fixation to the peristomal skin, 41 of the 60 patients used a Provox adhesive, 8 the Blom-Singer baseplate, 7 the Barton Mayo button, 1 the Provox Larytube and 3 baseplates of other brands. Thirty-eight patients (63%) mentioned that they applied additional (silicone) glue to assure a proper airtight seal. Eleven patients (20 %) experienced significant problems with the fixation of the adhesive to the skin. Removal of the adhesive was reported to be painful by 8 patients. Irritation related to the adhesive or to the additional glue was noticed by 7 and 11 patients respectively. No statistically significant correlations between the way of fixation, additional glue, irritation, the somewhat painful removal or the numbers of adhesives needed per day could be found.
Of the patients using an adhesive or baseplate, 20% was able to use the same adhesive or baseplate for longer than one day (range 1 1/2 – 7 days), while 60% had to change this once a day, and the remaining 20% changed the adhesive twice daily. As a reason for changing the adhesive/baseplate, patients reported mucus between skin and adhesive, perspiration as a cause of loosening the fixation and protrusion of the adhesive as a result of air pressure. Most patients (57%) described a combination of above mentioned reasons for the need to change the adhesive.

Regarding the use of the FreeHands HME cassette, the data showed that the majority of patients (88.5%) replaced the HME cassette 1-2 times a day. Assembling and disassembling the cassette and the FreeHands device was considered easy by all but 4 patients. No statistically significant changes over time (baseline versus 6-months) were seen regarding the aspects of coughing and sputum production (the majority of patients were regular HME users, anyhow). Despite the fact that the cough-relief valve opened easily for the majority of patients, two-thirds (67%) still preferred to remove the ASV before they had to cough. Overall, patients were satisfied with this special cough relief mechanism, because this functions independently of the closing mechanism of the speech valve itself.

Voicing and breathing

The 6 items of the questionnaires concerning the voice characteristics (intelligibility in face to face conversations and on the telephone, intelligibility in noisy surroundings, loudness, pitch and fluency) were combined into a more limited set of multiple-item scales according to Likert's method of summated ratings. The reliability of these scales, measured by Cronbach's alpha, was 0.65 at baseline and 0.75 at 6-months. A Student's t-test for repeated measures showed a statistically significant decrease over time (baseline versus 6-months; $P < 0.05$). Whereas these various voice aspects were rated as 'good' by the majority of patients (while using the HME), at the 6-months assessment these aspects were rated more often as 'fair' (using the FreeHands device). So, a slight shift downward on a 4-point scale (good, fair, moderate, poor) was noticed. However, the overall rating for speaking with the FreeHands device was still positive ('good' N=38, 'fair' N= 11, 'moderate' N=10 and 'poor' N=1). The objective measurements (see below) comparing the various stoma occlusion methods, also showed a better outcome for the voice parameters when using the Provox HME.

With respect to the perceived voice quality as rated by three investigators (as 'good', 'reasonable', or 'poor'), there was no statistical significant difference in frequency between the three stoma occlusion methods, although both at 1 month and at 6 months the percentage of patients with a 'good' voice was highest for the Provox HME (see **Table 3** for the 6-months' results). This voice quality judgment by the three investigators revealed a statistical significant correlation ($P<0.001$) between the 1-month' and 6-months' results for all three stoma occlusion methods (Pearson's coefficient 0.80 for HME, 0.86 for FreeHands, and 0.88 for Blom-Singer), indicating no changes in voice quality over time and/or no changes in this judgment over time.

Table 3 Perceived quality of voice as judged in consensus by three experienced investigators at the 6-months'follow-up examination (N=60)

Voice quality	Provox HME*	FreeHands HME*	Blom-Singer ATV*
Good	39 (65)	36 (60)	35 (58.3)
Reasonable	14 (23.3)	15 (25)	13 (27.7)
Poor	2 (3.3)	3 (5)	4 (6.7)
Missing value	5 (8.6)	6 (10)	8 (13.3)

*Number of patients (%)

Regarding the breathing aspects related to the FreeHands ('on-' and 'off'-position), only one patient had considerable problems breathing at rest when using the FreeHands device. During physical exertion, 36 patients (60%) found breathing quite to very difficult. However, more than two third of the patients (N=42) reported that by turning the device from the 'on-' into the 'off-position', the breathing problems during physical exertion were more or less solved and that in this way breathing was more comfortable. As reported by the patients, speaking with the FreeHands was not more tiresome than speaking with the HME or using a finger for occlusion of the stoma. However, 7 patients experienced some shortness of breath while speaking with Freehands.

Approximately half of the patients (N=28) heard a slight closing sound of the valve when they started to speak, and 7 of these patients judged this as quite to very annoying.
Although 66 patients of the total group to some extend had experience using the Blom Singer ASV only 8 patients in the study group were daily users of this ASV. Of these 8 patients, two did not show up for follow up after 6 months, but after telephone consultation appeared to stay with their original device. Of the remaining 6 patients, 3 preferred the Blom-Singer ASV, and 3 changed to Provox FreeHands HME.

EORTC Quality of Life questionnaires

Regarding the results of the EORTC questionnaires, no statistically significant changes in quality of life could be seen over the study period using the FreeHands. When looking at the means at baseline of the scales of the EORTC C30 questionnaire of the group who dropped out of the study (N=19) and the group who came back for the final assessment at 6 months (N=60) a slight difference could be noted. Overall, the means of the drop-out group were lower, but this was not statistically significant.

Objective voice and speech assessment

Data on the different objective parameters were determined with the three stoma occlusion methods after 1 and 6-months follow up (digital occlusion via the Provox HME (HME), and automatic closure with the Blom-Singer ATV, and the Provox FreeHands HME). Comparison between the results after 1 and 6 months showed no significant differences in any of the measurements, which suggest that there was no influence of increasing experience on these parameters. Therefore, in **Table 4** only the data of the different measurements per occlusion method after 6-months follow up are listed. The numbers of patients, who have been recorded per occlusion method are shown in parentheses (differences in patient numbers in this table are caused by the fact that not all patients were compliant to all tasks, e.g. due to fatique or fixation problems of the adhesive). Occlusion of the stoma via the HME demonstrated in all measurements significant better results than those for the Blom-Singer ATV and Provox Freehands HME. The maximum phonation time was significantly longer with FreeHands (mean 10.2 seconds; $P = 0.026$) than for the Blom-Singer device (mean 9.0). The same is true for the maximum phonation time while counting from 21 onwards, which was 10.7 seconds for the Blom-Singer and 14.5 seconds for the FreeHands device ($P = 0.004$). No significant difference in maximum loudness was seen between these 2 automatic valves ($P = 0.741$), whereas the minimum loudness was significantly better using the FreeHands ($P < 0.001$), which resulted in a significant wider dynamic loudness range with FreeHands ($P < 0.001$). With respect to the pauses needed in the standard read aloud text, there were no statistically significant differences between the Blom-Singer and the FreeHands device (a mean of 21.0 and 21.1 pauses respectively).

Further analysis showed no statistically significant differences in the various voice parameters at 6 months between the experienced ASV users ($N=6$) and the non-experienced users. Also no statistically significant differences in the same objective voice parameters could be found between the daily and the non-daily Freehands users.

Final compliance outcome

Ultimately, aside from the 15 (19%) daily users, three of whom switched back to the Blom-Singer ASV after the study period, another 40 patients (of the 45 non-daily users after 6 months; 51% of the total study group) indicated that they would continue using the FreeHands HME (on a irregular basis), because they considered this as a valuable additional rehabilitation tool for specific occasions like shopping and other social activities.

Table 4

	Provox HME	FreeHands HME	Blom-Singer ATV
Maximum phonation time (sec)	12.3(n=54)	10.2*(n=54)	9.0(n=50)
Maximum phonation time while counting (sec)	16.5(n=54)	14.5**(n=51)	10.7**(n=48)
Dynamic loudness range (dB)	27.1(n=55)	24.5***(n=54)	22.1***(n=53)
Number of pauses	16.4(n=54)	21.1(n=51)	21.0(n=50)

Data on the different objective parameters determined using the three stoma occlusion conditions.
The values in parenthesis indicate the number of patients who could be assessed (differences in patient numbers in this table are caused by the fact that not all patients were compliant to all tasks, e.g. due to fatique or fixation problems of the adhesive). The marked results are statistically significant differences between the Blom-Singer ATV and the FreeHands HME (*$p<0.05$;**$p<0.005$:***$p<0.001$)

Discussion

The present long-term follow-up study shows that with this new automatic speaking valve (ASV; Provox FreeHands HME) it is possible to acquire hands-free speech in an additional group of patients despite unsuccessful attempts in the past. Aside from 12 patients (15%), who now are using this new ASV on a daily basis, there are 40 irregular users (51%), who indicated that they are and would continue using this device as an additional rehabilitation tool for special occasions.

Over the past two decades several ASV's have become available, but in most studies investigating these devices, no higher success rates than 30% 'daily users' were reported, [6-10, 12] with two exceptions, reporting around 60% 'daily users'. [11, 13] However, comparison of success rates of these ASV's is rather difficult because of the diversity in definitions of daily or regular use, follow-up time, sample size, patient selection, use of different voice prostheses, and differences of peristomal fixation of the ASV. For example, the definition of daily use for at least two hours over a period of only 4 weeks is in our opinion not enough to judge long-term compliance for a relatively complicated rehabilitation device such as an ASV.[13] Because of the strict definition of truly every day use during the complete study period of 6 months, the current study shows a relative low percentage of 'daily users' (19% after 6 months) compared to other studies.

However, one has to keep in mind that for the majority of the patients this was a second attempt to acquire hands-free speech and a mean of more than 5 hours in daily use is above the results reported by others.[6-13] This sustains earlier suggestions that the use of different sets of magnets in the applied device diminishes the pressure on the seal of the adhesive during speech and coughing.[14] Together with the use of additional silicon glue in almost two-thirds of the patients, this is a likely explanation of the rather low frequency of changing the adhesive. In the current study, 20% of the patients could maintain the seal of the adhesive more than 24 hours, 60 % of them changed the adhesive only once a day, and 20% twice daily, and significant skin problems around the stoma were limited. Nevertheless, the problem of peristomal fixation still can be seen as one of the main reasons for limited success in compliance, because of the hassle around the application of the adhesive and the limited applicability of other stoma fixation possibilities, such as the Barton-Mayo tube (causing a widening of the stoma and thus loosening of the fixation/seal during wearing). Once the adhesive becomes loose, many of our patients switch back to their regular HME for the remainder of the day/evening.

An interesting aspect to mention from our study is that two-thirds of the patient group was still using the device after 6 months and indicated to keep using the device after the study period. None of the other studies described the patients, who are not using the ASV on a daily basis, and only Van den Hoogen et al. mentioned in their conclusion that the ASV might be considered as an additional rehabilitation tool for laryngectomized patients.12 It is our experience that patients often only take the trouble in applying the adhesive and the ASV for special occasions, such as shopping or other social events. This means that a strict definition of daily use might underestimate the real use and usefulness of this device.

In contrast to studies published by Zanoff, Pauloski and van den Hoogen, presenting smaller populations and showing no speech differences between finger occlusion of the tracheostoma and occlusion by means of an ASV, in the current study significant better results were found for finger occlusion via the Provox HME for all objective parameters.[7, 9, 12, 14] This can be explained when taking into account the results of van As et al., who found that the use of the Provox HME resulted in significant improvements of maximum phonation time and dynamic loudness range in comparison to direct finger occlusion of the stoma.[5] This positive influence of stoma occlusion via this HME also was reported earlier by Ackerstaff et al.[19] This explains the differences found between both ASVs on the one hand and HME occlusion on the other.

This difference probably would have been smaller or non-existent, like in the other studies mentioned, if the comparison had been made with direct finger occlusion of the stoma without the application of an HME.
According to the comparison between the two ASVs applied (Blom-Singer ATV and Provox FreeHands HME, shown in **table 4**) significant differences were observed with respect to the objective measurements (maximum phonation time, maximum phonation time while counting and the dynamic loudness range). The improvement achieved with the latter device most probably is due to the added technical refinements of the design by using magnets to support the different valve functions, as mentioned before. However, the somewhat unexpected finding in an earlier study that the dynamic loudness range of the FreeHands device was even larger than that with digital occlusion via the Provox HME could not be confirmed after 6 months.[14] The objective results in favour of the digital occlusion via a HME are in agreement with the subjective parameters derived from the questionnaires. Although the overall rating for speaking with the FreeHands HME was still positive at the end of the study period, the ratings of the voice aspects (intelligibility in face to face conversations and on the telephone, intelligibility in noisy surroundings, loudness, pitch and fluency) shifted slightly downwards by using the FreeHands Provox HME (at 6-months follow up) in comparison to the HME (at the start of the study). This slight reduction in voice quality due to the different stoma occlusion method, however, was never a reason to stop using the hands-free device.

The handling of the device over a longer follow-up period revealed no evident practical problems. Only 4 patients had some difficulty changing the HME cassette, which is necessary for fixation of the device in the peristomal adhesive. Also the possibility to turn the device from 'on-' into 'off-position' was appreciated and produced a further decrease of inconvenience with breathing during physical exertion, as reported in an earlier study.[12] The increased effort required to speak reported by 78% of the patients in study by van den Hoogen et al., was not found in the current study: speaking with the FreeHands was not more tiresome than digital occlusion by means of the HME. Also the breathing noises and clicks, caused by closing and opening the valve, were considered as less annoying (10%) compared to the 17%, as reported by van den Hoogen.[12]

With respect to the quality of life assessment, an earlier study, describing the same population, reported the need for additions to the standard questionnaires (EORTC C30, H&N 35) in order to detect function specific changes over time.[17] From the present study it becomes clear that the subjective significant differences in voice quality dimensions over time would have been missed, if only the standard questionnaires would have been applied.

The fact that no differences over time were found with any of the questionnaires applied with respect to the pulmonary problems is not surprising, since the FreeHands HME use is not different in terms of heat and moisture regulation and/or resistance than that of the regular HME used at baseline.

In conclusion, with this new ASV it appears possible to rehabilitate patients, who previously have been unsuccessful to acquire hands-free speech. Not only was daily ASV use possible for an additional group of patients, but this new device also was appreciated by many patients as an additional rehabilitation tool for specific occasions. Despite further statistically significant improvements in aspects of voice and breathing using this ASV, most likely as a result of the the use of different sets of magnets, improvement of peristomal adhesion is probably the main factor needed to further increase compliance rates. Nevertheless, this study shows that it makes sense to keep trying to achieve hands-free speech, even if attempts in the past have failed. Coaching the patient with respect to obtaining a good seal, trialing a stoma button, proper adjustment of the cough-relief valve, proper choice of membrane, and lowering back-pressure during speech may further improve compliance.

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Chapter 5

Summary and conclusions Samenvatting en conclusies

Summary and conclusions

Despite the increasing use (and success) of organ preservation strategies in the treatment of laryngeal cancer, total laryngectomy is often unavoidable to cure patients with advanced or recurrent disease. Therefore, it is still imperative to pay attention to the rehabilitation of the physical and psychosocial side effects of this mutilating surgery, in order to improve quality of life. This thesis focused on speech rehabilitation, but did not address the other two functions that need rehabilitation after total laryngectomy, i.e., respiration and olfaction.

Chapter 1 presents an introduction of the specific aims of the thesis, combined with some historical facts about rehabilitation after total laryngectomy.

Chapter 2 describes the largest series on prosthetic voice rehabilitation at the time of publication. During the observation period of 10 years with a median follow-up of 67 months, 2700 indwelling voice prostheses were in situ for 364,339 days in 318 total laryngectomy patients (1000 patient years). In this series, only 5% of the patients needed definitive closure of the fistula for various reasons, which means that in 95% of the cases, the device remained in situ in the long-term. Based on a mean voice quality score, 88% had fair to excellent voice production. The mean actuarial device life in relatuin with all indications for replacement was 163 days (median 89 days). As with any use of prosthetic appliances in the human body, the use of (indwelling) prostheses may give rise to adverse events, irrespective of the high success rate of vocal rehabilitation. To assess success rates and evaluate possible influencing factors, it is important to differentiate between 'device-related' reasons for replacement (leakage through the prosthesis (73%) and obstruction (4%)) and replacements due to 'fistula-related' events (leakage around the prosthesis (13%) and hypertrophy and/or infection of the fistula (7%)).
Significant clinical factors that increased device life were 'no radiotherapy' and age $>$70 years. The success rate in terms of (fair to excellent) voice quality was significantly influenced by the extent of surgery. By using an intensive and consistent multidisciplinary approach to problems, most of the inevitable adverse events encountered in approximately one tenth of the replacements in one third of the patients, could be solved adequately, which minimized the discomfort in total laryngectomy patients with (indwelling) voice prostheses.

Chapter 3 focused on neoglottic imaging. Videofluoroscopy proved to be an important evaluation tool to assess the neoglottis during oesophageal and tracheoesophageal speech. Although clinically valuable on an individual patient level, the descriptive nature of the evaluation and the lack of objective measurements hampered its wide use as a research tool.

Chapter 3.1 describes the development of videofluoroscopy into a more objective and reproducible evaluation instrument to analyse anatomical and morphological characteristics of the neoglottis. Also, the correlation between videofluoroscopy results and voice quality in tracheoesophageal speech is described, which has so far been lacking. The method to obtain quantitative measurements is easy and straightforward, using digitized images and special image evaluation software, with a reference marker to enable calculation of exact distances and surface areas.
The tonicity and the presence of a neoglottic bar during phonation were significantly related to voice quality, as were several of the quantitative measurements. Especially the minimal distance between the neoglottic bar and the anterior oesophageal wall at rest and during phonation and the index of the relative increase of the maximal subneoglottic distance from rest to phonation were valuable in this respect.
The clear correlation between the videofluoroscopy results and 'good' voice quality and the objective nature of the assessment protocol might increase the usefulness of this imaging technique in the rehabilitation of total laryngectomy patients.
Chapter 3.2 gives an example of the use of the above-mentioned quantitative videofluoroscopy to analyse the effects of a short myotomy of the upper oesophageal sphincter on the neoglottis. Using the visual assessment protocol and quantitative measurements, a group of twelve consecutive myotomy patients were compared to a group of seven non-myotomy patients (who had no palpable peroperative tonicity), operated on in the same period. In this group of 19 patients, most of whom had good tracheoesophageal voice quality, one clear neoglottic bar was always visible and none of them showed any signs of hypertonicity. Therefore, in our opinion, primary, lateral myotomy of the upper oesophageal sphincter is an essential part of surgery when patients receive primary prosthetic voice rehabilitation after total laryngectomy.
Endoscopic studies on the anatomical and morphological characteristics of the neoglottis have generally been performed with rigid or flexible stroboscopy. The presently available frequency-independent visualization methods, such as high-speed digital endoscopy (HS) or videokymography that are also used to study pathological laryngeal voices, had not been used for this purpose before.
Chapter 3.3 evaluated whether HS was a useful technique to investigate various characteristics of the neoglottis after total laryngectomy. We chose to use HS and not videokymography, because we were interested in the anatomy and morphology of the entire neoglottis and not just the vibrations of the mucosa on a single scanning line. Useful images could be collected for further evaluation that gave realistic visual information about the vibration of the neoglottis.

Especially the problem of the mistriggering through an unstable fundamental frequency of stroboscopy while studing irregular voices has been solved, as HS is frequency-independent. This chapter also presents the development of an evaluation protocol to describe the characteristics of the neoglottis. An assessment form for visual assessment was designed on analogy with the evaluation of stroboscopy images. Although this was a subjective method to describe the characteristics of the neoglottis, it gave a good impression of the wide variability in mucosal waves, forms and appearances of the neoglottis. Interestingly, mucosal vibrations were also seen in the reconstructed pharynges.
In accordance with the above findings, **chapter 3.4** evaluated the clinical value of HS versus the more widely used videofluoroscopy (VF) to obtain images of the neoglottis from total laryngectomy patients. In 37 laryngectomized patients who were using tracheoesophageal speech, anatomical and morphological characteristics of the neoglottis were studied by means of visual assessment of HS recordings and visual assessment and quantitative measurements of VF recordings, using previously published protocols. HS provided information that was complementary to that of VF with respect to the location of the vibration, presence of a mucosal wave, regularity of the vibration and closure of the neoglottis. The information provided by HS on the amount of saliva (regurgitation of barium in VF) and visibility of the origin of the neoglottis (presence of a neoglottic bar in VF) overlapped that provided by VF with respect. Additionally, relations were found between the visual assessments of the HS and some patient characteristics. Thus, HS provided additional insight into neoglottic characteristics that could not be studied with VF. The combination of the two imaging methods broadened our knowledge on tracheoesophageal voicing.

Chapter 4 assessed quality of life in a group of total laryngectomy patients and presents the results with a new automatic speaking valve (ASV). Baseline data from a multi-centre, prospective clinical trial were used to evaluate long-term aspects of this ASV in tracheoesophageal speech. In **chapter 4.1** EORTC questionnaires and an additional questionnaire that focused on specific postlaryngectomy problems measured quality of life. An assessment was carried out, to determine whether the EORTC questionnaires QLQ-C30 and QLQ-H&N35 gave enough detailed information to study specific quality of life related issues in 79 laryngectomized individuals. The quality of life dimensions as assessed with the standard EORTC questionnaires were compared to the information obtained with the additional questions that aimed to discover more detailes about e.g. voice and respiratory problems. Based on the EORTC quality of life (QoL) questionnaires, good overall and voice specific QoL level were found. The additional questionnaire obtained more specific information especially on voice and respiration.

For example, although more than three quarters of the patients expressed overall satisfaction with many aspects of their voice, 63% of them reported that speaking in a noisy environment was a problem. In addition, a significant relation (again) could be established between pulmonary problems and voicing problems, something that had also remained hidden with the EORTC questionnaires. These findings underline the necessity to develop and use more specific additional questionnaires as an adjunct to the existing EORTC questionnaires to study specific symptoms in total laryngectomy patients and especially to monitor intervention-related changes over time.

As mentioned above, a group of 79 laryngectomized patients (8 regular ASV users, 58 previously unsuccessful users, and 13 novel users) were selected to evaluate a new ASV. **Chapter 4.2** reports on the multi-centre, prospective clinical trial to evaluate the long-term results with the Provox FreeHands HME rehabilitation device. Compliance, aspects of voice, breathing and quality of life were analysed. Objective assessments were carried out on voice parameters (maximum phonation time, maximum phonation time while counting and dynamic range) in order to compare different stoma occlusion methods (digital occlusion via an HME and 2 ASVs). After 6 months, 19% of the patients were using the new ASV on a daily basis (for a mean of 5 hours a day), while 57% of the patients were using the device on an irregular basis as an additional rehabilitation tool in certain circumstances. Two thirds of the study group indicated that they intendedto continue to use of this new ASV after the study had ended. Analysis of the objective parameters showed statistically significantly better maximum phonation times and dynamic range with the new than with the formerly used ASV (Blom-Singer ATV). However, digital occlusion of the Provox HME still showed the best results on all the objective parameters. No statistically significant changes were seen in quality of life over the course of time. It appeared to be possible to rehabilitate a group of patients with this new ASV who had been unable to achieve hands-free speech in the past. Not only was daily ASV use possible for an additional group of patients, but also many patients appreciated this new device as an additional rehabilitation tool in specific circomstances. To further increase compliance rates, peristomal adhesion is probably the main factor that needs improvement and it might be worthwhile to draw attention to the significant benefit of this new ASV regarding aspects of voice and breathing using. This study showed that it makes sense to keep trying to achieve hands-free speech, even when attempts have failed in the past.

Conclusion

Unmistakable progress has been made in vocal, respiratory and olfaction rehabilitation after total laryngectomy, especially during the past two decades. It is a great achievement that presently, oral communication can be restored in the vast majority of patients. Despite this progress, the necessity for further research is still evident to keep striving for a rehabilitation result that equals normal laryngeal speech.

To further optimize postlaryngectomy rehabilitation, the device life of voice prostheses is one aspect that needs to be improved. Besides the results of studies performed in the fields of bacterial and yeast prevention that for example led to advice to consume probiotic food (yoghurts and skim milk) or even Coca Cola (!?), refinements to the prosthesis itself can also reduce frequency of replacement. The recently developed Provox ActiValve, designed to reduce Candida and "underpressure"- related replacements, has shown promising results with regard to device life prolongation.

Current neoglottic imaging techniques have provided insight into the relations between anatomical and morphological characteristics of the neoglottis and tracheoesophageal voice quality. When digital technologies become less expensive as can be expected in the near future, digital high-speed systems will be more widely available to clinicians and voice laboratories at a similar price to that of sophisticated stroboscopy units. Futuristic three-dimensional (CT and/or MRI) imaging techniques and detailed knowledge of the anatomical and morphological characteristics of new sound sources in alaryngeal speech could make 'phonosurgery' of the neoglottis more realistic, comparable with the present status of 'phonosurgery' in laryngeal speech.

To achieve higher compliance to hands-free speech, one important issue is the further technical refinement of peristomal adhesives. In addition, optization of the stoma during surgery (i.e. by sectioning of the heads of the sternocleidomastoid muscles) and more intensive training by speech therapists will help towards making the final rehabilitation touches. In order to analyse all these 'improvements' in terms of quality of life, specific and validated additions to the existing standard questionnaires should be more widely applied.

Samenvatting en conclusies

Ondanks de toename van het gebruik (en succes) van orgaansparende protocollen in de behandeling van maligniteiten van de larynx, blijft de totale laryngectomie vaak een onvermijdelijke ingreep om de patiënt te genezen van uitgebreide danwel gerecidiveerde maligniteiten. Daarom blijft aandacht voor de revalidatie van fysieke en psychosociale neveneffecten, als gevolg van deze mutilerende chirurgie, van groot belang, om de kwaliteit van leven te optimaliseren. Van de 3 functies die revalidatie behoeven na een totale laryngectomie, te weten, spraak, luchtwegproblematiek en reuk, zal dit proefschrift zich richten op het eerst genoemde aspect.

Hoofdstuk 1 beschrijft een introductie van de specifieke studie doeleinden gecombineerd met enige historische feiten betreffende de revalidatie na een totale laryngectomie.

In **hoofdstuk 2** wordt, op het moment van publiceren, de grootste serie patiënten beschreven die prothetische spraakrevalidatie hebben ondergaan. Tijdens de observatieperiode van 10 jaar, met een mediane follow up van 67 maanden, waren 2700 stemprotheses in situ gedurende 364.339 dagen bij 318 patiënten (1000 patiëntjaren). In deze serie was het slechts in 5% van de patiënten nodig de fistel definitief te sluiten, hetgeen betekent dat 95% van de patiënten langdurig een stemprothese in hun fistel droegen. Gebaseerd op een gemiddelde stemkwaliteits-score bleek 88% van de patiënten een redelijke tot excellente stem te hebben. De gemiddelde actuariële levensduur van de stemprothese, berekend over alle indicaties voor wisseling van de prothese, was 163 dagen (mediaan 89 dagen). Ondanks dit hoge succespercentage van de stemrevalidatie, geeft het gebruik van deze (verblijfs)protheses aanleiding tot bijwerkingen, zoals bij alle protheses die in het menselijke lichaam gebruikt worden. Tijdens het bepalen van de succespercentages en het evalueren van mogelijke factoren die van invloed zijn op de overlevingsduur van de prothese, is het belangrijk onderscheid te maken tussen 'prothese-gerelateerde' wisselindicaties (lekkage door de prothese heen (73%), obstructie van de prothese (4%)) en 'fistel-gerelateerde' wisselindicaties (lekkage rond de prothese (13%), en hypertrofie en/of infectie van de fistel (7%)).
Klinische factoren die significant waren voor het verlengen van de levensduur van de prothese waren het niet hebben ondergaan van radiotherapie tijdens de behandeling en een leeftijd ouder dan 70 jaar. De uitgebreidheid van chirurgie beïnvloedde de stemkwaliteit (redelijk tot excellent) significant. Door intensief en multidisciplinair problemen aan te pakken, kunnen de meeste onvermijdelijke bijwerkingen, vóórkomend in ongeveer een tiende van alle wisselindicaties en

in een derde van alle patiënten, adequaat worden opgelost, waardoor het ongemak van het gebruik van een (verblijfs) stemprothese tot een minimum beperkt kan worden.

Hoofdstuk 3 focust op de beeldvorming van de neoglottis. Videofluoroscopie (VF) heeft zich als een belangrijke methode van beoordeling bewezen in de evaluatie van de neoglottis, zowel bij oesofageale als bij tracheoesofageale spraak. Hoewel klinisch waardevol op het individuele vlak, hebben de beschrijvende manier van evalueren en het gebrek aan objectieve metingen, het algemene gebruik van videofluoroscopie voor wetenschappelijke studiedoeleinden in de weg gestaan.

Hoofdstuk 3.1 beschrijft de ontwikkeling van videofluoroscopie naar een meer objectief en reproduceerbaar meetinstrument voor de analyse van anatomische en morfologische kenmerken van de neoglottis. Ook wordt de correlatie tussen de videofluoroscopie resultaten en de resultaten van stemkwaliteitsmetingen bij tracheoesofageale spraak, waarover tot dusverre nog weinig bekend was, beschreven. De methode om kwantitatieve meetresultaten te verkrijgen is eenvoudig en rechtlijnig, door gebruik te maken van digitale beelden en speciale software om deze beelden te analyseren. Hierbij werd gebruik gemaakt van een referentiemaat, om afstanden en oppervlaktes exact te kunnen berekenen.

De toniciteit en het aanwezig zijn van een neoglottis tijdens spraak, waren significant gerelateerd aan de stemkwaliteit, zoals dat ook het geval was met verscheidene kwantitatieve maten. Vooral de minimale afstand tussen de neoglottis en de anterieure oesofaguswand, zowel tijdens rust als fonatie, en de index voor de relatieve toename van de subneoglottische afstand van rust naar fonatie, bleken zeer waardevol wat dit betreft.

Deze duidelijke correlatie van videofluoroscopische resultaten met 'goede' stemkwaliteit en het objectieve karakter van dit onderzoeksprotocol, zou mogelijk de bruikbaarheid van deze beeldvormende techniek voor de revalidatie van gelaryngectomeerden vergroten.

Hoofdstuk 3.2 geeft een voorbeeld van het gebruik van bovengenoemde kwantitatieve videofluoroscopie; een analyse van het effect op de neoglottis van een korte myotomie van de bovenste slokdarm sphincter tijdens een totale laryngectomie. Gebruikmakend van het perceptieve beoordelingsprotocol en de kwantitatieve metingen, kon een groep van 12 achtereenvolgende patiënten met een myotomie vergeleken worden met 7 patiënten zonder een myotomie (die peroperatief geen palpabele toniciteit hadden), geopereerd in de zelfde periode. Bij deze groep van 19 patiënten, van wie de meeste een goede tracheoesofageale spraak hadden, was altijd een duidelijke neoglottis te zien, en geen van deze patiënten vertoonde tekenen van hypertoniciteit. Daarom zijn wij van mening dat een primaire myotomie van de bovenste slokdarm sphincter een essentieel

onderdeel is van de operatie bij primaire prothetische spraakrevalidatie na een totale laryngectomie.
Endoscopische onderzoeken naar anatomische en morfologische karakteristieken van de neoglottis zijn meestal uitgevoerd middels starre of flexibele stroboscopie. De thans voor handen zijnde frequentieonafhankelijke methodes van visualiseren, zoals endoscopische digitale hoge-snelheids opnamen (HS) of videokymografie, ook gebruikt bij onderzoek naar pathologie van de laryngeale stem, werden niet eerder voor de gelaryngectomeerde stem gebruikt.
In hoofdstuk 3.3 vindt een evaluatie plaats of HS bruikbaar is als techniek om verscheidene kenmerken van de neoglottis te onderzoeken. Er is voor HS gekozen, en niet voor videokymografie, omdat we geïnteresseerd waren in de anatomie en morfologie van de gehele neoglottis en niet slechts in de trillingen van de mucosa, gemeten op een enkele onderzoekslijn. Dit hoofdstuk laat zien dat bruikbare beelden kunnen worden verzameld om realistische visuele informatie over de trillingen van de neoglottis te geven. In navolging op de evaluatie van de stroboscopische beelden, werd een visueel beoordelingsformulier ontwikkeld. Hoewel dit een subjectieve manier is van beoordelen van de kenmerken van de neoglottis, geeft het een goed idee over de grote variabiliteit van het mucosale golfpatroon en verschijningsvormen van de neoglottis. Het is interessant te zien dat er ook in gereconstrueerde farynges mucosale trillingen te zien waren.
In navolging op de bovengenoemde bevindingen laat **hoofdstuk 3.4** een evaluatie zien van de klinische relevantie van HS als aanvulling op de meer frequent gebruikte videofluoroscopie (VF) in de beeldvorming van de neoglottis is gelaryngectomeerde patiënten. Middels visuele beoordeling van HS opnames, perceptieve beoordelingen en kwantitatieve metingen middels VF, gebruikmakend van eerder gepubliceerde protocollen, werden de anatomische en morfologische kenmerken van de neoglottis in 37 gelaryngectomeerde patiënten onderzocht. HS verschaft aanvullende informatie op VF wat betreft lokalisatie van de trillingen, aanwezigheid van een mucosaal golfpatroon, regelmatigheid van de trillingen en sluiting van de neoglottis. Er is overlap in van de informatie verkregen middels beide methoden wat betreft de hoeveelheid speeksel (regurgitatie van barium bij VF) en de zichtbaarheid van het ontstaan van de neoglottis (aanwezigheid van een neoglottis bij VF). Ook werden relaties gezien tussen de visuele beoordeling van HS en enkele patiëntenkenmerken. Daarom verschaft HS aanvullend inzicht in kenmerken van de neoglottis die niet naar voren komen uit studies met VF. De combinatie van beide beeldvormende technieken ver groot het inzicht in de tracheoesofageale spraak.

Hoofdstuk 4 beschrijft een combinatie van de beoordeling van kwaliteit van leven en resultaten van het gebruik van een nieuwe automatische spreekklep (AS) bij een groep gelaryngectomeerde patiënten. In **hoofdstuk 4.1** wordt de kwaliteit van leven beoordeeld middels EORTC vragenlijsten en een aanvullende vragenlijst, die specifiek focust op problemen na een laryngectomie. Hiervoor zijn de basis gegevens gebruikt van een multi-institutionele, prospectieve klinische trial, die de lange termijn aspecten van deze automatische spreekklep bij tracheoesofageale spraak onderzoekt. Bij 79 gelaryngectomeerde patiënten werd beoordeeld of de EORTC vragenlijst QLQ-C30 en QLQ-H&N35 voldoende informatie verschafte om specifieke aspecten van gelaryngectomeerde individuen te kunnen bestuderen. Dimensies in kwaliteit van leven, zoals beoordeeld met de standaard EORTC vragenlijsten, werden vergeleken met informatie verkregen middels aanvullende vragenlijsten, bedoelt om meer gedetailleerde aspecten van bijvoorbeeld spraak en luchtweg problematiek te ontdekken. Gebaseerd op de EORTC kwaliteit van leven (KvL) vragenlijsten, werd een goede algemene en spraak specifieke KvL gevonden. Echter de aanvullende vragenlijst leverde meer specifieke informatie op met betrekking tot spraak- en luchtwegproblematiek. Bijvoorbeeld, ondanks dat meer dan drie kwart van de patiënten in het een algemeen tevreden was over vele aspecten van de stem, kwam uit de specifieke vragenlijst naar voren dat het spreken in een rumoerige omgeving door 63% van de patiënten als problematisch ervaren. Ook werd er (opnieuw) een significante relatie gezien tussen luchtwegproblematiek en spraakproblemen, wat niet naar voren kwam uit de resultaten van de EORTC vragenlijsten. Deze bevindingen onderstrepen de noodzaak van het ontwikkelen en gebruik van meer specifieke aanvullende vragenlijsten als een toevoeging aan de reeds bestaande EORTC vragenlijsten, wanneer onderzoek gedaan wordt naar specifieke symptomen in gelaryngectomeerde individuen, met name om interventie gerelateerde veranderingen in de tijd te ontdekken.
Zoals eerder genoemd, was deze patiënten groep uiteindelijk geselecteerd om een nieuwe AS (Provox FreeHands HME) te evalueren.
Hoofdstuk 4.2 beschrijft lange termijn resultaten van dit revalidatie middel in een multi-institutionele prospectieve klinische trial. Bij 79 gelaryngectomeerde patiënten (in meerderheid dagelijkse HME-gebruikers; 8 reguliere, 58 voormalige, niet-succesvolle, en 14 nieuwe automatische-spreekklepgebruikers) werden gebruik van deze nieuwe AS, aspecten van de spraak, ademhaling en kwaliteit van leven geanalyseerd. Objectieve stemanalyse werd verricht (gebruikmakend van de maximale fonatietijd, maximale fonatietijd tijdens tellen en het dynamische luidheidsbereik) ter vergelijking van 3 verschillende stoma-afsluitmethoden (vingerafsluiting met de HME, en 2 verschillende automatische spreekkleppen). Na 6 maanden gebruikte 19% van alle patiënten de nieuwe AS dagelijks (met een gemiddelde van 5 uur per dag),

terwijl 57% van de patiënten de nieuwe klep onregelmatig als aanvullend hulpmiddel voor speciale gelegenheden gebruikte. Twee derde van de studiegroep gaf aan deze nieuwe AS ook na de studieperiode door te willen gebruiken. Wat betreft de objectieve parameters, werd er een significant langere maximale fonatietijd en groter dynamisch luidheidsbereik geobserveerd bij de nieuwe AS vergeleken met de andere AS (Blom-Singer AS). Toch vertoonde vingerafsluiting middels de HME bij alle objectieve parameters de beste resultaten.
Gedurende de studieperiode werden geen significante veranderingen in kwaliteit van leven waargenomen. Met deze nieuwe AS lijkt het mogelijk een groep patiënten te revalideren, bij wie eerdere pogingen om vingervrij te spreken niet succesvol waren. Niet alleen was het dagelijkse gebruik mogelijk voor een aanvullende groep patiënten, ook vele patiënten apprecieerden deze nieuwe AS als een aanvullend hulpmiddel tijdens speciale gelegenheden. Ondanks significante verbeteringen wat betreft aspecten van spraak en ademhaling bij deze nieuwe AS, zal een verbetering van de peristomale bevestiging de belangrijkste factor zijn die kan leiden tot verbetering van de succespercentages in gebruik. Niettemin laat deze studie zien dat het zinnig vingervrije spraak aan te moedigen, ondanks dat pogingen in het verleden zijn mislukt.

Conclusie

Onmiskenbare vorderingen, vooral de laatste 20 jaar, zijn er geboekt op het gebied van spraak-, luchtweg- en reuk- revalidatie na totale laryngectomie. Het is een hele vooruitgang dat tegenwoordig bij de grote meerderheid van deze patiënten de verbale communicatie kan worden hersteld. Ondanks deze gunstige ontwikkelingen, blijft het noodzakelijk te streven naar revalidatieresultaten, die vergelijkbaar zijn met laryngeale spraak. Dus is het duidelijk dat verder onderzoek noodzakelijk blijft.
Om revalidatie na laryngectomie verder te optimaliseren, zal vooruitgang moeten worden geboekt op het gebied van onder andere de levensduur van de stemprothese. Naast de resultaten op het gebied van bacterie- en gistpreventie, resulterend in bijvoorbeeld adviezen tot gebruik van probiotische voeding (yoghurt en karnemelk) of zelfs Coca Cola (!?), kunnen ook verfijningen in de stemprothese zelf leiden tot reductie van de frequentie van wisselingen. De recent ontwikkelde Provox ActiValve, ontworpen om de Candida- en 'onderdruk-gerelateerde' prothesewisselingen te verminderen, liet veelbelovende resultaten zien. Zoals reeds aangetoond, verschaffen de huidige technieken van beeldvorming inzicht in de relatie tussen anatomische en morfologische kenmerken van de neoglottis en tracheoesofageale stemkwaliteit. Zodra digitale technologieën minder duur zullen zijn, wat op korte termijn verwacht mag worden, zal digitale hoge-snelheids beeldvorming meer algemeen beschikbaar komen voor clinici.

Dit zelfde geldt voor stemlaboratoria. Samen met toekomstige driedimensionale (CT en/of MRI) beeldvormende technieken, kan de kennis over de anatomische en morfologische kenmerken van de nieuwe geluidsbron in alaryngeale spraak worden geoptimaliseerd en zou 'fonochirurgie'van de neoglottis realiteit kunnen worden, vergelijkbaar met huidige mogelijkheden van 'fonochirurgie' in laryngeale spraak.
Wat betreft de vingervrije spraak, zal verdere verbetering van de peristomale aanhechting van de AS moeten worden gerealiseerd ten einde een verbetering in het langdurig en dagelijks gebruik te verkrijgen. Daarnaast zal gedurende de ingreep, verdere chirurgische aandacht geschonken moeten worden aan het stoma, zoals o.a. het klieven van de kop van de musculus sternocleidomastoideus. Ook intensieve(re) training van de patiënt door de logopedist(e) is een vereiste voor de 'finishing touch' in spraakrevalidatie. Om vervolgens al deze 'verbeteringen' te kunnen analyseren in termen van kwaliteit van leven, zullen specifieke en gevalideerde aanvullingen op de reeds bestaande standaard vragenlijsten meer moeten worden gebruikt.

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Curriculum Vitae

Bas Maximiliaan Reinier Op de Coul werd op 9 juli 1971 geboren in Nijmegen. In 1989 behaalde hij het eindexamen aan het R.K. Gymnasium Beekvliet te St. Michielsgestel. Na 1 jaar Farmacie te hebben gestudeerd i.v.m. uitloting, is hij in 1990 begonnen aan de studie Geneeskunde aan de Rijks Universiteit te Utrecht. In 1998 werd het artsexamen behaald en is hij gaan werken als arts-assistent Keel-, Neus-, en Oorheelkunde in het Antoni van Leeuwenhoek Ziekenhuis te Amsterdam. In dit zelfde jaar werd ook begonnen aan dit proefschrift onder leiding van prof. dr. F.J.M. Hilgers. Per 1 januari 2000 begon hij in het UMC St. Radboud te Nijmegen aan zijn opleiding tot KNO-arts onder leiding van achtereenvolgens prof. dr. P. van den Broek, prof. dr. C.W.R.J. Cremers en prof. dr. K. Graamans. Op 1 januari 2005 volgde zijn registratie tot KNO-arts. In het halve jaar dat hierop volgde was hij fellow in de aangezichtschirurgie olv dr. K. Ingels, KNO-arts/ Aangezichtschirurg. Per 1 januari 2006 zal hij zich vestigen als KNO-arts in het Jeroen Bosch Ziekenhuis te 's- Hertogenbosch. Hij is getrouwd met Libuse Froger en zij hebben samen een dochter Kiki (2003) en een zoon Duco (2005).