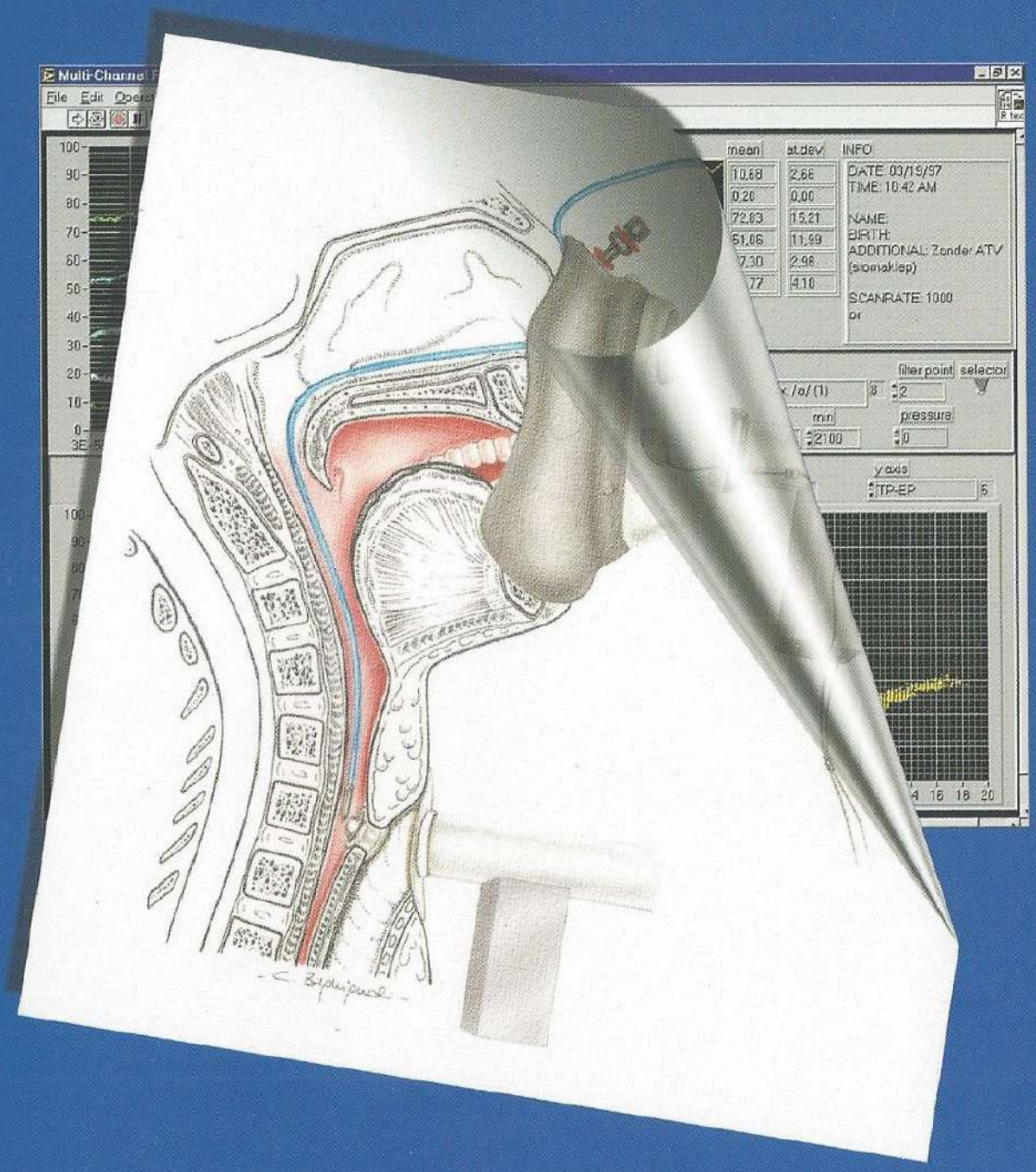
PHYSICAL ASPECTS OF PROSTHETIC VOICE REHABILITATION AFTER TOTAL LARYNGECTOMY



WILKO GROLMAN

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Physical Aspects of Prosthetic Voice Rehabilitation After Total Laryngectomy

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Physical Aspects of Prosthetic Voice Rehabilitation After Total Laryngectomy

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Table of Contents

Chapter I

General Introduction

General Introduction

Head and neck cancer accounts for approximately 5% of all malignancies and is the fourth most common cancer in males.[1] In the United States there are approximately 30,000 new cases yearly. The functional deficits and deformities that often occur by the disease due to the treatment underline the importance of head and neck cancer. Sensory functions of taste, smell, hearing, balance and vision are, depending on the tumor location, at risk. Voice, speech quality and swallowing are frequently effected. The air-conditioning effect of the upper airway may be temporarily (tracheotomy) or permanently (total laryngectomy) lost. Deformities in the head and neck can create profound debilitation on the physical and psychosocial functions.[2] From this point of view, successful treatment of this group of malignancies cannot be measured solely in terms of survival rate.[3]

Laryngeal Cancer

Within the group of head and neck malignancies, laryngeal cancer is the most common. Ninety percent of laryngeal cancers are squamous cell carcinomas originating from the epithelial lining of the laryngeal mucous membrane. The etiology of squamous cell carcinomas is mainly related to smoking and alcohol intake, particularly the combination of both.

A clear distinction needs to be made between glottic cancer (the true vocal cords), cancer of the supraglottic part of the larynx (false vocal cords, arytenoids, aryepiglottic folds and the epiglottis) and subglottic cancer. Cancer involving the glottis accounts for approximately 65% of the laryngeal cancers. Subglottic cancer is rare (5%). This distinction is made because of the differences in symptoms, tumor spreading patterns and therapy modalities of these different sites.

The most important symptom in this patient group with glottic cancer is persistent hoarseness. In a more advanced stage dysphagia and dyspnea occurs. Referred otalgia may be present but generally indicates deep supraglottic involvement. Cervical lymphadenopathy is more frequent in supraglottic cancers than in glottic lesions. The supraglottic area has a rich

lymphatic drainage while the true vocal cords are devoid of lymphatic drainage. As a result cancer confined to the vocal cord rarely presents with lymph node involvement. Since hoarseness is a relative early symptom in glottic cancer, these tumors are generally smaller than supraglottic cancers at first detection.

The overall 5 year survival of glottic cancer is 85%. When looking at the different stage groups, the 5 years survival is for stage I: 95%, II: 85%, III: 60% and IV: 35%. The overall 5 year survival of supraglottic cancer is 55%. For stage I this is: 65%, II: 65%, 55% and 40%.

The risk of second primary tumors, especially if the patients continues smoking and drinking alcohol, has been reported as high as 25%.[4] Furthermore, patients who smoke during radiation therapy appear to have lower response rates and shorter survival times than those who do not.[5]

Treatment Modalities of Laryngeal Cancer

As with any cancer, precise staging is of utmost importance as it dictates the treatment modalities. These treatment modalities differ to some extent for the sub-sites within the larynx and also for the institution involved. Depending on the stage the therapy will consist of radiation or surgery (including laser treatment) or a combination of the two. Chemotherapy, as of yet, has no place in curative treatment.

The larynx has three major functions: phonation, air passage and a sphincter function with which it protects the lower airways. Conservation laryngeal surgery has emphasized the importance of the larynx as an airway and sphincter. Loss of voice due to disease or treatment is a serious handicap, but an ineffective airway or inefficient sphincter may be fatal.[6]

It is impossible to determine a standard treatment for each tumor stage and sub-site because many factors play a role in the final decision which therapy is best. Anatomic considerations and the patient's health and preference, are a few additional factors that can play a decisive role in therapy choice.

Total laryngectomy is mostly performed in the more advanced stages of disease and in radiation therapy failures. For glottic and supraglottic cancer this would be stages II and III, depending of course on location and spread. More conservative surgical procedures like supraglottic horizontal

laryngectomy, vertical hemilaryngectomy and frontolateral hemilaryngectomy each have their specific indications.

Total Laryngectomy

Total laryngectomy includes resection of the hyoid bone, pre-epiglottic space, thyroid cartilage, cricoid cartilage, and one to four tracheal rings. The hypopharynx constrictor muscles are sectioned from the lateral edge of the thyroid cartilage and cricoid insertions. After removal of the specimen, the trachea is sutured to the skin of the neck, either in the original skin incision or in a separately made incision. The constrictor muscles are usually reconstructed in the midline to support a one or two layer mucosal closure in a effort to reduce fistula formation.[7] During this procedure a myotomy and/or a unilateral neurectomy of the pharyngeal nerve plexus is performed to facilitate tracheoesophageal voice rehabilitation which is later discussed in more detail.

Impact of Total Laryngectomy

For the person who has had a laryngectomy as treatment for laryngeal cancer, postoperative recovery includes physical, psychological and social adjustments.[3] The physical aspects will be discussed in more detail in the following chapters. It is well recognized that psychological sequelae of head and neck surgery include anxiety, depression and decreased vigor.[8-10] The loss of the natural voice is one of the greatest sources of psychological distress.[11]

There have been numerous attempts to assess the psychosocial functioning and quality of life of laryngectomized patients. Mathieson et al, described that significant predictors of patient distress are pre-/post surgical counseling (i.e. pre-surgical visit by laryngectomee), illness factors (i.e. presence of current illness), patient satisfaction with social support from family and friends and lifestyle concerns (i.e. changes in relationships with friends).[12]

A fair number of laryngectomized patients return to employment after their operation. Romney found that post surgical employment does help successful rehabilitation.[13] Richardson pointed out however, that post surgical employment did not statistically relate to other measures of social functioning.[14] Therefore, clinicians should be aware that return to employment

is not a conclusive indicator of the patient's social functioning.
The importance of including the spouse in the pre- and post operative counseling has been confirmed by researchers.[15-18] Spouses have been demonstrated to have higher scores on psychological tests concerning depression, fatigue and tension, during the course of the disease and its treatment.[19]

History

The history of the first laryngectomy and the attempts to restore voice is fascinating. A brief chronological summary of events is given. In the second half of the 19th century, the main German industries were chemicals and textiles. These were important to medicine because of industrial complimentary products like aniline dyes and anaesthetic gases. The first time that anaesthetic gas was applied to a human being was about 1848.[20] Although the microscope was invented by Van Leeuwenhoek in the 17th century its use in medicine started only after Gehrlach showed, around 1850, that tissues could be stained differently with natural dyes. Aniline dyes further improved the quality of tissue staining which boosted histology and histopathology to new heights. Histology was started under Henle, Schwann and others. Virchow started histopathology in 1856.
During this era, laryngeal pathology could only be "diagnosed" on clinical grounds but not by visualization, let alone by pathological examination. Therefore, any laryngeal disease was rarely diagnosed. Important to the advances in laryngology was the discovery of the laryngoscope by Manual Garcia, a Spanish singing teacher, in 1854. Its usefulness in medicine was soon realized and people like Morell MacKenzie (1837-1892) and Czermak used this technique to explore the larynx. Garcia was invited to London in 1855 to demonstrate his technique of visualization of the larynx for the medical profession.
Indirect laryngoscopy to biopsy the larynx was perfected by MacKenzie in the 1870's. Before the discovery of cocaine as an anesthetic in the 1880's ice chips were used to suppress the gagging of the patient being examined. MacKenzie was the first to write a standard textbook on the throat.
The first laryngectomy, reported to the German Surgical Society in 1874 by Gussenbauer, was performed on a 36 year old religious instructor by

Theodore Billroth (1829-1894).[21] The patient had been hoarse for a period of 3 years and had been treated by cauterization with silver nitrate and liquor ferri injections. As the tumor grew it caused stridor which disappeared after removal of bits of tumor. The patient had a subglottic tumor that was mainly located on the left side. From the tissue samples, taken out of the larynx, the diagnosis epidermoid carcinoma was histologically made. The patient was admitted to Professor Billroth's clinic in November 1873. Cautious, partly because of the prior work done by his assistant Vincenz Czerny, who in 1870 experimentally laryngectomized five dogs of which four died, Billroth decided to carry out a laryngofissure on November 21, 1873. The tumor was excised while preserving the right vocal cord. Unfortunately, by the middle of December laryngoscopy revealed massive granulations in the larynx. These were originally regarded as benign, but during Billroth's second operation on December 31, 1873, tumor recurrence was apparent. The patient was woken up and after explanation of the situation consensus was reached. The larynx was removed and the superior thyroid arteries ligated and the hyoid bone and epiglottis were left in place. The trachea was sutured to the skin. During this procedure the patient cleared blood from the trachea himself. The total operation took 1 hour and 45 minutes. Four hours after the operation bleeding occurred and was dealt with by compression with sponges. The patient was nourished with a gastric feeding tube through which supposedly mostly wine was passed. The 8th day the patient started to eat even though the pharynx was not surgically closed.
Four months after surgery, the patient was discharged, after having learned to speak with an artificial larynx designed by Gussenbauer. This artificial larynx shunted air from the trachea past a reed into the pharynx. The patient had a loud and clear monotonous voice. Billroth's patient died one year after surgery due to tumor recurrence.
Many surgeons realized this procedure had great potential and the second laryngectomy soon followed.[22] Heine's patient died after six months. In 1881, Foulis reported on 27 recorded cases of total laryngectomy. Half of these patients died of pneumonia or other infections within the first week of surgery, another 25% died of tumor recurrence within ten months.[23]

Crown Prince Frederick of Germany, troubled by hoarseness, consulted a Berlin laryngologist in May 1887. The doctor found a lesion of the left vocal cord and the clinical diagnosis of cancer was made. MacKenzie was called from England to perform biopsies by indirect laryngoscopy. It is probable that MacKenzie advised the emperor, who had been a regular pipe smoker for more than 30 years, to stop smoking.[24] He believed that nicotine was a systemic poison: it was hot smoke that harmed the voice.[24] Virchow personally studied the slides and reported the tissue as benign. A second biopsy, performed in London five weeks later, gave the same result. Histology opposed the clear clinical diagnosis of cancer. The professors of surgery at the University of Berlin advocated laryngectomy on clinical grounds. Several months later the diagnosis of cancer was obvious. At the time of the definitive diagnosis, a tracheotomy was needed for subglottic obstructions which merely delayed Frederick's death.

By the beginning of the 20th century, Gluck reported the mortality of laryngectomy being 8.5%. An extreme low mortality rate when considering the major problems that occurred with anesthesia, wound infection and shock.[25] In 1906, the mortality rate for radical neck dissections was 13%.[26]

The tragic story of Frederick underlined the long lasting disagreement between advocates of laryngeal biopsy and its skeptics. As late as 1922, practitioners opposed laryngeal biopsy being misleading and inducing spread of cancer.[25]

The importance of radiation therapy in modern treatment of laryngeal cancer has been well established. One of the pioneers in radiation therapy is of course Roentgen who discovered new rays that could penetrate opaque materials and which were emitted from a special vacuum tube in 1895. These rays could penetrate human tissue without direct pain or other feelings. It was recognized that these new rays did induce redness of the skin, blistering and ulcerations. The Curies isolated radium chloride in 1898, which was first used in 1901 in patients. X-rays were, in the early days, used for various ailments. In the beginning of this century, the low voltage X-ray machines were developed followed by the ortho-voltage machines. In 1922, the first laryngeal cancers were treated successfully with radiation therapy.[27]

During a regular meeting of the Chicago Laryngological and Otological

Society Dr. M. Reese Guttman reported on the difficulties of voice rehabilitation and one remarkable patient.[28] In Guttman's report the difficulties of electromechanical speech aids are discussed followed by esophageal speech related problems. He realized that certain anatomic conditions helped in regaining esophageal voice. " Roughly, patients can be divided into two classes, those that will talk and those that will not. Those that will talk apparently have the anatomic parts that are necessary to carry on conversation; by that is meant that they are able to swallow air into the esophagus and then belch it forth. They also have a well functioning cricopharyngeus, which apparently acts as a vicarious larynx."

During the same meeting Guttman also described one of his patients that was unable to communicate after his total laryngectomy. This patient however, used a heated ice pick with which he had made a fistula from the trachea into the hypopharynx. Whenever the patient occluded his tracheostoma air was shunted from the trachea towards the hypopharynx inducing resonance which made clear loud speech possible. The physicians were amazed. To avoid leakage of esophageal content into the airway and to avoid spontaneous closure of the fistula the patient used a goose quill.[28] Inspired by his patient Guttman started performing this fistula technique using a diathermy needle. Nevertheless, results were disappointing. Fistula stenosis formed a recurrent problem.[29]

Types of Voice Rehabilitation

Basically, there are three voice rehabilitation techniques after total laryngectomy: electromechanical speech, esophageal speech and tracheo-esophageal (shunt) speech. Each of these techniques has its strengths and weaknesses. The external air shunting devices with or without a reed are not being discussed since they do not play a role in current voice rehabilitation these days.

Electromechanical Speech

Within this group, there are transcervical and intraoral devices. Both rely on the principle of introducing an electromechanical vibration that can be heard as a tone. The transcervical device (e.g. Servox) is placed against

tissue of the neck that will transmit the tone to the oral cavity (figure 1.1). The remaining intact structures of the vocal tract (tongue, lips and teeth) will modulate the tone. This articulation will than produce speech. Devices like the Servox are rechargeable and have volume and pitch control (figure 1.2).
The intraoral device (e.g. Cooper-Rand) introduces the sound source through a tube directly into the oral cavity. Voice generation occurs in the same way as with the transcervical devices.
The major advantage of both devices is that basic speech is learned quickly by most patients and does not interfere or delay the mastering of other forms of alaryngeal speech. Furthermore, this form of voice rehabilitation produces a loud voice. However, certain patient conditions prevent the use of these devices. Severe surgery and radiation therapy induces fibrosis of the neck hampering the transmitting of the tone towards the oral cavity. Limited dexterity also determines the successful use of an electrolarynx.

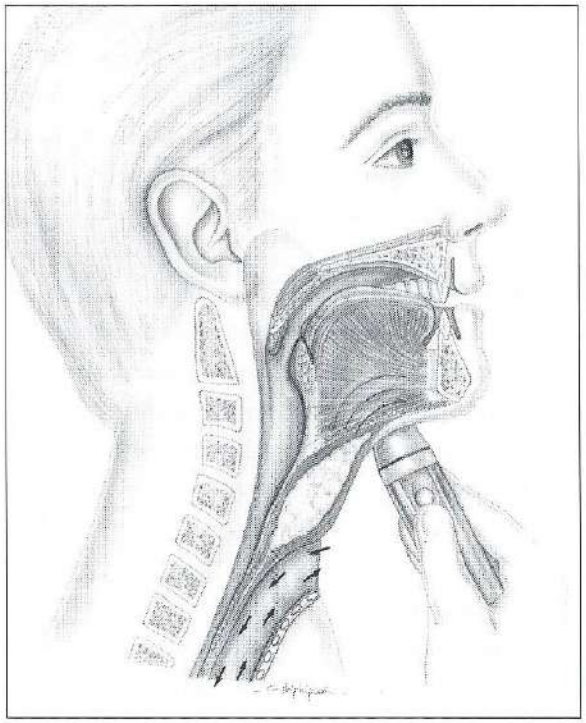

Figure 1.1: Drawing of voice rehabilitation following total laryngectomy using a electrolarynx.

Although these devices are quite expensive, this voice rehabilitation technique is still considered to be one of the cheaper options.
The major disadvantages of these electromechanical devices is the distinct voice quality. The voice production sounds mechanical and even robot like, distracting the listeners attention. The electrolarynx requires the use of a hand and has a conspicuous appearance.
Electromechanical devices can be a useful treatment option in the early post-operative phase when the patient can not use other voice rehabilitation techniques, thereby limiting the frustration of speechlessness. Electrolarynx devices can also be of value in addition to other voice rehabilitation methods

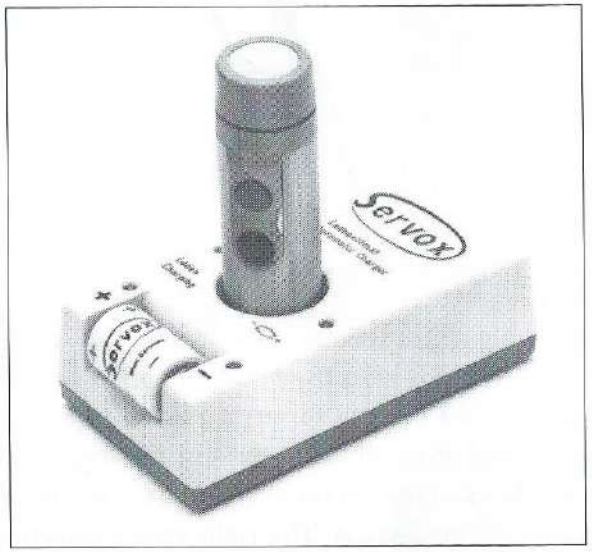

Figure 1.2: Photograph of the Servox electrolarynx.

Esophageal Speech

Esophageal speech is based on the technique in which the patient transports a small amount (±75 ml) of air into the esophagus. Probably due to an increased thoracic pressure, the air is forced back past the pharyngo-esophageal (PE) segment to induce resonance. This resonance is the sound source that allows speech. Rapid repetition of the aforementioned air trans-

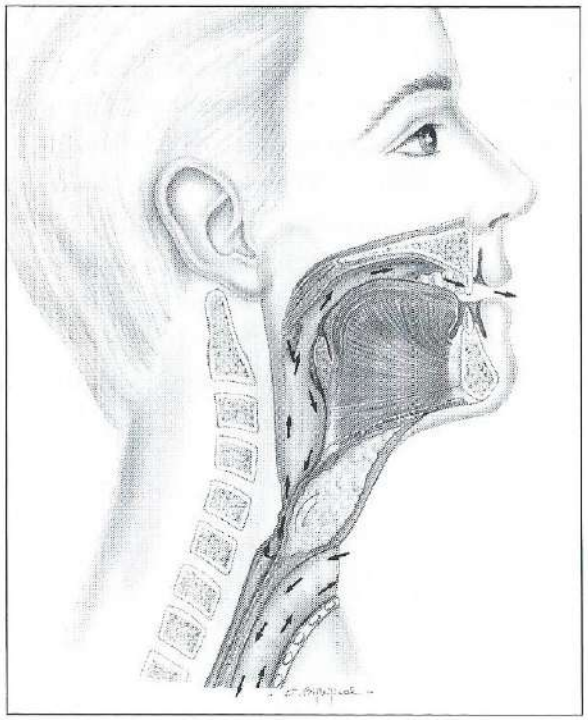

Figure 1.3: Schematic drawing of esophageal speech.

port can produce understandable speech (figure 1.3).
There are various techniques to transport air to the esophagus. With the injection technique the tongue forces air back into the pharynx and esophagus. In the first phase of this technique the tongue forces air in the mouth back into the pharynx. In the second phase the back of the tongue forces the air into the esophagus. The right synchronization of these two phases is of great importance transporting the air into the esophagus. With the inhalation methods of esophageal speech the patient creates a pressure in the esophagus that is lower compared to the atmospheric pressure. Since there is a lower pressure in the esophagus, air will flow through the mouth past the PE-segment into the esophagus. The patient will need to inhale to be able to create a low endo-thoracic and esophageal pressure. The last technique of capturing air is by means of swallowing air into the stomach.

Advantages of esophageal speech are the cost aspect since it does not require expensive devices and prostheses, hands-free speech and a more natural sounding voice compared to electrolarynx assisted speech.
The main disadvantage is its success rate of acquiring useful voice production which is reported to be as low as 25%.[30] Furthermore, esophageal speech results in low-pitched (60-80 Hz) and low intensity speech which frequently results in poor intelligibility.[31]

Tracheoesophageal Speech

Starting from the first total laryngectomy, devices that shunted air from the lungs towards the pharynx were the first used as means of voice rehabilitation. The philosophy behind the development of these devices is logical. The lungs provide a "large" air volume that can be used to generate voice.[32] All tracheoesophageal speech methods are based on this concept. Previously, relatively big devices were used to shunt air from the lungs towards the pharynx, until the introduction of surgical fistulas in the late 1950s.

Surgical Tracheoesophageal Fistulas

By constructing a tracheohypopharyngeal or tracheoesophageal shunt in a laryngectomee, the potential for a new voice can be developed. Conley and Asai, were the pioneers who developed surgical techniques to create a shunt. Conley in 1959 described a surgical technique with which he used a autogenous vein graft as a fistula towards the pharynx.[33] Asai, used a dermal tube from trachea towards the hypopharynx.[34,35] Since the late 1950s a variety of shunt procedures has been devised or modified for vocal rehabilitation.[36-42]
Staffieri formed what he called a "neoglottis phonatoria". During laryngectomy, he draped the anterior pharyngeal wall over the end of the cut trachea and made a slit in the draped part.[43]
Amatsu, used a technique with which he constructed a tracheoesophageal fistula using the membranous part of the trachea and if needed the subperichondrial plane of the tracheal cartilage to make the fistula inner lining. In one of his articles, he described 30 patients of which 23 obtained conversational abilities. However, 9 patients had aspiration problems due

to incontinence for esophageal content.[44] A high percentage which is considered unacceptable nowadays. In this patient group 5 patients ended up with a stenosis of the surgical fistula.

Two key complications that all tracheoesophageal shunt procedures share are (1) subsequent leakage from the esophagus into the trachea due to incontinence of the surgical fistula and (2) stenosis of the fistula making voice production impossible.

Mark Singer and Eric Blom experienced the same complications in patients that had had Amatsu fistula surgery. Combining past experiences like Guttman reported, they developed their endoscopic puncture technique with insertion of a silicon voice prosthesis.[45]

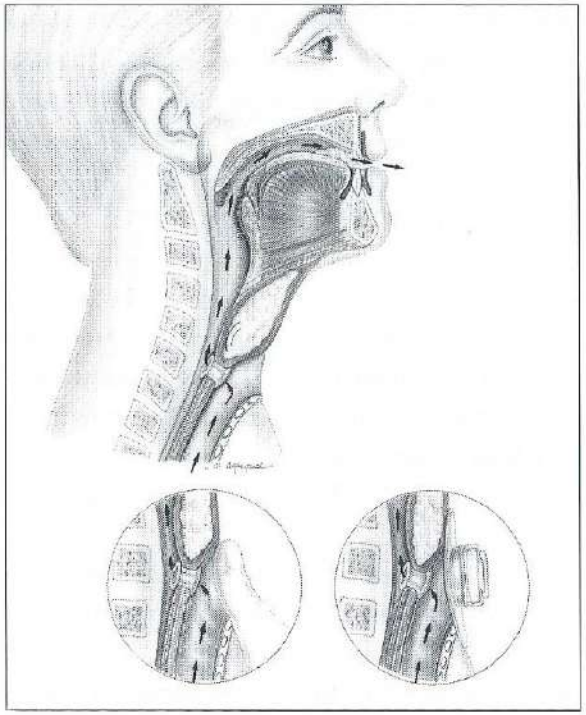

Figure 1.4: Schematic drawing of tracheoesophageal voice rehabilitation using a voice prosthesis. Manual stoma occlusion or tracheostoma valve occlusion is needed to divert air towards the esophagus.

Tracheoesophageal Puncture (TEP)

Singer and Blom were the first to introduce an efficient and safe tracheoesophageal puncture technique, with insertion of a silicone voice prosthesis, for voice rehabilitation after total laryngectomy (figure 1.4).[45] In their first publication on this technique, they described 60 patients who underwent this procedure. All patients had an insufflation test before the secondary puncture. Ninety percent of the patients had a fluent speech, a remarkable high percentage that was never achieved before with other techniques of voice rehabilitation. They also reported no operative complications and frequent leakage from the esophagus to the airway was non existent. This technique meant a major break through and is still considered, apart from modifications, to be the method of choice for voice rehabilitation in most patients. Later, they showed that there is some decrease over time in success rate from 94% to 83%.[46] High voice rehabilitation success rates were also reported by others.[47,48]

The original voice prosthesis was a hand crafted piece of tubing which worked as a one way valve. It allowed air to pass towards the esophagus to enable voicing and kept esophageal content out of the airway. The commercially available Duckbill, which was a derivative of the hand grafted device, followed shortly. The Duckbill prosthesis is inserted into the fistula through the tracheostoma (antérograde or frontloading insertion) and is taped to the peristomal skin.

Soon others jumped onto the bandwagon and started modifying and developing their own voice prosthesis.[49-55]

Panje introduced a prosthesis that was quite similar but which had an additional flange that helped the voice prosthesis to stay in the fistula, a concept refined with the Groningen prosthesis. This fixation method is currently known as indwelling or semi-permanent fixation.[49]

Since the Duckbill prosthesis, that has a relatively high resistance to airflow, the emphasis on making low resistance prostheses started in the second half of the eighties.

The main advantages of this method are: the relatively good voice quality compared to the other voice rehabilitation techniques, and the high success rate of achieving usable voice requiring limited teaching.

Major disadvantages of this method are: the daily maintenance of the prosthesis by the patient, the recurrent leakage of the prosthesis after a period of time and the therefore required replacement by the clinician, the costs, and for most patients needing a hand to occlude the tracheostoma. Although complications associated with TEP are infrequent, they may occur. Leakage around the prosthesis due to TEF enlargement is reported in 5-8% of the patients.[56-58] Occurrence of granulation tissue formation around the voice prosthesis is reported in approximately 5%. The more serious complication of aspiration of the voice prosthesis is seen in 1-5%.[57,58] The last complication is dependent of the type of voice prosthesis used.
Good voice prostheses nowadays have the following characteristics: reliable and safe use, frontloading insertion technique, indwelling fixation and low resistance to airflow.

Frontloading versus Backloading Insertion
The first voice prosthesis that Eric Blom introduced was a frontloading device: the Duckbill voice prosthesis. It is inserted through the tracheostoma into the TEP. This method of insertion is relatively patient "friendly" compared to later on developed, backloading (retrograde insertion) devices. The latter devices are passed through the mouth with a guidewire towards the tracheoesophageal fistula (TEF). The drawback of a backloading device lies mainly in the fact that many patients experience gagging during replacement. Using topical anesthetics in the mouth reduces this gagging but that by itself is not patient "friendly". The early Dutch voice prostheses were backloading devices. From a design point of view, backloading devices have the advantage that the esophageal flange is thicker or more rigid so the retention of the device into the fistula is better. It can be safely concluded that all frontloading devices compromise slightly on the esophageal flange that is thinner and more pliant. This is necessary to allow for the frontloading insertion into the fistula. This compromise nonetheless reduces the retention capabilities of the device. It is doubtful, however, that this reduced retention would lead to significantly increased extrusion of the voice prosthesis since the forces acting upon it are generally low.

Indwelling versus Non-indwelling
Non-indwelling prostheses are more easily inserted into the TEF. They can be safely removed for cleaning or replacement by some patients themselves. This has an obvious advantage: the patient is more independent from his or her clinician. The patient needs teaching by the clinician to assure safe handling. Non-indwelling prostheses have low retention capabilities which make them more likely to be extruded and dislocated. The patient needs to be aware of this possibility since the complications can be severe, like obliteration of the TEF or aspiration of the device.
Indwelling prostheses have two flanges enabling semi-permanent fixation. This type of prosthesis is not intended for removal and replacement by the patient. The patient needs to see a clinician for these tasks. This makes indwelling prostheses relatively "carefree" as long as they function. When leakage through the device occurs the patient needs to visit a clinician. Indwelling prostheses are commonly used in the Netherlands, in other countries like the United States their use is not as widely accepted.

Frontloading Indwelling Voice Prostheses
The Blom-Singer low resistance voice prosthesis, Provox 2 voice prosthesis and VoiceMaster voice prosthesis are discussed in more detail in appendix.

Surgery to Promote Tracheoesophageal Voice Rehabilitation
It has long been recognized that the initial surgery to remove cancer has great influence on the outcome of esophageal and tracheoesophageal voice rehabilitation. In 1934, Kallen wrote: "the surgeon should be interested in preparing the patient as favorably as possible for the phonetician. He should save as much tissue as is safely possible".[59]
It is well known that certain patients that have had a total laryngectomy will have problems with tracheoesophageal voice production. The method of PE-segment reconstruction (neoglottis) and stoma size are two examples.
When air passes from the trachea through the voice prosthesis into the esophagus it should pass upwards through the PE-segment to produce sound. Several factors may hamper the passage of air past the PE-segment, such as PE-segment spasm. In non operated individuals the upper

esophageal sphincter (cricopharyngeal muscle) protects the airway from esophageal contents. This physiological reflex has proven to be counter productive in about 12% up to 32% of the laryngectomized patients who encountered hypertonicity or spasm when attempting TE-speech.[60,61] Esophageal insufflation testing before total laryngectomy may be of help to identify voice failures. Fluoroscopy in these cases will show a posterior bulge of the pharyngeal constrictors indicating muscle contractions.[62,63] Blom et al., report that almost 40% of patients assessed for secondary voice rehabilitation require a pharyngeal myotomy.[7]

Myotomy of the pharyngeal constrictors and cricopharyngeal muscle was used successfully to eliminate PE-segment spasm. Although myotomy is a successful method there are some reports on complications associated with the procedure.[7,61,64] Complication rates range between 17% and 32% and include hematoma, infection, gastro-esophageal reflux etc.[60,61] Post-surgery fistula formation seems to increase with myotomy and is reported between 7-9%. A possible reason for this increase can be the disturbance of vascularity which may cause ischemia or a small lesion of the feeding tract. Disappointing voice results may also occur when a myotomy is too extensive, which will cause hypotonic voice results or too conservative which will not eliminate the spasm.[64] It is difficult to decide how far the myotomy should extend in the individual patient. Those surgeons that do not close the constrictor muscle frequently do not need to do a myotomy, however the incidence of fistula formation in theory is likely to increase.

Hemi-neurectomy of the nerves innervating the cricopharyngeal and constrictor muscles is another method to avoid spasms during air passage. During total laryngectomy, these nerves are relatively easy to access. In a prospective study researchers showed that 87.5% developed fluent speech after pharyngeal plexus denervation.[7] In a later study, Blom et al., reported mean fundamental frequency to be significantly higher for patients who received a neurectomy (111.1 Hz) only compared to those who received a myotomy (82.7 Hz) or a combination of the two (90.4 Hz) during reading tasks.[65] They assume that this finding is likely to be caused by the PE-segment that keeps more tension with neurectomy. In the same article, they report that after 9 months 33% of the neurectomy patients experience less

fluent speech compared to 10% for the myotomy group. Re-innervation may be an explanation for this observation. Neurectomy is also complicated by the fact that it is very difficult, if not impossible, to identify all innervating nerve branches without intra-operative EMG.

Neurectomy also seems to effect lower oropharyngoesophageal swallow efficiencies more than myotomy during radiographic examinations. Nonetheless, different patient groups do not seem to suffer from significantly different swallowing problems.[66]

The most recent development is the larynx transplant. In January 1998, Marshall Strome led a team of Cleveland Clinic physicians who performed what may be a successful total larynx transplant on a patient who's larynx was destroyed due to a motor accident 19 years earlier. Even though, this patient spoke a few words 3 days after surgery, it remains to be seen whether the long term results will be satisfactory. The immuno-suppressors needed to avoid organ rejection are likely to stay contraindicated in the patient group that has had a total laryngectomy as a therapy for cancer. Total larynx transplant will not be a treatment option in the near future for the total laryngectomized patient group.

Effects of Lost Nasal Functions

The functions of the nose that are of importance for respiration are filtering and conditioning air during inspiration, preserving heat and water loss during expiration and its air flow resistance. The nose is an effective filter for particles larger than 30 mm. These particles are deposited in the mucus covering the nasal epithelium and are transported towards the hypopharynx. The nose and nasopharynx are also effective in increasing the water content and temperature of inspired air. This conditioning is necessary to maintain a healthy mucosa of the tracheobroncheal tree.

The mucosal lining of the tracheobroncheal tree consists of secreting and ciliated epithelial cells that transports mucus to the hypopharynx. This epithelial lining is covered by a mucus layer which is produced by the secreting cells. The mucus is transported to the hypopharynx. It consists of two layers: the upper viscous gel layer which is transported along the tips of the cilia and a watery, low viscosity sol layer which surrounds the cilia.[67]

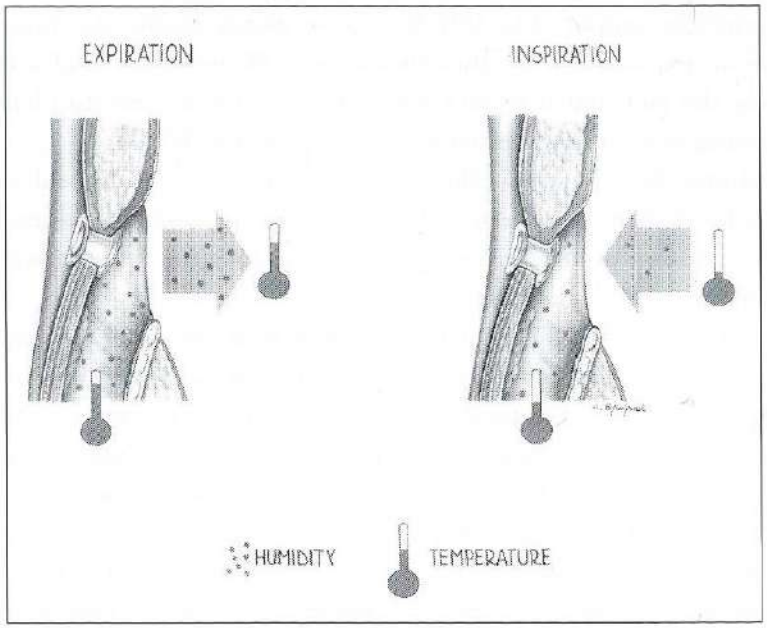

Figure 1.5: Schematic drawing of the trachea, tracheostoma and esophagus. During expiration, the laryngectomized patient loses heat and moisture to the ambient air. During inspiration, relatively dry and cool air enters the airway. Thermometers and circles indicate temperature and relative humidity respectively.

Alteration of the mucus layer, especially the sol layer will decrease the ciliary beat and thereby the escalator transport function towards the hypopharynx. The constitution of the mucus layer can be affected by systemic hydration and by air humidification and air heating.

Laryngectomized patients have lost their respiratory functions of the nose since they breath through their tracheostoma in the neck. Figure 1.5 illustrates the problem that laryngectomees encounter. During expiration, a relatively high amount of the heat and moisture contained in the expired air is lost. During inhalation, relatively cool and dry ambient air enters the tracheobroncheal tree.

The trachea and conducting airways are now highly involved in the air conditioning process. Consequently, the mucus composition becomes more viscous decreasing the escalator transport. This process has clearly been

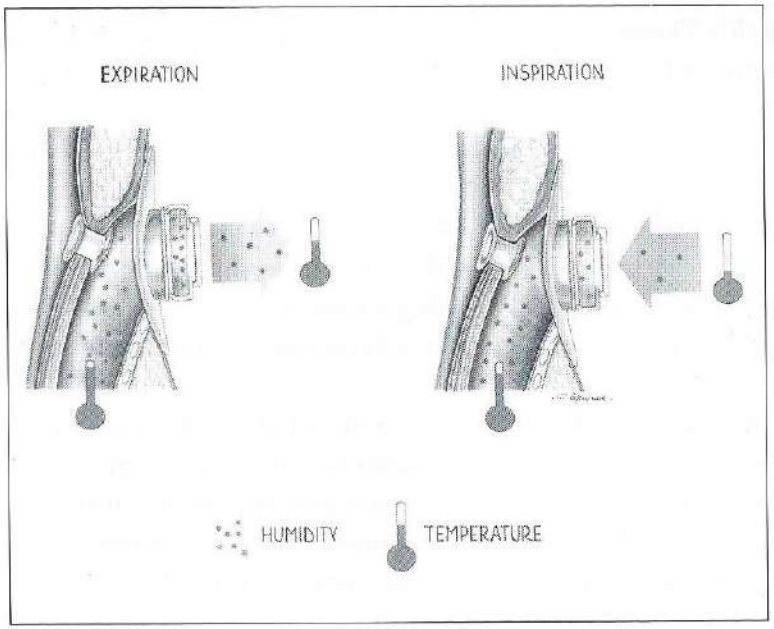

Figure 1.6: Schematic drawing of the airway of a laryngectomized patient using a Heat and Moisture Exchanger (HME). During expiration, air passes through the HME that traps the heat and moisture. During expiration, dry ambient air passes through the HME, picking up heat and moisture. Thermometers and circles indicate temperature and moisture respectively.

demonstrated in animal studies.[68,69]

Many laryngectomized patients complain about excessive amounts of phlegm production. This can partly be explained by the lost air conditioning and filtering that has occurred as well as the epithelial changes due to the years of smoking that most of these patients have done.

Airway Protection After Total Laryngectomy

A heat and moisture exchanger (HME) partly restores the important respiratory functions of the nose. This simple filter captures heat and moisture from the expired air. During inhalation, the air picks up some of the deposited heat and moisture from the HME, thereby raising the temperature and water content of the air entering the tracheobroncheal tree. Figure 1.6 is a schematic drawing of this process.

Aim of this Thesis

Prosthetic and surgical factors are part of a complex multi-factorial web that determines successful voice rehabilitation after total laryngectomy. Little is known about the physical aspects of the prosthetic devices used in this patient group. A better understanding of these physical aspects may allow the clinician to increase the successful rehabilitation and ultimately help the patient to cope better with his or her disabilities. Further development or complete new prosthetic designs may be necessary if their intended application area requires better or different physical properties.

The general aim can be divided into a number of specific questions:
Is there a technique available that allows an anatomic study, with the emphasis on the physical dimensions, of the region of interest in living patients?
Is stereolithography a usable technique to construct three-dimensional models of the trachea, esophagus and voice prosthesis?
What are the advantages and disadvantages of using a tracheostoma valve especially the Blom-Singer Adjustable Tracheostoma Valve (ATV)? What percentage of our patients is successful using an ATV? What are the factors that determine success rate and failure? How do patients rank their own voice when using the ATV compared to manual occlusion? What is the effect of heat and moisture exchanger use in our patient group?
What are the aerodynamic characteristics relevant in a tracheostoma valve? How do tracheostoma valves compare and differ when measuring these physical aspects? What are the shortcomings of these valves and can they be improved?
Is there an objective method with which the performance of heat and moisture exchangers is measured? What has to be modified to create a measurement setup suitable for the type of HMEs used in our patient group? Are there efficiency differences between the common HMEs used by the laryngectomized patient? What are the construction and daily cost differences?
Is it possible to design a computer instrumentation setup that simulates the human situation in the sense that the pressure determines flow opposed to flow controlled measurement setups? Is it possible to measure pressure/airflow curves, pre-load, valve leakage and inter-prostheses differences? What are the aerodynamic differences of the five low pressure voice prostheses?
How to design an instrumentation setup that measures *in vivo* aerodynamics of alaryngeal speech? How do *in vitro* and *in vivo* measurements compare? Can differences be explained? What are the average airflows, pressures and intensities during different phonation tasks? Is it possible to determine pressure, flow and intensity relationships?
Can we measure the efficiency of energy transformation during phonation? What is the average power loss caused by the voice prosthesis? At what aerodynamic power levels do laryngectomized patients phonate?

Contents of this Thesis

In chapter 2, a new technique of rapid prototyping is discussed. We needed three-dimensional models of tracheostomas including their surrounding tissue. Models that reveal the physical dimensions and relations between important structures were needed for prosthesis prototyping (voice prosthesis & tracheostoma valve) and measurement apparatus design.
The Blom-Singer adjustable tracheostoma valve is currently the only tracheostoma valve that allows simple alteration of its aerodynamic characteristics and that allows the simultaneous use of a heat and moisture exchanger.
In chapter 3, the first experiences with this device are discussed.
It is well recognized that tracheostoma valves can be a valuable addition for laryngectomized TEP speakers since they allow speech without digital stoma occlusion. There are currently three different tracheostoma valves easily available. These valves differ in construction and use.
In chapter 4 aerodynamic measurements and design differences are discussed. As discussed earlier laryngectomy causes fundamental changes in anatomy. One of these changes is the disconnection between the upper and the lower airways. The air conditioning effect of the nose is lost. Heat and moisture exchangers are designed to compensate for this lost air-conditioning nasal function.

In chapter 5, the differences of four heat and moisture exchangers are demonstrated using a modified ISO 9360 standard.
In the tracheoesophageal speaking patient, the air from the lungs passes through the voice prosthesis, the PE-segment and hypopharynx to exit from the mouth and nose. The intra tracheal pressure needed for phonation is the sum of resistances of each part of the tract at a given airflow rate. The voice prosthesis is the first flow limiting part in line in this phonatory tract. Chapter 6 discusses the *in vitro* aerodynamic properties of five different voice prostheses.
In chapter 7, the *in vivo* aerodynamic and intensity measurement technique is described. The average airflows, pressures and sound intensities at different phonation tasks are discussed and compared.
In chapter 8, aerodynamic and acoustic power calculations are used to determine the vocal efficiency of tracheo-esophageal phonation. These results are compared with the laryngeal vocal efficiencies.

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Chapter 2

Three-dimensional Models of the Tracheostoma using Stereolithography

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Abstract

The availability of an accurate three-dimensional (3-D) model of the tracheostoma and trachea of the laryngectomy patient would be of great help in prototyping of endotracheal prostheses. Stereolithography has been described for skull and jaw models but never for soft-tissue reconstructions of the trachea.

CT was performed on tracheostomas of eight patients. The CT data were used to make 3-D models by means of stereolithography. Inverted CT data were used to create air contour models of the same tracheostomas.

Eight soft-tissue and eight air contour models were reconstructed from CT data, showing accuracy and great detail.

In this paper, we present a previously unreported application of the stereolithography technique. Measurements and prosthesis prototyping, which are impossible to perform on tracheostomas in patients, can now be executed safely. We are using the 3-D tracheostoma models in our research project to develop an endotracheal fixation method for tracheostoma valves.

Introduction

Patients who lose their vocal cords due to laryngectomy can regain speech in several ways. Following laryngectomy, the best quality of speech is obtained using a voice prosthesis also known as tracheoesophageal speech.[1-3] The voice prosthesis is a one-way valve that is placed in an artificial fistula between the trachea and esophagus. After occlusion of the tracheostoma, the prosthesis allows air to be forced towards the esophagus, inducing resonance facilitating speech. Saliva, other liquids and food can not pass through the one-way valve leading to the trachea. This form of speech requires the patient to use his hand to occlude the tracheostoma. Consequently, the patient needs to maintain at least one hand clean to be able to speak, which limits his movements.

In 1982, the first tracheostoma valve was introduced by Blom and Singer reducing the need for manual occlusion of the tracheostoma. This tracheostomal valve is positioned over the tracheostoma and is open during normal respiration. When the patient wants to speak, he forces air through the tracheostomal valve, resulting in its closure. A well-known problem of tracheostomal valve use is the fixation method: adhesives are used to attach the valve housing to the peristomal skin, creating an air-tight seal. The duration of this air-tight attachment is highly variable and is determined, for example, by phlegm production, back pressure, peristomal anatomy etc.[4] To make the usage of tracheostomal valves less cumbersome and applicable in a greater number of laryngectomy patients, a new fixation method and a better understanding of the anatomy altered after laryngectomy are needed.

An endotracheal fixation of the tracheostomal valve might eliminate some of the drawbacks of the peristomal fixation. For this reason, a precise anatomical study of the tracheostomal region is needed. Our initial attempts in making compound silicone molds of the tracheostoma to visualize shape; contour and size were unsuccessful. The risk of not being able to remove the mold from the tracheostoma on completion and the risk of silicone spillage in the airways were the major grounds for exploring alternative methods of reconstruction.

CT-scans or MRI data as a basis for three-dimensional (3-D) on-screen reconstructions are of limited value because of the difficulty of interpretation and the lack of prototype testing. These limitations forced us to investigate techniques that allow 3-D modeling from CT-scans or MRI data.

The manufacture of 3-D models (reconstructions) based on CT-scans or MR data has been possible for some years. Probably the best-known technique is the computerized milling process. The CT or MR data are used to manufacture two half-axis milled models often made of polyurethane foam. Milling tools are limited in their usefulness for reproducing complex anatomical structures.[5]

Recently another technique, stereolithography, has become available: stereolithography originated in the aerospace industry as a prototype-manufacturing tool and offers a unique way to display patient anatomy.[6] This technique has received some attention in the medical literature for its use in reconstructions of bony tissues, especially the skull.[6-12] The wide range of its possible uses is illustrated by articles reporting this technique for coronary artery reconstructions, stereovectorcardiography and the skull reconstructions of a 5,300-year-old mummy.[13-15] This technique has the advantage that more complex structures can be reconstructed in one piece and that the accuracy is high.[10] It seems to work especially well with bone reconstruction, but its applicability on soft-tissue and air contour reconstructions, such as those needed for the tracheostoma and the esophagus, has been unknown.

In this paper, we present a previously unreported application of the stereolithography technique: the reconstruction of the tracheostoma, esophagus and trachea of laryngectomy patients. Since the start of this project started in July 1993 and eight 3-D models made of artificial resin of the patients' tracheostomas, have been reconstructed using this technique.

Materials & Methods

Computed Tomography

In eight laryngectomized patients, the tracheostoma was imaged with conventional CT (Somatom Plus, Siemens Medical Systems, Erlangen Germany). Calibration of the CT-scanner is needed to be able to check the accuracy of the stereolithographic process. To achieve a 1:1 ratio on the scan, an object of known shape and size was used for the calibration. After calibration, the CT-scans had the same dimensions as the scanned object.

CT-scanning started just cranially of the patient's tracheostoma and stopped 5 cm caudally, using contiguous 2-mm-thick slices. This resulted in 25 CT-scans per patient. The CT-scan parameters were 120 kVp, 125 mA, 2.2 s, scan time and zoom factor 6.0. The 2-D images were archived on a magnetic data carrier. This data carrier was used as the input medium for the image-processing computer of the stereolithographic system.

Stereolithography

After reading the CT-scan data in the image-processing computer, the threshold is set, using the intrinsic high contrast between the soft tissue and air, resulting in the segmentation of the airway and other air-filled structures. Manual drawing is not necessary. The CT-Modeller™ software performs an interpolation on the data, which results in 0.25-mm-thick layers. A computer-directed laser draws the digital CT scan information onto a platform in a basin of synthetic liquid resin (figure 2.1;1). Wherever the ultraviolet laser light intersects the liquid resin, the resin solidifies due to polymerization: long molecules are formed. Once one layer is drawn, the platform is lowered slightly beneath the liquid resin surface again, followed by the next interpolation of the CT-scan image which is drawn by the computer on top of the previous layer (figure 2.1;2).

Layer after layer is built this way, resulting in a 3-D reconstruction (figure 2.1;4) of this soft tissues of the tracheostoma.

After the soft-tissue reconstruction of the tracheostoma, the CT-scan images of the patients are inverted. After the reconstruction, the CT-scans of the patients are inverted. The inverted images then highlight the air con-

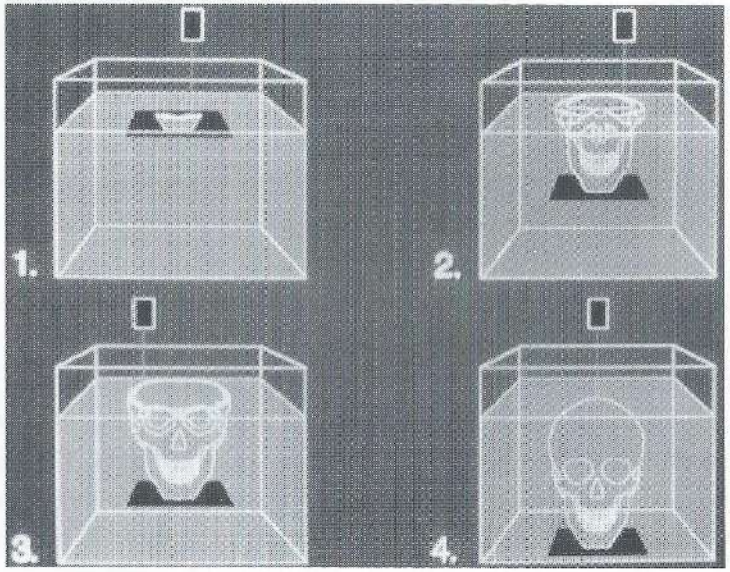

Figure 2.1: A schematic illustration of a skull drawn by a laser in a basin with liquid resin. CT-scans and MRI-images can be transformed into 3D-models using this stereolithographic technique. Illustration 1-4 shows the logic sequence of the reconstruction process. Figure used with permission from Materialise N.V.

tours of the scanned area, which facilitates the construction of 3-D models of the air contours.

To validate the accuracy claimed in the literature, we tried to compare the models with the patient in two ways: first, the 3-D models were compared with the patient's anatomy, then with the calibrated CT-scans.

Results

The tracheostomas of eight patients were scanned, resulting in eight 3-D soft-tissue models. Figure 2.2 demonstrates the 3-D model of a tracheostoma in one of the scanned laryngectomy patients. In these models, the contour of the trachea as well as the Provox voice prosthesis are visible.[16] In some of the 3-D models, the air-containing esophagus is clearly visible.

The following step was the inversion of the CT-images from which eight 3-D

air contours were made. These air contours reveal the air column of the tracheostoma, the esophagus and their connection, the voice prosthesis cavity. Figure 2.3 is a photograph of one of the inverted 3-D models of the tracheostomal area.

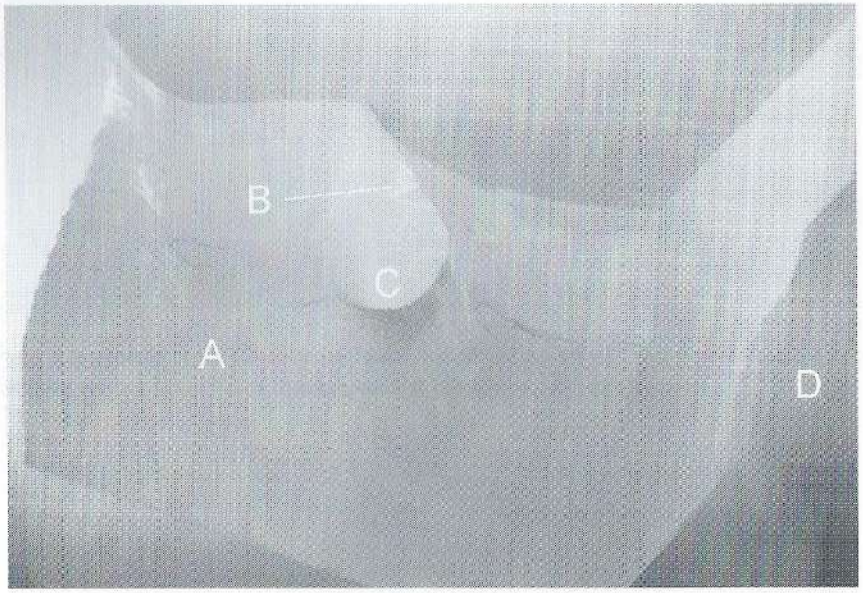

Figure 2.2: 3-D model of a tracheostoma of a laryngectomized patient (soft-tissue). Peristomal anatomy (a), voice prosthesis (b), trachea (c), and the left lung apex (d) are visible.

In an attempt to validate the accuracy of the technique, we tried to compare the 3-D models with the patients' anatomy and to measure the photographs and the 3-D models. Comparison of the 3-D models with the patients revealed a few apparent differences, which seem to be related to the patients' movements during the scanning process. Comparison of the 3-D models with the calibrated CT-scans was only possible for the first and last CT-scans. Any other comparison turned out to be impossible. The shape, size and dimensions of the first and last scans appear to be identical.

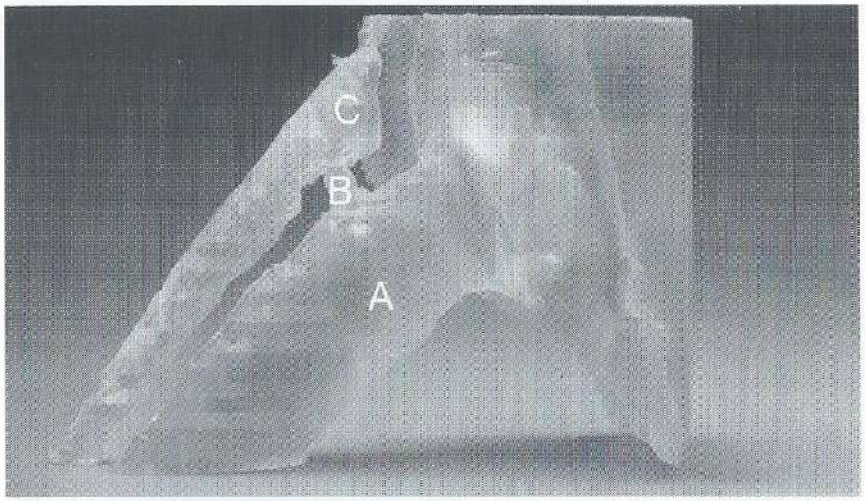

Figure 2.3: A 3-D model of the tracheostoma made of inverted CT data. Right lateral view of the air-figure of the trachea (a), voice prosthesis (b) (tracheoesophageal shunt) and the esophagus (c) are visualized.

Discussion

For laryngectomy patients with a voice prosthesis, speech without the use of a hand is possible using a tracheostomal valve. One of the drawbacks in using the tracheostomal valve is the cumbersome valve and the limited time in which some patients can maintain a leak-proof seal, which is essential for the use of the tracheostoma valve. We believe that an endotracheal fixation may resolve some of the current disadvantages of the peristomal fixation method. For the development of an endotracheal fixation, a precise anatomical study is needed of the tracheostoma and its surrounding tissues. Our attempts to make molds of the tracheostoma using compound silicone failed mainly because of the risks involved for the patient.
Computer screen 3-D reconstructions are of limited value because of the impossibility of prototype testing and the difficulty of interpretation.
3-D modeling has been described in the literature, as have milling and stereolithography. Stereolithography is superior over milling because it makes

the manufacture of more complex models and one-piece models possible.
We decided to make 3-D models of an area, which had not been reported previously. Computer techniques make it possible to reconstruct air contours after inverting the CT data. The tracheostomas of eight patients were reconstructed in 3-D soft-tissue and air contour models. The details of the models are of good quality.
In our models, we attempted to check the accuracy of stereolithography reported in the literature. This is a difficult task because of the complexity of the anatomical structures involved. Our study would not have been done if the anatomy could have been visualized in an other way; this implicated that the testing of the accuracy is difficult.
We compared the 3-D model with the patient's anatomy: the accuracy seems high, although movement artifacts are visible. These movement artifacts occur during the CT-scanning phase. A helical CT-scan, which was not used in this study, could further limit the movement artifacts and make overlapping thinner slices possible because of its higher speed.
We compared the 3-D models with the calibrated CT-scans. Due to the complexity of the models and the interpolation of the contiguous scans, only the first and last CT-scans are comparable. We could not measure any size and shape differences with a marking gauge and concluded that the 3-D models are accurate but reveal movement artifacts.
The 3-D models of the air and soft tissue contours are considered to be helpful in the anatomical study of the tracheostoma and the related structures and will furthermore assist us in the future design of endotracheal prostheses for laryngectomy patients. The proportions and relations between the tracheostoma and the esophagus are striking. Even the silicone voice prosthesis can be clearly seen in the tracheoesophageal fistula (figure 2.3).
At this moment, we consider the high costs (US $ 1,000) involved in making 3-D models a limitation for routine clinical use. However, this technique is useful for research projects in which very detailed 3-D models are required.
The reconstructed 3-D models of the tracheostomas prove that stereolithography can be a useful technique in making soft-tissue air contours. The tracheostoma models are ideal for measuring and prototyping, which are difficult, inaccurate or even impossible to perform safely without this

technique. Stereolithography is a promising tool in 3-D modeling of upper airway soft-tissues.

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Chapter 3

First Experiences with the Blom-Singer Adjustable Tracheostoma Valve

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Abstract

The Blom-Singer® adjustable tracheostoma valve is a new tracheostoma valve, introduced in 1992 to improve voice rehabilitation after total laryngectomy. Little research has been done to evaluate the benefits of this valve.
Our study evaluates the advantages and disadvantages of using this device. Eighteen laryngectomized patients with a low-resistance Provox® voice prosthesis received an ATV, using minimal selection criteria. The patients are evaluated according to a specific protocol. The effectiveness of the HumidiFilter, valve and fixation method and the benefits are evaluated.
Approximately 66% of the 18 patients are still using the ATV. We report the differences between the current users and the dropout group.
Patient factors are discussed that seem to have an impact on the effective use of the valve, such as age and mucus production. We consider the ATV to be a valuable device for fingerless speech in the laryngectomized patient.

Introduction

Following the introduction of the first successful laryngectomy by Billroth in 1873, the need for voice rehabilitation became important. Esophageal speech and electrolarynx devices were the most common methods used to produce alaryngeal speech. The success rate of mastering esophageal speech is relatively low, although the percentages vary considerably.[1-3] An other drawback of esophageal speech is that the voice is often hoarse. Electrolarynx speech is easier to master, but the voice is very monotone and unnatural. These drawbacks have motivated researchers to find improved methods for creating speech after laryngectomy.
During a meeting of the Chicago Laryngological and Otological Society in 1931, Dr. M. Reese Guttman introduced a puncture with a needle, from the tracheostoma to the hypopharynx. This procedure was inspired by a desperate patient whom had made a fistula with a red hot ice pick, and subsequently produced a good voice.[4,5]
In the 1970s, many surgical techniques were performed attempting to produce voice, but not many gave acceptable results.
In 1980, Singer and Blom introduced a tracheoesophageal (TE) puncture technique and silicone voice prosthesis. This endoscopic technique creates a tracheoesophageal puncture in which the voice prosthesis is placed.[6] After digital occlusion of the tracheostoma, air passes through the voice prosthesis to the esophagus, inducing resonance of the hypopharynx. This resonance can be heard as a tone, facilitating speech. The quality of voice prosthesis speech is higher than other methods currently employed.[7,8]
In 1982, Blom at al.[9] introduced a tracheostoma valve, to be used with a low-resistance voice prosthesis, which is placed over the tracheostoma. With forced expiration, the valve closes, causing occlusion of the tracheostoma. Tracheostoma valves eliminate the need for the patient to use digital tracheostoma occlusion. Although not all tracheostoma valves are glued to the peristomal skin, the majority is.
Some authors have reported fixation problems of the tracheostoma valve to the peristomal skin. These authors describe alternative methods of tracheostoma valve fixation.[10,11,12]

Another advancement by Blom and Singer (Inhealth) in 1992 was the introduction of the adjustable tracheostoma valve (ATV). The ATV offers two enhancements over their previous device: 1) the closing pressure of the ATV is adjustable by the patient without removing the valve from the tracheostoma; the adjustment is made by a simple rotation of the valve. 2) The ATV features a Humidifilter (heat and moisture exchanger) which is attached to the outside of the valve. This filter collects heat and moisture from expirated air. During inspiration, air flows through the filter, gaining heat and moisture from the Humidifilter. Studies show that heat and moisture exchangers help to condition the inspirated air, thereby partly functioning as a normal nose.[13]

The introduction of this new tracheostoma valve allowed us to test the value of this valve in laryngectomized patients using a Provox® voice prosthesis. This voice prosthesis is a low-resistance biflanged indwelling device that is installed during laryngectomy and replaced approximately every 5 months in an out patient setting.[3,14]

In April 1993, a cooperative project started between the Academic Medical Center, Amsterdam, the Dr. Daniel Den Hoed Cancer Center and the University Hospital Rotterdam to evaluate the Blom-Singer® ATV.

Materials and Methods

The ATV is a plastic valve with an adjustable silicone diaphragm. When the silicone valve diaphragm is adjusted by rotation of the faceplate the closing pressure is altered (figure 3.1). This adjustment can be performed while the tracheostoma valve stays attached to the tracheostoma. The Blom-Singer® Humidifilter is a foam filter treated with chlorhexidine and lithium-chloride and is placed on the faceplate, on the outside of the valve. The Humidifilter is a heat and moisture exchanger that has an air-conditioning effect on the inspirated air.

The valve is attached over the tracheostoma and housed in a fixation ring. This ring is attached to the skin with adhesives, double sided foam or tape

discs and glue. The fixation ring and the foam and tape disks are available in two sizes.

To evaluate the value of the new ATV in laryngectomized patients with a voice prosthesis, we used a minimum set of criteria: the laryngectomized patient is currently using a voice prosthesis with adequate speech; the patient is physically and mentally capable to manage the daily care and use of the ATV valve, either by himself or with help of family; the patient is motivated to use the tracheostoma valve. Patients with previous tracheostoma valve use were excluded from this study, as they would cause a bias in the total study population.

Since April 1993, laryngectomized patients with a Provox® voice prosthesis have received the new ATV in a specially developed outpatient program. The doctor gives instructions as to the use of the ATV and how to apply the valve to the skin around the tracheostoma. Patients are advised not to sleep with the valve in place. The fixation ring can remain in place during

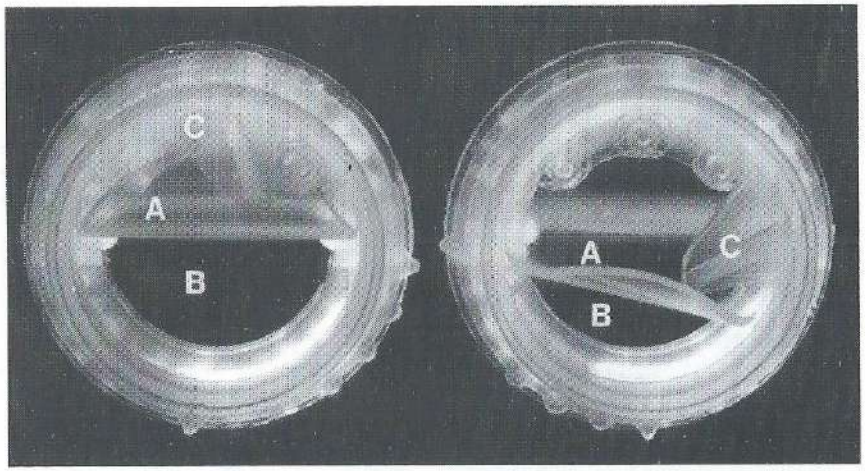

Figure 3.1: Photograph of two Blom-Singer Adjustable Tracheostoma Valves seen from the tracheal side. A: silicone diaphragm, B: valve opening, C: plastic notch, that determines the position of the silicone diaphragm. Left valve has the silicone diaphragm in its most open position, resulting in a higher closing pressure. Right valve has the silicone diaphragm in its most closed position, resulting in easier closure during expiration. The plastic notch (C) pushes the silicone diaphragm as illustrated in the right valve, determining the position of the silicone diaphragm. Clock wise rotation of the silicone diaphragm, when the valve is attached to the tracheostoma, results in closure of the valve, as shown in the right valve.

the night, if the patient prefers this. The patient is regularly evaluated and supplied with Humidifilter, glue and other necessities for the use and maintenance of the valve. During each visit to the outpatient office, patients are evaluated according to a specific protocol. On the first visit, the patient was asked about his level of mucus production prior to valve use. The patient is evaluated with a questionnaire that assesses the effectiveness of the Humidifilter, valve, fixation method and the benefits of the valve usage.
After this interview, the speech pressure is measured during normal conversation. This speech pressure is measured with a manometer (Portex). The speech pressure reflects the average endotracheal pressure on the seal and the tracheostoma valve. The assumption was made that a higher speech pressure (back pressure) increases the chance of air leakage around the seal attachment.
In addition to the ENT examination, patients are also examined by a speech therapist. These results are not discussed in this article.

Results

Our study includes 18 patients, of which 12 still use the valve. Five patients stopped and one patient died of a non-related disease. The patient that died is excluded from further calculation.
The average age of the current user is 56.5 years, compared to 66.0 years for the drop-out group, making the user group on average 9.5 years younger

Table 3.1: Overview of non-users (drop-out group) and users data **S**=sex (f=female & m=male), **Age** in years, **Surgery** =Surgery date, **TNM**=according the TNM classification, **RT**=Radiotherapy, **Start**=Starting date, **Use**=Weeks of ATV use, **Pressure**=Pressure during normal speech in cm H_2O, **Seal**=average amount of hours daily of air tight seal of ATV, **Usage**=usage per day of the ATV, **Mucus**=mucus production indicated by patient, **Prod.**= mucus production after period of ATV use with Humidifilter (= equal / - decrease / + increase), **Application**=application ease (easy = easy / diff. = difficult / help = help is needed during application), **Voice**=voice quality judged by the patient, **Comp.**= speech with valve related to speech with manual stoma occlusion (better / same / worse), **Benefit**=benifit of using the ATV indicated by the patient. Note: patient no. 6 is omitted from the table because of death of a non-related disease (6 weeks follow-up).

Non-users No.	S	Age	Surgery	TNM	RT	Start	Use	Pressure	Seal	Usage	Mucus	Prod.	Application	Voice	Comp.	Benefit
1	f	62	17/9/92	T0N0M0	70 Gy	15/7/93	0	40	0	0	high	=	easy	bad	Worse	none
2	m	65	2/4/93	T1N0M0	66 Gy	15/7/93	9	30	24	8	high	=	diff. + help	reasonable	same	min.
5	m	80	19/7/91	T2N0M0	70 Gy	15/7/93	13	30	3	6	high	=	easy	reasonable	same	none
7	m	60	18/1/93	T1N0M0	68 Gy	31/3/93	12	18	5	5	High	=	diff. + help	reasonable	same	min.
9	f	63	11/9/90	T3N0M0	70 Gy	15/7/93	2	20	48	6	High	=	easy	good	same	none
Average		66.0					7.2	27.6	16.0	5.0						

Users No.	S	Age	Surgery	TNM	RT	Start Use	Pressure	Seal	Usage	Mucus	Prod.	Application		Voice	Comp.	Benefit
3	m	44	17/11/92	T3N1M0	70 Gy	15/7/93	39	30	5	5	min.	=	diff. + help	good	better	high
4	m	74	21/7/92	T2N0M0	70 Gy	15/7/93	39	25	54	24	min.	-	easy	good	better	high
8	m	32	10/2/93	n/a	n/a	28/7/93	37	22	42	12	min.	=	easy	reasonable	better	high
10	m	73	4/12/92	T2N0M0	50 Gy	14/4/93	52	25	30	14	Intermed.	-	easy + help	reasonable	better	high
11	m	41	30/10/92	T3N0M0	68 Gy	31/3/93	54	35	12	12	min.	-	easy	good	better	high
12	f	64	24/11/92	T2N0M0	70 Gy	15/7/93	39	22	24	24	High	-	easy	good	better	high
13	m	61	27/5/92	T3N0M0	70 Gy	15/10/93	26	25	5	4	Intermed.	=	easy	reasonable	same	min.
14	m	65	18/3/91	T4N2M0	70 Gy	15/10/93	26	25	48	14	Intermed.	-	easy	good	better	high
15	m	56	10/5/88	T3N0M0	60 Gy	15/10/93	26	25	48	5	High	+	easy	good	same	high
16	m	49	1/6/93	T3N0M0	70 Gy	24/1/94	11	35	5	5	min.	=	easy	good	better	high
17	m	46	26/5/92	T1N0M0	70 Gy	24/1/94	11	18	18	18	min.	=	easy	good	same	high
18	f	73	15/12/92	T4N0M0	50 Gy	1/10/93	28	30	24	12	min.	-	easy	good	same	high
Average		56.5				32.326.4	26.3	12.4								

than the dropout group (table 3.1).
The average time of use of the ATV in the current user group is 32.3 weeks, compared with 7.2 weeks in the dropout group.
There is only a marginal difference in the speech pressure between the two groups. The current user group, the pressure is 26.4 cm H_2O compared to 27.6 cm H_2O in the dropout group.
The average time that the seal adheres well to the skin in the current user group is 26.3 h, while this is 16.0 h for the dropout group.
The total average daily valve use for the current user group is 12.4 h. The dropout group patients used the valve only 5.0 h a day.
Seven patients of the current user group have minimal mucus production before using the ATV, 3 intermediate and 2 high. All patients in the dropout group have high mucus production, prior to the valve use.
After use of the valve with the Humidifilter, six current users noticed a substantial decrease in mucus production, five patients noticed no difference at all and one patient an increase. None of the patients of the dropout group observed any effect on the mucus production, while using the Humidifilter.
The application of the valve to the tracheostoma is easy for 10 of our patients from the current users and requires no assistance from the family. Two patients in the group need assistance with the application. One finds the application easy, while the other experiences some difficulty. The application of the valve in the dropout group is considered easy by three and difficult by two of the patients.
The adjustability of the ATV is one of the new features of this valve. The patient can easily adjust the ATV, while staying on the tracheostoma, by rotation of the valve.
In spite of the ease of adjustability, our patients only occasionally use this feature. In general, a patient adjusts the valve to a preferred closing pressure without readjusting it for the rest of the day. The design of the ATV was intended to be this way according to Blom (pers. commun.). During prolonged exercise some patients open the ATV fully or remove the ATV from the tracheostoma.
Nine patients in the current user group consider their voice to be of 'good quality', while 3 patients say that their voice is of 'reasonable quality'. In

the nonuser group, three patients claim to have a 'reasonable voice' quality, one a 'bad voice' quality and one a 'good voice' quality.
In the user group, the influence of the ATV gives eight patients a better voice quality and four patients notice no difference. Of the nonusers, four patients notice no difference and one a decrease in voice quality.
Eleven patients of the current user group express good benefits by using the new ATV, and one patient observes only minimal benefit. All patients in the dropout group seem to have no or minimal advantage from the ATV valve.

Discussion

Approximately 66% of all the patients are still using the ATV (one patient died of a non-related disease). The current user group is on average 9.5 years younger than the nonuser group. Age might have an influence on the successful use of the ATV, since the patient needs some skill to be able to handle the ATV effectively. A possible explanation for the relative high dropout rate is the limited selection criteria used. No selection on speech pressure, age or mucus production was made.
Blom (pers. commun.) has shown that the lower the speech pressure, the longer the ATV seal duration, with users in the 20-35 cm H_2O range achieving the desired 10-15 h/day.
The average use of the ATV is 12.4 h a day for the current users. This is certainly influenced by the fact that it is advised not to sleep with the valve, as a precaution. Two patients, however, have reported that they do sleep with the valve, with no apparent complications.

Speech pressure
A speech pressure (endotracheal phonation pressure) between 20 - 30 cm H_2O, during normal conversation, is considered by our group to be optimal. In the total group, no one has extremely high speech pressure. The speech pressure found in the dropout group is not considered to be a factor for patient dropout. However, the person with the highest average speech

pressure of 40 cm H_2O dropped out. This individual later received a myotomy of the cricopharyngeal muscle but was not reentered into this study.

Fixation

The average time for the leak-proof seal attachment was approximately 10.3 h longer for the user group than the nonuser group. The length of time the seal maintains a leak- proof attachment to the tracheostoma influences the usage of the ATV. There is a tendency for patients not to reapply the seal the same day after it starts leaking. Only one patient out of the total group reapplies his seal twice a day.

Skin irritation, characterized by redness and painful areas, occurred in four of the total patient group. A short period of nonuse healed all skin problems with these patients.

Mucus production & coughing

Mucus production is an important issue in the success of tracheostoma valve use. High mucus production makes tracheostoma valve usage more difficult and inconvenient. Every time a patient needs to cough or clear mucus, he must remove the valve from the fixation ring. If the patient does not remove the valve from the fixation ring prior to coughing, he increases the chances of creating air leakage of the seal or valve malfunction. In both situations, the patient needs to reapply the seal or readjust the valve, respectively. All patients have indicated that the tracheostoma valve closes automatically during coughing and sometimes with high physical activity.

The patients of the current user group have on average less mucus production prior to starting with the ATV than the nonuser group. All patients in the nonuser group are prone to high amounts of mucus production. The use of the Humidifilter gives no reduction in mucus production in the nonuser group. A possible explanation for this is the limited hourly use of the valve and Humidifilter per day. Another possible explanation is that the Humidifilter is unable to alter the mucus production because of the irreversible pulmonary damage due to years of smoking.

Six of the 12 current users notice a mucus reduction within the first 10 days of use of the ATV with the Humidifilter. This particular mucus production is probably caused by irritation of the airways by unconditioned air and is therefore influenced by using the Humidifilter. The increase in mucus production in one patient lacks explanation.

Patients' view

Applying the seal and valve to the tracheostoma is considered easy with most current users, while the nonusers experienced more difficulties. Fear of getting the glue into the trachea was the main reason for patients to ask for assistance from family members during the application of the ATV.

All patients in the nonuser group, as was expected, say they experience no or minimal benefit using the ATV. All remaining patients, except one were very enthusiastic about the new valve. Some patients say they never want to speak without the ATV again.

By not using a finger or the thumb for occlusion of the tracheostoma, less attention is drawn from the listeners to the tracheostoma during speech. This is considered by the patients to be an important addition in the successful process of voice rehabilitation.

All patients in the current user group experience more spontaneous speech although they feel they lost some intensity of speech compared to digital occlusion speech. Voice analyses performed on the speech of first Blom-Singer® tracheostoma valve users showed no significant differences of intensity or other parameters.[15,16] Williams et al., [17] however reported differences in perceptual characteristics between prosthetic (first Blom-Singer® tracheostoma valve) and digital tracheostoma valve occlusion speakers, when judged by different groups. Others suggest that the intelligibility with tracheostoma valve voice prosthesis speakers is less during conversation because of tracheostoma valve noises.[18] We feel voice analysis on the ATV is required to evaluate speech with the ATV.

Apart from the mucus production, patients indicate they like to use the Humidifilter for reasons such as less cold air in their trachea during inspiration and the subjective belief of increased protection against bacteria. The size of the valve, extraneous noises during speech from the valve and high prices for parts and Humidifilters are drawbacks pointed out by most patients.

The use of the ATV by voice prosthesis speakers is a valuable addition for a

considerable group of patients. We observe that severe mucus production, in our group of patients, is a major contraindication in ATV use. Selecting according to mucus production would make the success rate of ATV use higher. Some of the drawbacks of the ATV such as size, fixation and the extraneous noises should be subject to further improvement in a next-generation tracheostoma valve design.

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Chapter 4

Airflow and Pressure Characteristics of Three Different Tracheostoma Valves

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Abstract

Tracheoesophageal speakers can achieve speech without digital occlusion by using a tracheostoma valve. Laryngectomized patients who are successful with this device can regain considerable freedom. However, little is known about which valve suits the patient best. Valve aerodynamics may give a guideline for its use. Three major tracheostoma valves, each divided in 4 subtypes, were repeatedly measured in this study. Dynamic pressure and airflow rate signals were sampled through an analog-digital interface into a computer. Considerable aerodynamic differences were observed between the tested valves. The maximum airflow rates, closing pressures and resistances at low velocities were compared. The presented data may help increase the successful use of tracheostoma valves in tracheoesophageal speakers. Patient factors and additional valve factors should always be taken into account. Further clinical study to validate the clinical relevance of these data is needed.

Introduction

After total laryngectomy, voice rehabilitation becomes a very important issue. Tracheoesophageal speech is currently the best method of postlaryngectomy voice rehabilitation.[1,2] A voice prosthesis is positioned in a tracheoesophageal puncture. The prosthesis consists of a one-way valve that allows air to pass from the trachea to the esophagus, inducing resonance and thereby facilitating speech. One of the drawbacks of voice prosthesis speech is that it requires digital tracheostoma occlusion.

In 1982, Blom and Singer introduced the first tracheostoma valve that eliminated the need for digital tracheostoma occlusion.[3] This tracheostoma valve is contained in a special housing that is glued to the peristomal skin. Using the tracheostoma valve helps the patient regain considerable freedom, because it leaves both hands free. Further, the patient acquires more spontaneous speech, and draws less attention to the stoma from the listener. Since the initial introduction of the first Blom-Singer® tracheostoma valve, other tracheostoma valves have been introduced.

Unfortunately, not all laryngectomized tracheoesophageal speakers are successful in using a tracheostoma valve. Successful tracheostoma valve use is dependent on patient factors, physician and speech pathologist factors, and tracheostoma valve factors. As reported earlier by our group, important patient factors are phlegm production prior to valve use, back-pressure, age, motivation etc.[4] Teaching the patient how to use the tracheostoma valve may certainly influence his or her ability to work with the device. Valve-related factors such as the aerodynamics, price and availability may be important for successful use, also.

A tracheostoma valve needs to meet certain aerodynamic characteristics. During normal respiration, the tracheostoma valve must remain open to allow air to pass through. At the same time, the resistance to airflow of the tracheostoma valve needs to be relatively low so it will not cause discomfort. When a patient wants to speak, the tracheostoma valve must close through forced expiration, enabling the air to pass through the voice prosthesis to the esophagus.

To date, aerodynamic characteristics of the three commercially available tracheostoma valves have not been investigated. Knowledge of the valves aerodynamics may help to determine which valve best suits a specific patient.
In this article, we present the various aerodynamic characteristics of the Tracheostoma Valve I (hereinafter referred to as the "Bivona I"; Bivona Medical Technologies, Gary, Ind), the Blom-Singer® Adjustable Tracheostoma Valve ("Blom-Singer ATV"; Inhealth Technologies, Carpinteria, Calif), and the Tracheostoma Valve II large ("Bivona II"; Bivona Medical Technologies). Dynamic flow and pressure measurements were performed on each of these valves and their subtypes.

Materials

Three different commercially available tracheostoma valves were evaluated. These valves were the Bivona I, Blom-Singer ATV and the Bivona II. These three tracheostoma valves were tested in four subtypes as described below.

Tracheostoma valve description:
Bivona I: The Bivona I (figure 4.1a) valve consists of a plastic housing with a silicone diaphragm. The valve has four subtypes, which are determined by the thickness of the silicone diaphragm. This valve is not adjustable, so when a patient requires different valve characteristics, a change of valve is required. The thicker the silicone diaphragm, the higher the closing pressure. The subtypes are called ultralight, light, medium and firm.

Blom-Singer® Adjustable Tracheostoma Valve: The Blom-Singer ATV is a relatively new valve that was introduced in 1992 (figure 4.1b). There is one configuration of this valve and it is adjustable by rotating the faceplate, thereby determining the position of the silicone diaphragm. The position of the silicone diaphragm determines the valve aerodynamic characteristics.
The Blom-Singer ATV is the only valve that facilitates the use of a heat and moisture exchanger (HME; Humidifilter). To allow comparison between the three valves we excluded this HME option during the valve measurements because of its possible influence on the valve characteristics.
The measurements of this valve were performed with the faceplate at 0°, 30°, 60° and ± 90° rotation resulting in four different valve conditions (0° being the most open valve position).

Bivona II: The Bivona II valves consist of a flat valve with a spring mechanism. The strength of the spring determines the closing pressure. Four different springs are provided with the valve, i.e., 15, 20, 25, 30 g. The Bivona II valves have a pressure relief mechanism that should keep the valve to malfunctioning during high-pressure occurrences, e.g., during coughing. The pressure relief mechanism was not tested in this study.

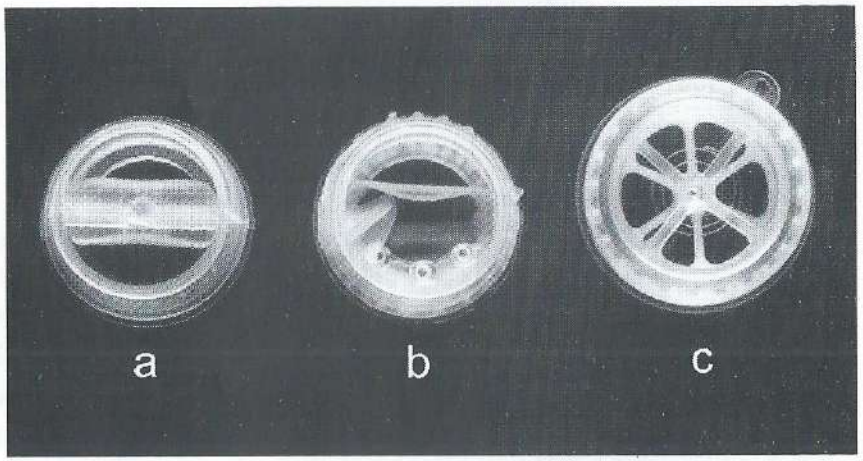

Figure 4.1: A photograph of the tested tracheostoma valves, a = Bivona I (light), b = Blom-Singer ATV at ±90° and c = Bivona II large (15 g spring). (Ratio 1:1)

Methods

Figure 4.2 is a schematic drawing of the experimental setup. A valve is placed in the universal valve housing before each measurement. The valve housing is of the same type used in the patient.

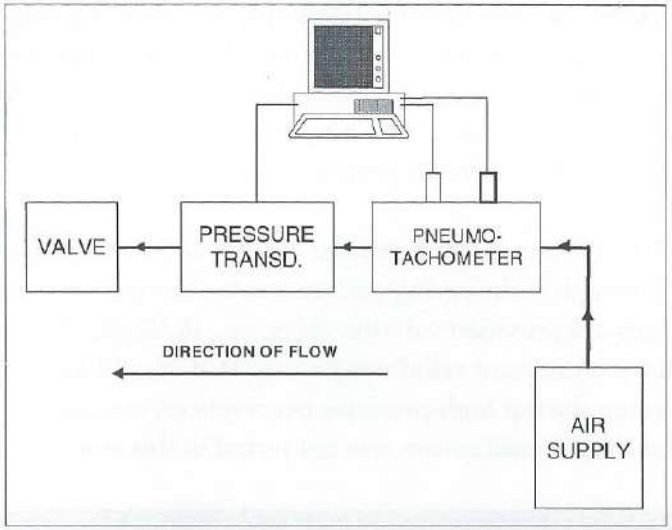

Figure 4.2: Schematic diagram of the instrumentation setup for the dynamic measurements. 1 = air supply (pump), 2 = pneumotachograph, 3 = pressure transducer, 4 = valve fixation point (universal valve housing).

The airflow for the measurements was generated by a variable electric air pump. A pressure transducer (Statham) and a pneumotachograph (Siemens) were connected in front of the tracheostoma valve, as illustrated in figure 4.2. The pressure and flow meter were linked to an IBM compatible computer through an analog-digital (AD) interface, sampling the analog transducers outputs at 100 Hz. A software data acquisition program was used. The raw signal, containing an excess of high-frequency components, was low-pass filtered after the measurements.

The airflow rate was increased gradually while the pressure and flow were simultaneously registered. The airflow rate was increased until the valve closed, instantly reducing the flow of air to zero. The resistance for airflow rates of ¼, ½, ¾ and 1 L/s were calculated for all valves, because these flow rates are representative of flows during normal rest breathing and breathing during mild exercise. From these data, the approximate closing pressure and maximum airflow were derived. Additional measurements were performed to determine the opening pressures. The measurements were repeated four times to check reproducibility.

Results

The aerodynamic characteristic curves derived from these measurements allow calculation of the maximum airflow through the devices, the resistances at given airflow rates, and the closing pressures.

Maximum Airflow. These values indicate the maximum airflows that these tracheostoma valves allow to pass through without closing. Table 1 contains the averaged maximum flow rates (in liters per second) of the valves tested and their standard deviations. The results show a high reproducibility, as indicated by the low standard deviation. The Bivona I allows the highest airflow (3.41 L/s) through the device before closing; the Bivona II with the 15g spring shows the lowest maximum airflow (1.28 L/s).

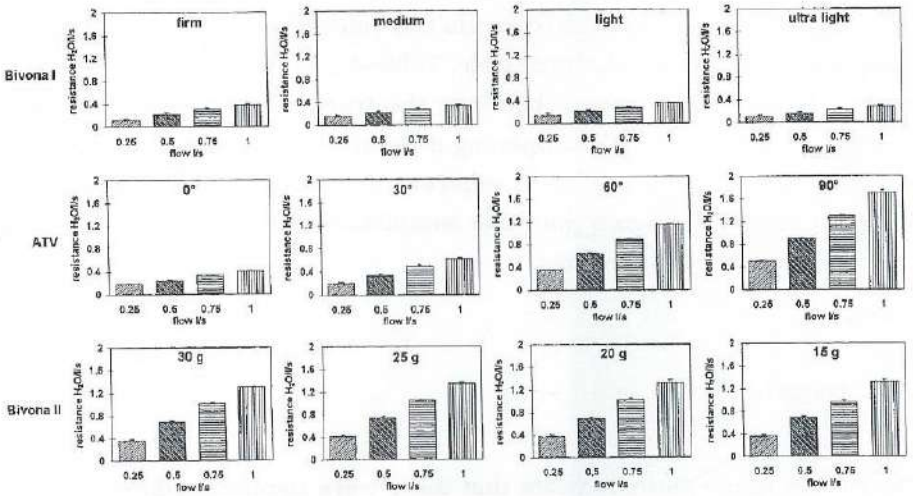

Figure 4.3: Resistances of various valves with subtypes measured at ¼, ½, ¾ and 1 L/s. Bivona I = Bivona Tracheostoma Valve I, ATV = Blom-Singer Adjustable Tracheostoma Valve and Bivona II = Bivona Tracheostoma Valve II large. Standard deviation is shown in each graph.

Resistance. The resistances of these tracheostoma valves were calculated to the patient-relevant airflow rates (rest and mild exercise breathing). The resistance (pressure/flow) of all valves at ¼, ½, ¾ and 1 L/s airflow rate are

shown in figure 4.3. In all the graphs, the standard deviation is also illustrated. These values are highly reproducible.

Closing Pressure. This closing pressure (in centimeters [H_2O]) represents the total pressure needed to result in complete tracheostoma valve closure (see table 4.1). This pressure is an indication of the expiratory effort the patient needs for achieving tracheostoma valve closure to allow phonation. The closing pressure is a summation of the opening pressure and the pressure needed to overcome the resistance of the tracheostoma valve an instant before closure. The measurements during the closing phase are less reproducible because of their highly transient nature and because of the resonance of silicone valves (Bivona I and Blom-Singer ATV) during this phase.

Opening Pressure. The opening pressure (in centimeters H_2O) represents the pressure at which the valve opens spontaneously after being closed (see table 4.1). The clinical meaning of this value is that when the endotracheal pressure (backpressure) drops to this value, the valve will open spontaneously, making speech impossible. Table 4.1 shows a considerable difference in opening pressure between the tracheostoma valves and the subtypes of the Bivona I. The opening pressure of the Blom-Singer ATV is the same for all subtypes, as is inherent to its design. Adjustablility is achieved, not by changing the valve compliance, but by merely changing the position of the diaphragm.

Discussion

The results of the study indicate that there were significant differences in aerodynamic characteristics between tracheostoma valves and their respective subtypes. These differences are not unexpected, because of the differences in valve construction.

Maximum Airflow Rate. The maximum airflow rate represents the maximum airflow rate that a tracheostoma valve will allow without closing. This maximum airflow rate represents the threshold that a patient can breathe without closing the valve. During exercise, the patient can breathe up to this threshold without having unwanted spontaneous valve closure. Patients need to be able to reach this maximum airflow rate during forced expiration, however, to make the valve closure possible when wanting to speak. Therefore, a very high threshold does not necessarily identify a better valve, since it may require much effort by the patient to close the valve. A low threshold may be disadvantageous because of the tendency for spontaneous closure during normal daily activities, although speech would be relatively effortless.

Clinically, the knowledge of the maximum airflow rates can help to deal with patient complaints about unwanted spontaneous closure during exercise, or, conversely, complaints about valve closure that requires too much effort. The Blom-Singer ATV and Bivona type II large are adjustable valves. The former is adjusted by simple rotation of the faceplate, and the latter, by replacing the spring within the valve. For a patient with a Bivona I valve, changing the maximum flow characteristics involves changing of the valve

Table 4.1: The maximum airflow rates (Max. Flow) of the three tracheostoma valves with their subtypes. The standard deviation of the repeated measurements (SD) of each valve has been calculated and given in the second column. Biv I = Bivona Tracheostoma Valve type I, ATV = Blom-Singer Adjustable Tracheostoma Valve, Biv II = Bivona Tracheostoma Valve type II large.

	Max. Flow		Closing Pressure	Opening Pressure
Valve Type	(L/s)	SD	(cm H_2O)	(cm H_2O)
Biv I Firm	3.41	0.05	27	21.5
Biv I Med	2.68	0.05	16	10.2
Biv I li	2.50	0.13	12	9.0
Biv I UL	2.31	0.06	10	7.1
ATV 0°	2.38	0.02	18	12.5
ATV 30°	2.24	0.05	18	12.5
ATV 60°	1.72	0.01	18	12.5
ATV 90°	1.68	0.02	18	12.5
Biv II 30g	1.67	0.02	12	6.9
Biv II 25g	1.94	0.06	10	5.2
Biv II 20g	1.39	0.04	6	4.2
Biv II 15g	1.28	0.04	4.5	3.0

to another subtype.

The maximum airflow rate of the Bivona II with the 25g spring is unexpectedly higher than with the 30g spring. Comparison of the springs revealed the 30g spring is shorter than the 25g spring. The springs were not erratically exchanged, since the pressure needed for total closure of the valves are in accordance with their relative strength (figure 4.3C).

The 30g spring does require a higher pressure for total closure than the 25-g spring: approximately 12 cm H_2O versus 10 cm H_2O, respectively. The reproducibility of the maximum airflow rates is good, as can be seen from the standard deviations in table 4.1.

Resistance. We looked at the resistance (pressure/airflow) of the tracheostoma valves using four different airflow rates (¼, ½, ¾ and 1 L/s). These airflow rates were used because they represent airflow rates from rest to mild exercise for healthy individuals.

The resistances of the tested valves are shown in figure 4.3. The reproducibility is good for the resistances measured, as illustrated by the standard deviations in figure 4.3.

For reference, we looked at the reported expiratory resistance of the upper airway in the literature. Although the patient is no longer able to breathe through the nose, the comparison is logical. Cole et al., report the upper airway (larynx, pharynx, and nose) expiratory resistance at rest to be 4.1 cm H_2O/L per second in healthy individuals.[5] Wheatley et al., report an expiratory nasal resistance of 3.2 and 2.0 cm H_2O/L per second at rest and during exercise, respectively.[6]

This comparison with the upper airway is important, because the tracheostoma valve should not exceed the upper airway resistance. When the resistance of a tracheostoma valve is too high, the patient will experience discomfort such as dyspnea. No data are available indicating at what airway resistance discomfort is experienced, and there is certainly great interpatient variability.

The Bivona I and the Blom-Singer ATV at 0° both have the lowest air resistances. When the Blom-Singer ATV is turned to the most closed position (± 90°) the resistance increases, as can be seen in figure 4.3. The inner diameter in the Blom-Singer ATV at 90° is considerably smaller than in the

0° position, accounting for the increase in resistance. The Bivona II has, on average, a higher resistance for all its subtypes compared to the other valves. All valves have resistances well below the reported resistance of the nose, for the four flow rates measured.

Closing Pressure. The closing pressure (in centimeters H_2O) serves as an indication of the effort needed for tracheostoma valve closure. The closing pressure is a combination of the airflow resistance through the device just before closure and the pressure needed to overcome the silicone diaphragm compliance. The closing pressure is one parameter that indicates the ease of tracheostoma valve closure. The higher the closing pressure, the more effort a patient needs to use to close the tracheostoma valve.

Each Bivona I subtype has a different silicone diaphragm thickness. These different thicknesses result in different compliances and therefore different closing pressures. The Bivona I valve (firm subtype) has the thickest silicone diaphragm and, as a result, the highest closing pressure of the valves tested (approximately 27 cm H_2O).

The Blom-Singer ATV has one closing pressure for all of its subtypes, which is consistent with its design. The adjustability of the Blom-Singer ATV is achieved by altering the position of the silicone diaphragm. This positioning does not affect the compliance of the diaphragm itself; therefore, the closing pressure of the Blom-Singer ATV remains unaltered.

The closing pressure of the Bivona II is determined by the strength of the spring used within it. The 30g spring has the highest closing pressure.

Opening Pressure. The opening pressure (in centimeters H_2O) represents the pressure at which the valve opens spontaneously after being closed (see table 4.1). The clinical meaning of this value is that when the endotracheal pressure (backpressure) drops to this value, the valve will open spontaneously, making speech impossible. A patient should not be given a tracheostoma valve with an opening pressure that exceeds the phonation pressure (endotracheal pressure needed to phonate). The phonation pressure is determined by the resistance of the voice prosthesis, the resistance of the PE segment, hypopharynx, and mouth, and the loudness of phonation. A phonation pressure of 20 to 30 cm H_2O is generally accepted

as being desirable. The Bivona I is the only tracheostoma valve that may exceed the phonation pressure in certain patients, because its opening pressure is 21.5 cm H_2O. If the opening pressure were higher than the phonation pressure, the patient would be unable to phonate, because of unwanted spontaneous opening of the tracheostoma valve. The other tracheostoma valves have a sufficiently low opening pressure and this problem should not occur.

Additional valve factors. There are other factors to be considered when choosing a tracheostoma valve. The Blom-Singer ATV currently is the only valve that allows the use of an HME. Heat and moisture exchangers help to condition the inspired air.[7,8] The air inspired through a HME is warmer and has a higher humidity, somewhat like air inspired through a normal nose. Pleghm production can often be reduced by an HME.[4] Using the HME with the Blom-Singer ATV does however, increase the airflow resistance of the valve. Whether the combined air resistance of the Blom-Singer ATV with a HME will be higher than the airflow resistance of the normal nose is unclear at this point.

All tracheostoma valves produce noise while closing, and this noise influences the intelligibility of the laryngectomized patients.[9] The extraneous noise level produced by the valves during closure was not simultaneously measured in this study. Our clinical experience with these valves does indicate differences; the Bivona valves appear to make more noise during closure. Currently, the extraneous noise production, of the tracheostoma valves is under investigation.

The Bivona valves could be improved by clearly indicating the subtype. The Bivona I would be improved by having the silicone diaphragm thickness printed on the valve or on the silicone diaphragm itself. The Bivona II would be improved by having insertable springs with different colors. With these small changes, the patient would be visually assisted in determining what valve subtype he or she is using, which is difficult at the present time.

Clinical implications. There are numerous complaints expressed by laryngectomized patients that are related to aerodynamic tracheostoma valve factors. However, the most frequent complaints are related to non-aerodynamic factors, like peristomal fixation problems of the valve housing. Nonetheless, aerodynamic-related complaints can be dealt with by using the

presented data from this study. The two most frequently heard complaints in this category are unwanted spontaneous closure and complaints of too high a resistance of the tracheostoma valve during normal breathing, resulting in shortness of breath.

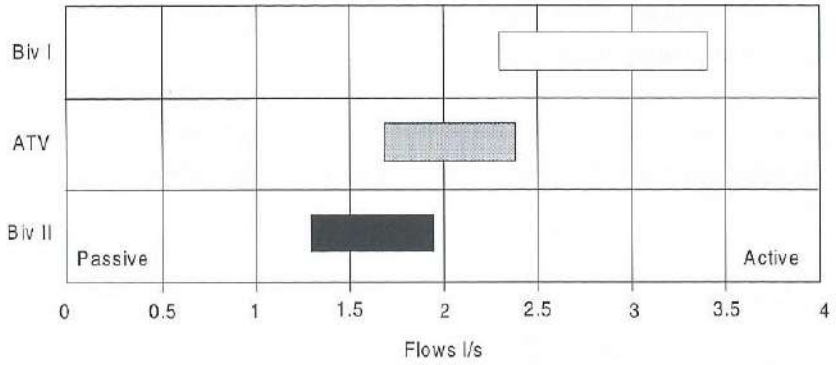

Figure 4.4: Graph with the maximum flow ranges for each valve. Biv I = Bivona Tracheostoma Valve type I, ATV = Blom-Singer Adjustable Tracheostoma Valve, Biv II = Bivona Tracheostoma Valve type II large. Low airflow rates indicate passive patients and higher flow ranges indicate more active patients.

Figure 4.4 can assist the clinician, when the tracheoesophageal speakers complain about unwanted spontaneous closure of difficulty closing the valve during speech. Figure 4.4 displays the maximum airflow ranges for the three tracheostoma valves. When unwanted spontaneous closure occurs frequently, a tracheostoma valve should be chosen that is located further to the right in figure 4.4 compared to the valve currently being used (higher maximum airflow rate). When the patient is frequently unable to close the tracheostoma valve for speech, the opposite applies (lower maximum airflow rate). A valve with a high closing pressure sometimes also results in complaints of speech that takes too much effort. Table 4.1 shows the closing pressures for the different tracheostoma valves and subtypes.

A valve with a high closing pressure sometimes also results in complaints of speech that takes too much effort. Table 4.1 shows the closing pressures for the different tracheostoma valves and subtypes.

If the patient complains about too high a resistance, a valve is needed that has a lower resistance. Figure 4.3 gives guidelines on what valves have a low resistance during resting breathing and which have a relatively high resistance. Some patients experience shortness of breath as soon as a tracheostoma valve is in place over the stoma, even with valves with low airflow resistances. This population may not be able to work with any tracheostoma valve at present.
Spontaneous frequent opening of the tracheostoma valve during speech is uncommon, but may theoretically occur with the Bivona I. Table 4.1 shows all the opening pressures; alternative tracheostoma valves may be tried.

Conclusion

Knowledge of the aerodynamics of the tracheostoma valves, as presented in this report, combined with good understanding of the patients needs such as daily physical activity, pulmonary status, peak flow capabilities, and phlegm production, may increase the success rate of tracheostoma valve use. In our clinic, the valve usage success rate is approximately 66%.[4]
Aerodynamic characteristics of tracheostoma valves, however, are additional factors that need to be considered in the attempt to optimize the process of speech without digital occlusion. It is very important to identify factors that will allow a broader use of tracheostoma valves for laryngectomized patients and allow them to regain considerable freedom and more spontaneous speech. Successful voice rehabilitation involves not only assisting the laryngectomized patient with speech, but also improving the ease and quality of speech.
A clinical study is further needed to evaluate the contribution of valve aerodynamics relative to the individual patient factors that determine successful tracheostoma valve use.

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Acknowledgments

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Manufacturers

Listed below in alphabetical order are the manufacturers of the tracheostoma valves used in this study.

Valve	Manufacturer	Address/Phone
Adjustable Tracheostoma Valve	Inhealth Technologies	1110 Mark Avenue Carpinteria, CA 93013-2918 USA (800) 477-5969
Tracheostoma Valve & Tracheostoma Valve II large	Bivona Medical Technologies, Inc.	5700 West 23rd Avenue Gary, IN 46406 USA (800) 424-8662

Chapter 5

An Efficiency Comparison of Four Heat and Moisture Exchangers Used in the Laryngectomized Patient

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Abstract

Bypassing the upper airway places the burden of humidification on the lower airway. For this reason passive heat and moisture exchangers (HMEs) are used in the laryngectomized patient in an attempt to minimize the effect of lost upper airway function. We measured efficiency, airflow resistance and calculated the costs of four HMEs used in the laryngectomized patient. The HMEs were measured according a modified International Standards Organization (ISO) 9360 standard. The airflow resistance was measured at flow rates of 15, 30 and 60 L/min. The measurements were repeated three times. Costs were calculated with two realistic scenarios. The study found that there are significant differences in moisture output and airflow resistance between the HMEs tested. There are major daily cost differences between these devices also. This study shows that filter material and size influence the HME's moisture output efficiency and airflow resistance considerably. The construction differences, filter, and housing type have great influence on the daily HMEs costs. We believe that knowledge of the efficiency in combination with the average daily costs of the HMEs allows the clinician to make a balanced choice of which filter to use.

Introduction

Air humidification in the normal respiratory tract is remarkably efficient, even at extremes of ambient temperature. The exquisite architecture of the nose and nasopharynx assures that air reaching the carina is 34°C to 35°C and relative humidity of 90% to 100%. Further warming occurs through the expanse of the lower airways until air reaches 100% saturation at 37°C in the alveolus. During exhalation, the upper airways reclaim much of the added heat and moisture, losing only a small amount to the atmosphere. During a typical day, the normal respiratory tract will lose approximately 350 kcal of heat and 250 ml of water.[1]

Total laryngectomy causes major degradation to speech and nasal functions. Speech can be regained by tracheoesophageal puncture with insertion of a silicone voice prosthesis, esophageal speech, or use of electrolarynx. Tracheoesophageal puncture is rapidly becoming the voice rehabilitation method of choice.[2] Singer and Blom first introduced an endoscopic technique for tracheoesophageal puncture and a silicone valved prosthesis in 1980.[3] The introduction of the first tracheostoma valve in 1982 (Blom-Singer) allowed some of the patients to regain speech without finger occlusion of the tracheostoma.[4] Unfortunately, not all laryngectomized patients are able to effectively use this valve mainly because of excessive phonation pressure, phlegm production and difficult peristomal fixation.[5] To date, a small number of different tracheostoma valves is available. These valves differ in valve mechanism, aerodynamic characteristics, and the ability to simultaneously use a heat and moisture exchanger.[6]

Total laryngectomy bypasses the upper airway, diminishing filtration and placing the burden of humidification on lower airway structures. This results in greater heat and water loss from the respiratory tract, increased mucus secretions and loss of normal ciliary function.[7] It has been well established that the use of a heat and moisture exchanger (HME) partly compensates for the loss of upper airway function.[8,9]

The working mechanism of a passive HME is illustrated in figure 5.1. The expired air passes through the HME, which is positioned in front of the airway. The expired air passes through the filter and deposits some of its

moisture and heat in the filter (figure 5.1A). During the inspiration the air passes back through the filter, picking up the previously deposited moisture and heat from the filter (figure 5.1B).
In the laryngectomized patient, these passive HMEs are placed over the tracheostoma by peristomal adhesion.

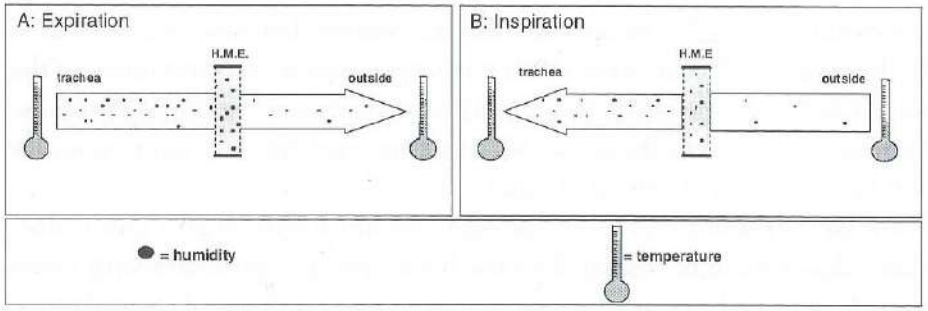

Figure 5.1: The working mechanism of a passive heat and moisture exchanger (HME) during expiration (A) and inspiration (B).

In this study we present a laboratory efficiency measurement of four HMEs according to a modified version of the International Standards Organization (ISO) 9360 test setup.[10] For each HME we measure the moisture preservation efficiency and pressure drop over the device at known airflow rates to calculate its resistance and the dead space volume. Finally, we assessed the differences in fixation and construction and calculated the costs of average daily use.

Materials

The HMEs used in this study are discussed in alphabetical order by product name (see table 5.1).

Blom-Singer HumidiFilter

This HME is a synthetic open-cell foam disc of 1¼ inches in diameter and ¼ inch thickness (figure 5.2). The filter is impregnated with chlorhexidine

and lithium-chloride. The former is used to control bacterial colonization, the latter to enhance moisture collection. The filter is used in a special Blom-Singer HumidiFilter holder that allows easy manual occlusion. Furthermore, the same filter can be used simultaneously with the adjustable tracheostoma valve.

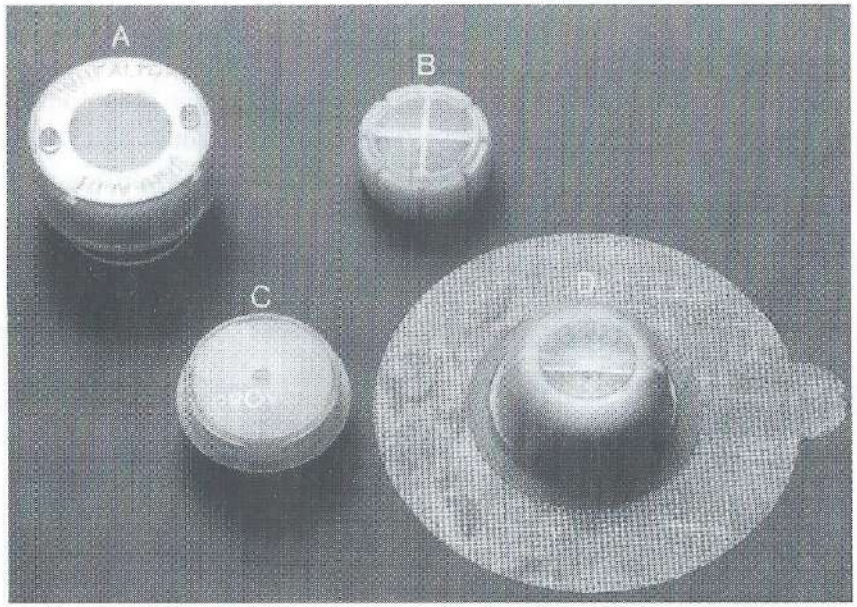

Figure 5.2: The tested devices. A, Blom-Singer HumidiFilter; B, Free Vent; C, Provox Stomafilter; and D, Stom-Vent 2.

Free Vent

The Free Vent HME is a spun-fiber filter impregnated with calcium chloride salt (figure 5.2). This hygroscopic salt is used to enhance the water preservation during expiration. The fixation of the housing is achieved with an adhesive tape that is prefixed to the disposable housing.

The Provox Stomafilter System

The Stomafilter is an open-cell foam filter impregnated with calcium chloride salt and an unknown antibacterial substance (figure 5.2). Calcium is a

hygroscopic salt used to enhance the filter's efficiency. The Provox Stomafilter has a manual valve feature to facilitate stoma closure by the patient. The patient must still use a finger to operate the valve to achieve stoma closure. The valve with the HME inside is disposable. The prefixed adhesive tape on the housing makes it an easily applied device, but it also is disposable, which causes additional costs.

Stom-Vent 2

The Stom-Vent 2 HME is an absorbent corrugated paper filter that is not impregnated with salts (figure 5.2D). This makes the total device disposable. This is the only filter that cannot be removed from its housing in cases in which the patient requires a filter change or wants the clear phlegm from the tracheostoma.

Table 5.1 Manufacturers of Heat and Moisture Exchangers Listed Alphabetically by Product.

Device	Manufacturer	Address (Phone)
Blom-Singer HumidiFilter	Inhealth Technologies	1110 Mark Avenue, Carpinteria, Ca 93013-2918 USA (800-477-5969)
Free Vent	Pharma Systems AB	Rubanksgaten 9, 741 71 Knivsta, Sweden (800-306-0594)
Provox Stomafilter	Atos Medical AB	P.O. Box 183, S-242 22 Hörby, Sweden (800-306-0594)
Stom-Vent 2	Louis Gibeck AB	P.O. Box 711, 194 27 Upplands Väsby, Sweden (800-306-0594)

Methods

All devices were tested using a modified version of the International Standards Organization (ISO) 9360 test apparatus.

The modifications to the ISO 9360 standard consist of the following:

1. ISO 9360 uses a ventilator to push gas into the system and allows it to passively exhale. In order to simulate spontaneous breathing, our system draws gas through the system and pushes gas back out. This is achieved by putting the ventilator on the opposite side of the lung model.
2. ISO has tidal volume and respiratory frequencies of 500 mL/20 bpm, 1.0 L/10 bpm, and 1.0 L/20 bpm. To more accurately represent the patients in whom we are interested, we chose a more normal tidal volume and respiratory frequency for these studies (400 mL/15 bpm).
3. Because we use a calibrated piston ventilator to simulate breathing, it is not necessary to measure tidal volume. The ventilator has a set stroke that controls volume. For this reason, we excluded the pneumotachograph. No other modifications of the ISO 9360 standard were used.

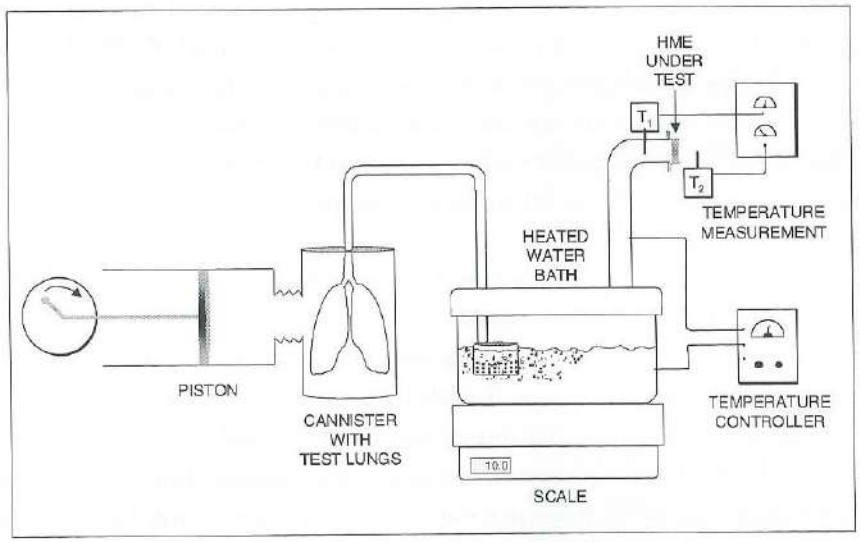

Figure 5.3: Simplified drawing of the modified International Standards Organization (ISO) 9360 test rig.

A lung model was constructed per the ISO standard, consisting of a heated water bath (Puritan Bennett, Cascade I), two rubber test lungs in a rigid chamber, and a piston ventilator (figure 5.3). The entire apparatus was mounted on a balance to determine weight loss from the water bath. Temperature of the water bath was controlled so that gas exiting the lung model was at 34 °C and 100% relative humidity. Measurements of water loss and

returned humidity were made as follows. The system was run without a device in place to establish a control for water loss (37.6 $\pm$ 1.0 mg H_2O/L). To check product consistency three of each of the devices were tested for a period of three hours each.

At the end of the 3 hour period, water loss was recorded. Moisture output was then calculated according to ISO 9360:

$$\text{moisture output} = 1 - \left(\frac{\text{water loss with HME}}{\text{water loss without HME}} \times V_I / V_E \right) \times 37.6 \quad (\text{mg } H_2O / l)$$

V_I equals inspired minute ventilation, V_E equals expired minute ventilation, and 37.6 is the absolute humidity of expired gas at 34 °C. The ISO 9360 standard does not supply a guideline on measuring the heat preservation of HMEs. For this reason we did not measure the heat preservation of the filters. However, heat preservation is inexorably related to the water preservation therefore the moisture output supplies an indication for the heat preservation also.

Pressure drop over the device was measured by directing known air flow-rates of 15 L/min, 30 L/min, and 60 L/min through the devices and measuring pressure drop using a differential pressure transducer. These flow-rates represent breathing at rest and with light exercise in humans. From the pressure drop the device resistance can be calculated.

Average daily costs were calculated using the realistic daily needs. These consisted of: one HME filter per day and application of one fixation every day. To calculate the influence of prolonged use of the peristomal fixation we calculated the daily costs when changing the fixation only once every 4 days. The estimated use of nondisposable fixation housings was assumed to be 6 months. After this period of 6 months the semipermanent housing typically needed replacement because of cracks and stiffened material. The Blom-Singer HumidiFilter holder is a device that is considered to be a nondisposable device also, therefore the price of this holder was only included once in the average daily costs calculation. Where possible, the least expensive fixation adhesives were chosen for the cost calculation. The average total costs were calculated over a period of 1 year.

Statistics

We used an one-way analysis of variance (ANOVA) to calculate significance of the differences in moisture output and the pressure drop at various air flow rates between the devices. In addition we used the Student-Neuman-Keuls test to identify which of these filters differ significantly. The SPSS 6.1 version for MS-Windows was used.

Results

Moisture Output

The Free Vent has a significantly lower moisture output compared with the three other filters. The Provox Stomafilter has a significantly lower moisture output performance than the Blom-Singer HumidiFilter and the Stom-Vent 2. There is no significant difference between the last two filters (table 5.2).

Table 5.2 Moisture Output and Pressure Drop of the Four Heat and Moisture Exchangers Measured.*

Device	Moisture Output (mg H_2O/L)	Pressure Drop (cm H_2O) 15 L/min	30 L/min	60 L/min
HumidiFilter	23.8	0.19	0.54	1.88
HumidiFilter	24.0	0.19	0.59	1.67
HumidiFilter	24.2	0.21	0.60	1.63
Free Vent	20.6	0.25	0.67	1.90
Free Vent	20.1	0.23	0.63	1.76
Free Vent	21.2	0.25	0.64	1.99
Stomafilter	23.1	0.20	0.61	1.93
Stomafilter	22.8	0.23	0.64	2.01
Stomafilter	23.5	0.24	0.63	1.98
Stom-Vent 2	24.5	0.16	0.47	1.09
Stom-Vent 2	24.1	0.14	0.51	1.06
Stom-Vent 2	24.7	0.17	0.48	1.14

Pressure Drop

There are significant differences in pressure drop at 15 L/min, 30 L/min ($P < 0.001$) and 60 L/min ($P < 0.0001$) between the HMEs. The Stom-Vent 2

has a significantly lower pressure drop at 60 L/min than the three other filters. The Blom-Singer HumidiFilter has a significantly lower pressure drop compared with the Provox Stomafilter at 60 L/min.

Costs

The daily costs of the four devices are shown in table 5.3. The daily costs of changing both the filter and the fixation to the tracheostoma once a day are listed in column one. The daily costs in column two represent the costs when changing the filter daily and changing the fixation once every 4 days.

Table 5.3 Average Daily Costs of Various Heat and Moisture Exchangers (US $).

Device	Changing filter and fixation every day	Changing filter every day and fixation every 4 days
HumidiFilter	1.31	1.14
Free Vent	3.75	1.88
Stomafilter	4.80	2.89
Stom-Vent 2	2.25	NA

In figure 5.4, the cumulative costs are calculated for each device over a period of 1 year. The solid markers represents the cumulative costs when changing the filter and the fixation daily. The hollow markers represents the cumulative costs when changing the filter once a day and the fixation every 4 days. The Stom-Vent 2 filter cannot be changed separately from the fixation housing, therefore there is no line with hollow markers in figure 5.4 for this device.

Discussion

The addition of a HME increases the amount of water vapor in the patient's inspired gas. For example, in our laboratory setting the absolute humidity in the room (23°C and 35% relative humidity) would be 5.0 mg H_2O/L. In order to raise the temperature and water content of this gas to 37 °C and 100% relative humidity, the respiratory tract would have to add 39 mg H_2O/L gas. With a HME in place the temperature and humidity of

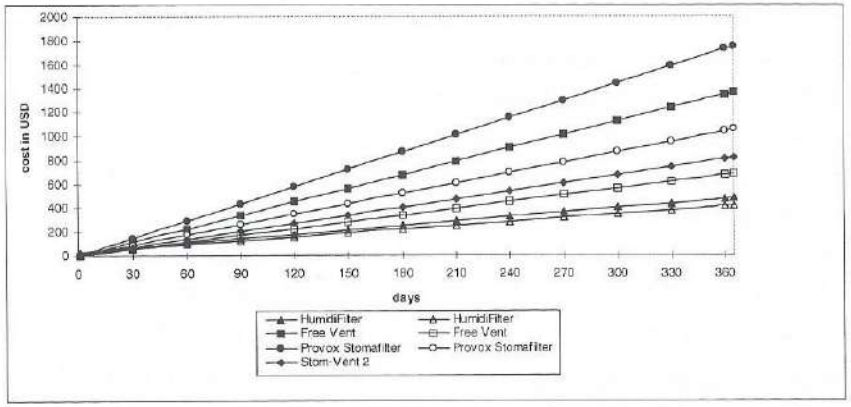

Figure 5.4: The cumulative annual costs of using heat and moisture exchangers. Solid marker represents filter and fixation change once a day; open marker represents daily filter change and fixation change every 4 days. Note that the Stom-Vent 2 does not have a separate fixation housing, meaning the housing must be changed daily.

the patient's inspired gas increases resulting in an absolute humidity of 22.8 mg H_2O/L, more than quadrupling environmental conditions. In this situation the burden on the lower respiratory tract is considerably less and integrity of the respiratory mucosa should be maintained. However, not all laryngectomized patients benefit from a HME, because some patients cannot maintain a HME over their tracheostoma because of extreme phlegm production. Others do not seem to react to the HME during use, which is probably because of the permanent damage to the lungs from years of smoking. When advising a patient to use a HME it is probably best to use one with a high water preservation efficiency (high moisture output). None of the filters tested here are as efficient in water preservation as the nose. In addition, aspects like ease of use and daily costs are important factors to consider.

Moisture Output

In our measurement setup, according to the modified ISO 9360 standard, a hypothetical perfect HME (100% efficiency) would result in a moisture output of 37.6 mg H_2O/L. This HME would not lose any water. On the contrary, a HME without water preservation capabilities would result in a moisture

output of 0. Therefore, a higher moisture output from an HME implies better water preservation in the patient.
The Stom-Vent 2 and the Blom-Singer HumidiFilter have the highest water preservation abilities, on average: 24.4 mg H_2O/L and 24.0 mg H_2O/L, respectively. These two filters show a significantly better moisture output performance than the Provox Stomafilter and the Free Vent filter (table 5.2). The Stom-Vent's absorbent corrugated paper proves to be a very efficient water preservation concept, despite the absence of hygroscopic salt impregnation. The Blom-Singer HumidiFilter has the largest total filter volume, which may explain its high moisture output characteristics. This filter uses lithium chloride, a hygroscopic salt, to improve the water preservation abilities.
The Provox Stomafilter has a better performance than the Free Vent, 23.1 mg H_2O/L and 20.6 mg H_2O/L on average, respectively. Both of these filters contain calcium chloride as the hygroscopic salt.
Our data suggest that the filter's water preservation abilities mainly depend on filter design and not so much on the use of hygroscopic salt. This study shows that the absorbent corrugated paper filter is very effective, even in a relatively small device. The open cell foam filters measured in this study worked well, but use hygroscopic salts. We believe that the Blom-Singer HumidiFilter outperforms the Provox Stomafilter mainly because of the total filter volume. Apparently, the spun fiber filter (Free Vent) is not as efficient a principle as the other filters.

Pressure Drop

The pressure drop is the pressure needed to achieve a certain airflow rate through the HME. The pressure drop over the filters was measured using airflow rates of 15 L/min, 30 L/min and 60 L/min which represent breathing at rest and light exercise. The Stom-Vent 2 has a significantly lower pressure drop when compared with the three other filters. The Blom-Singer HumidiFilter has a significantly lower pressure drop compared with the Provox Stomafilter. No significant differences in pressure drop were found between the Provox Stomafilter and the Free Vent filter.

Device resistance can be calculated by the following formula:

$$resistance = \frac{pressure\ drop}{airflow\text{ - }rate}$$

The average device resistance at 60 L/min for the Blom-Singer HumidiFilter is 1.7 cm H_2O/L/s, for the Free Vent 1.9 cm H_2O/L/s, for the Provox Stomafilter 2.0 cm H_2O/L/s and for the Stom-Vent 2 1.1 cm H_2O/L/s.
For reference and comparison, we obtained the reported expiratory resistance of the upper airway from literature. Cole et al., report the upper airway (larynx, pharynx, and nose) expiratory resistance at rest to be 4.1 cm H_2O/L/s, in healthy individuals.[11] Wheatley et al., report an expiratory nose resistance of 3.2 and 2.0 cm H_2O/L/s at rest and during exercise, respectively.[12] The comparison with the upper airway is important because the HME's resistance should not exceed the upper airway resistance. When the resistance of a HME is too high, the patient is likely to experience discomfort such as dyspnea. All of the devices tested do not exceed the physiological upper airway resistance.
It has been reported that some airway resistance increases the tissue oxygen saturation. These authors explain their findings by the shift of the equal pressure point because of increased airway resistances resulting in opening up of collapsed lower airways, thereby improving the ventilation to perfusion ratio.

Construction & Costs

The daily cost of using a HME is important because the laryngectomized patient often uses such a device for a prolonged period of time or even for the remainder of his life. If the use of a HME is not fully or partly paid for by a health insurance company the expense can be high. Therefore, we looked at the daily and annual costs during two estimated average scenarios, the first being daily filter and fixation change, the second being daily filter change and housing fixation change every 4 days. The Stom-Vent 2 is the only one-piece device (filter and housing being one), therefore the second scenario is not applicable for this filter.
The Blom-Singer HumidiFilter has the most time-consuming fixation

method of the tested devices. When a patient needs to reapply the fixation housing he needs to remove the double-sided tape disc from the semipermanent housing. After the removal of the old double-sided tape disc, the patient needs to apply a new tape disc to the housing before placing it over the tracheostoma. It is cost-effective to use a semipermanent housing while only changing the adhesive tape, but it implies a sacrifice on ease of use. This is the least expensive of the measured devices in both hypothetical cost scenarios. Changing the housing every 4 days has little effect on the daily costs because the fixation tape disc is inexpensive (table 5.3). The annual costs for this filter would be $479.37 and $415.49 for both situations, respectively.

The Free Vent filter uses disposable fixation housings and is therefore easy to apply to the peristomal skin. One disadvantage of this device is the removal of the filter from the fixation housing when in place. The manual advises to use a special metal hook to remove the filter from the housing, but this makes the procedure more complicated for the patient. The Free Vent HME is the second most expensive filter during scenario one. However, when the fixation is changed every 4 days the daily costs drop, becoming the second cheapest device. The annual costs for this filter would be $1368.75 and $684.38 for both situations, respectively.

The Provox Stomafilter is the most expensive device among the HMEs tested. In both scenarios this filter turns out to be the most expensive, however this device has a manual valve to assist the patient in closing his stoma for speech. The annual costs for this filter would be $1752.00 and $1053.94 for both situations respectively.

The Stom-Vent 2 is an one-piece, totally disposable device. This HME is probably the easiest to apply to the peristomal skin. Because of this one-piece concept, the patient cannot remove the filter from the housing when he wants to clean phlegm from his stoma. The patient has to remove the entire device and reapply it again afterwards. The Stom-Vent 2 costs could only be calculated according scenario one. The annual cost of using this filter is $821.25.

As indicated in this article, we like to stress the importance to take multiple HME factors into consideration before choosing a HME.

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Chapter 6

Aerodynamic Properties of Five Different Voice Prostheses Used in the Laryngectomized Patient

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Submitted

Abstract

Since the introduction of the total laryngectomy for extensive or recurrent laryngeal cancer, voice restoration has become important. Voice prostheses are widely used for this purpose. The prostheses vary in characteristics: there are differences in insertion and fixation but also the aerodynamic characteristics of the prostheses are important. We measured five different types of low-pressure voice prostheses in a newly developed test setup. This computerized setup automatically measures and accurately calculates the aerodynamic characteristics.

The results show differences between the tested types of voice prostheses in pressure/flow profiles, pre-load and in one prosthesis inadequate closure of the valve.

The data presented in this article will help the clinician to decide on which prosthesis to use and hopefully to increase the success rate of tracheoesophageal speech in the laryngectomized patient.

Introduction

It is generally accepted that tracheo-esophageal speech with a voice prosthesis results in the best voice quality after total laryngectomy. This method of voice rehabilitation was first introduced by Blom-Singer in 1979.[1] Furthermore, tracheo-esophageal puncture (TEP) has a high success rate of 80 percent and more with relatively few complications.[2-4] One of the drawbacks of TEP assisted speech is the requirement of digital occlusion of the tracheostoma, needed to divert the air from the lungs to the esophagus. Realizing this disadvantage, Blom-Singer introduced a tracheostoma valve in 1982 that allowed speech without digital stoma occlusion.[5] In the years that followed other tracheostoma valves have been introduced.

Unfortunately, not all laryngectomized patients are able to use a tracheostoma valve. Prior work done by our group showed that approximately 60% of the laryngectomized patients could successfully use a tracheostoma valve. Factors that determine successful tracheostoma valve use are, among others, low phlegm production and low endotracheal phonation pressure.

High phlegm production is frequently seen in the laryngectomee because of the absence of air conditioning by the nose and mucosal damage to the lungs due to years of smoking.

The endotracheal phonation pressure is the pressure needed to enable air shunting from the trachea through the voice prosthesis into the esophagus to produce voice. This endotracheal phonation pressure is determined by three factors: voice prosthesis aerodynamics, pharyngo-esophageal resistance for airflow and loudness of speech. A low endotracheal phonation pressure is beneficial for the patient because it results in less effort to speak and improves the chance of successful use of tracheostoma valves. In order to achieve the lowest endotracheal phonation pressure in the individual patient it is important for the clinician to know the different aerodynamic characteristics of the available voice prostheses.

In this manuscript we present the *in vitro* aerodynamic characteristics of five low resistance voice prostheses used in voice rehabilitation after total laryngectomy.

Materials

The following low-pressure voice prostheses were used:

Blom-Singer indwelling low-pressure voice prosthesis (Gelcap): This device is a low resistance flap valve prosthesis that is inserted into the tracheo-esophageal (TE) fistula through the tracheostoma (frontloading) (figure 6.1A).

Groningen Ultra Low resistance (thick): This device is a modified version of the low resistance Groningen slit valve prosthesis (figure 6.1B). This prosthesis is inserted into the fistula through the mouth with the aid of a guidewire (backloading).

Provox prosthesis: This flap valve device is inserted through the mouth with the aid of a guidewire (figure 6.1C).

Provox2 prosthesis: This prosthesis is a modified version of the Provox device. The Provox2 allows for both the backloading and frontloading principle (figure 6.1D).

VoiceMaster: This is a recently developed ball-valve frontloading device (figure 6.1E).

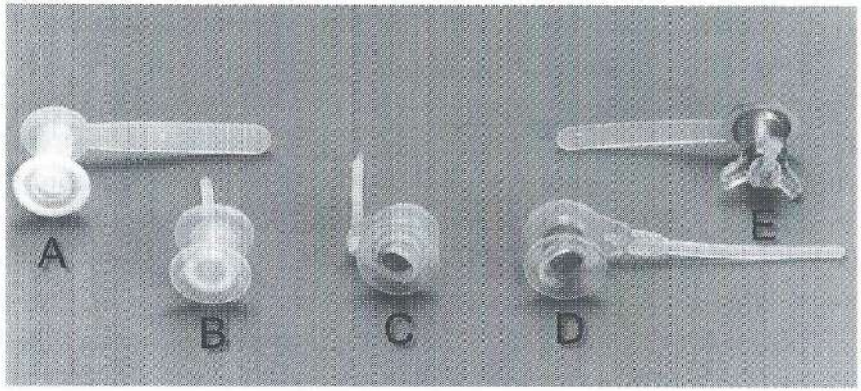

Figure 6.1: Photograph of the 5 prostheses types used in this study. A) Blom-Singer Gelcap (indwelling low resistance) prosthesis, B) Groningen Ultra Low resistance (thick), C) Provox prosthesis, D) Provox 2 prosthesis and E) VoiceMaster prosthesis.
Ten prostheses of each type were used in this study to enable us to calculate the mean values and standard deviations of the aerodynamic characteristics of each prosthesis type. All devices were directly obtained from the manufacturers.

Methods

Voice prostheses contribute to the endotracheal phonation pressure in the laryngectomized patient. We simulated the in vivo situation with a custom made setup, in order to determine the aerodynamic characteristics of several types of voice prostheses and their contribution to the endotracheal phonation pressure.

The built setup consists of an airflow regulating pressure controller, a mass flow meter, an accurate pressure transducer and a personal computer equipped with data acquisition software to analyze the generated data.

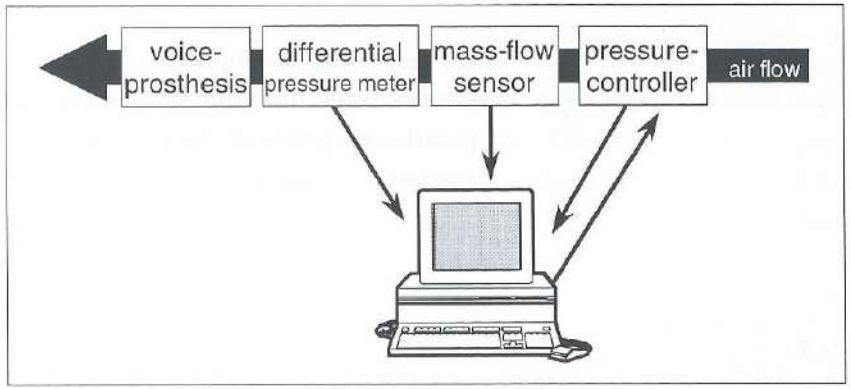

Figure 6.2: Simplified schematic drawing of the setup used. The small arrows indicate the communication between controlling and sensor devices and the computer. The big arrow indicates the air flow direction.

Specific characteristics of the setup (figure 6.2):

Pressure controller (Brooks Rosemount): used to regulate the airflow through the prosthesis to achieve a similar condition as in humans. The pressure controller regulated the airflow to obtain a semi-saw-tooth pressure pattern with one-minute intervals. Airflow used in this study ranged from 0 l/s. to 0.35 l/s.

Mass flow meter (Honeywell & Sierra Instruments): used because this device is independent for pressure and temperature changes and has a high accuracy.

Accurate pressure transducer (Setra model 206): differential pressure-measuring device, used to measure the pressure-drop over the prostheses.
Personal Computer: Pentium 200 MHz with an analog-digital digital-analog converter (National Instruments).
Data acquisition software (LabVIEW 4 for Windows 95, National Instruments): used to control the pressure controller and thus regulate the air flow through the devices and to acquire the multi-channel input from the sensors used and to perform the data analyses. Each prosthesis underwent a ten-minute period of testing before the data from the sensors was recorded into the computer. Furthermore, each prosthesis was measured ten times to see whether any variations in the measurements occurred.

Because of the high accuracy of the test setup the following aerodynamic data can be measured: air flow/pressure curves, differences within one prosthesis type and between different prostheses, pre-load (the pressure needed to open the valve of the voice prosthesis), inadequate valve closure (air leakage).

Results

From the acquired data of the performed in vitro measurements the airflow – pressure relations can be determined. The acquired data have been plotted into graphs, generating airflow – pressure curves, as illustrated in figure 6.3.

The plotted data illustrate the pressure decrease (cm H_2O) caused by the voice prosthesis at different airflow rates (l/s). The standard deviations, an indication of production variability of a prosthesis type, have been incorporated into the plot. Furthermore, pre-load and inadequate valve closure can be read from the graph.
Air flow/pressure curves and standard deviations:
As illustrated in figure 6.3, the differences in pressure-drop between the

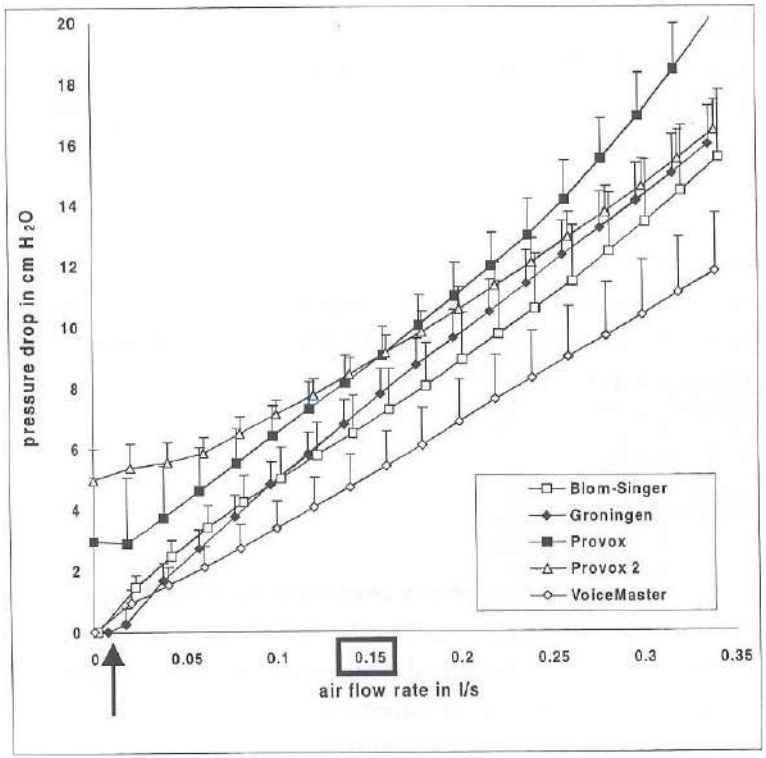

Figure 6.3: Graphs of aerodynamic curves of 5 different voice prostheses. Pressure drop (cm H_2O) over the prosthesis is plotted against the airflow rate (liters per second). The standard deviation is included for each prosthesis. The arrow indicates non-closure of the Groningen Ultra Low resistance (thick) prosthesis. 0.15 on the X- axis is boxed to indicate the average air flow rate during comfortable speech in the patient.

devices become more apparent at higher airflow rates. These differences are most pronounced between the Provox and the VoiceMaster. When compared, the Provox2 has an improved airflow/pressure-drop curve to the Provox. The VoiceMaster prosthesis causes the lowest overall pressure drop, the Blom-Singer Gelcap prosthesis the second lowest.
All standard deviations are limited; the Groningen Ultra Low resistance (thick) has the lowest standard deviations.

Pre-load:
The Provox and the Provox2 are the only two devices with a pre-load, respectively 3.0 and 4.9 cm H_2O. Variations in pre-load were measured and when Provox and Provox2 are compared a higher variation is seen for the latter.

Inadequate valve closure:
Only one prosthesis failed to close completely after valve opening: the Groningen Ultra Low resistance (thick). The arrow in figure 6.3 indicates the inadequate valve closure.

Discussion

Voice prosthesis assisted speech is a very successful method of voice rehabilitation after total laryngectomy. This technique gained wide acceptation after its introduction by Blom and Singer in 1979. In the years that followed many improvements in prosthetic aspects and surgical procedures have allowed the patient to regain a better voice production.
Several enhancements on the prosthetic side have been made over the years, these include tracheostoma valves, first introduced by Blom-Singer in 1982, and modifications in voice prostheses design.[5-11] Important aspects to pursue in voice prosthetic design are frontloading easy insertion, indwelling (semi-permanent fixation of the voice prosthesis in the TE-fistula of the patient) and low resistance to airflow.
The ease of voice production in the voice prosthesis using laryngectomized patient, is dependent on the endotracheal phonation pressure (EPP). The height of the EPP is formed by the sum of the pressure drops over the voice prosthesis, the PE-segment, mouth and nose as a function of airflow. As the voice prosthesis influences the EPP, a prosthesis with low resistance to airflow is favorable and will decrease the effort needed for phonation.
It has been stated in previous publications[12-13] that minimal resistance to airflow through a voice prosthesis is expected to enhance the efficiency of

tracheoesophageal voice production. Also, a low endotracheal phonation pressure is one of the prerequisites to allow tracheostoma valve assisted speech, because there will be less traction to the airtight fixation of the valve to the peristomal skin.[14] On the other side, a certain device resistance is assumed to be critical because of gastric distention due to esophageal insufflation with low resistance voice prostheses.[15] The exact reason for this observation is not well understood.
Previously, EPPs in patients using a low resistance voice prosthesis have been reported to range from 20 to 30 cm H_2O during comfortable phonation. To be able to estimate the relative contribution of the voice prosthesis to the endotracheal phonation pressure, we need to know the average airflow in the patient. Furthermore, we need to assume that the *in vitro* obtained data are applicable for the *in vivo* situation.
In vivo measurements have indicated that the average flow rate through the prosthesis is 0.15 (0.07-0.30) liters per second (LPS) at comfortable phonation.[8] Others report that the average air flow at comfortable phonation ranges from 0.10 to 0.30 LPS.[16]
We present the *in vitro* aerodynamic data of five different low resistance voice prostheses that are currently available on the market. The airflow range used in this study is from 0.0 to 0.35 LPS to ensure the full range of flow rates as seen in the patient.

Airflow/pressure curves:
The introduction of low resistance voice prostheses has greatly improved the successful rehabilitation of the laryngectomized patient. All the measured prostheses are of the low resistance type. There are evident differences between the prostheses as can be seen in the curves in figure 6.3. These differences are most notable in the low airflow ranges between 0 to 0.05 l/s and in the high airflow ranges above 0.3 l/s. It is most desirable to have a voice prosthesis that has a minimal raise in pressure-drop as the air flow increases, thus resulting in a horizontal graph.
The variability between prostheses of the same type is indicated by the standard deviation plotted in figure 6.3. Minimal variability between one prosthesis type in highly desirable because that makes the device more

predictable for the clinician and patient. All standard deviations are limited; especially those of the Groningen low resistance prosthesis.
According to the literature the average *in vivo* air flow rate during comfortable speech through the prosthesis is 0.15 l/s. If indeed the average airflow during comfortable phonation in voice prosthesis assisted speech is 0.15 l/s and the average endotracheal phonation pressure is approximately between 20 and 30 cm H_2O, the relative prosthesis contribution can be calculated using figure 6.3.[14,17] At an airflow of 0.15 l/s the pressure drop of the Provox prosthesis is 8.7 cm H_2O. This corresponds with 43% and 29% of 20 and 30 cm H_2O endotracheal phonation pressure measured during comfortable speech with this prosthesis. This means that if the assumptions are valid this prosthesis accounts for respectively 43% and 29% of the total resistance of the phonatory tract during comfortable phonation. With these results one can conclude that the voice prosthesis still contributes considerably to the endotracheal phonation pressure. Nonetheless, we need to be careful to translate *in vitro* measurements to the *in vivo* situation until accurate *in vivo* measurements have been published.

Pre-load:
The pre-load is the pressure needed to open the voice prosthesis valve.
Our average pre-load (opening pressure) value of 3.9 cm H_2O for the Provox voice prosthesis is not in agreement with the value of 0.3 cm H_2O found by others.[17] We believe that our setup is more accurate than those used in earlier studies. In our study we have used a very accurate pressure controller to vary the pressure in front of the prosthesis, enabling us to determine the pre-load. Other researchers have used airflow controlling devices to perform the *in vitro* measurements that make it nearly impossible to measure the prosthesis pre-load. Heaton et al. measured the pre-load (which they called the forward opening pressure) using prostheses that were taken straight out of their boxes.[18] We believe that the values obtained from a prosthesis that is taken directly out of its box are not representative because we observed that pre-load values are lower after the initial measurement. For that reason we insufflated the prosthesis for a period of ten minutes to obtain a steady state before recording the measurements.

The importance of the pre-load of prostheses is not well understood. A pre-load may help prevent unwanted valve opening during swallowing and normal respiration which frequently can be seen in patients using a device without a pre-load. Currently, there are no data available on the role of valve opening during swallowing or respiration and the occurrence of aerophagia. A slight pre-load may be of further importance for the lifespan of the prosthesis as it may prevent early leaking. This needs further clinical assessment. A slight pre-load may be desirable, but a too high pre-load would be counter productive in voice production as it would require more effort from the patient to pass air through the prosthesis.

Inadequate valve closure:
A voice prosthesis should close adequately to prevent leakage of esophageal contents into the trachea. The Groningen Ultra Low resistance (thick) prosthesis does on average not fully close as indicated by the arrow in figure 6.3. The fact that this prosthesis leaks air does not directly imply that it would also leak fluids from the esophagus into the trachea since fluids need a bigger opening compared to air. However, our data suggest that this prosthesis is prone to leakage. Another problem with a prosthesis leaking air would be that it makes esophageal speech difficult. The ingestion of air needed for esophageal speech is difficult because the air leaks from the esophagus away through the voice prosthesis.

Conclusions

There are many aspects of a voice prosthesis to consider before choosing one for the laryngectomized patient. The aerodynamic characteristics are just one aspect to take into account. It is generally assumed that a low resistance prosthesis is beneficial for voice production. It is not understood whether aerophagia increases when using prosthesis with a lower resistance although there has been a report on this.
We developed a setup to perform in vitro tests with different types of low

resistance voice prostheses. The results revealed different aerodynamic characteristics for all of these types.

As the airflow resistance influences the endotracheal pressure needed for comfortable voice production, it is important that the clinician is aware of these aerodynamic differences.

Two of the measured prostheses have a pre-load but the exact benefit of the pre-load is for as yet not well understood. It may be favorable in preventing the aerophagia detected in users of the low resistance prostheses. One of the measured prostheses showed inadequate valve closing.

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Chapter 7

Aerodynamic and Sound Intensity Measurements in the Tracheoesophageal Speaking Patient

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Submitted

Abstract

One of the reasons why tracheoesophageal voice results in a better voice quality when compared to the other voice rehabilitation methods is that the lungs supply the driving force and air volume. We built a computer assisted setup to measure the aerodynamics in tracheoesophageal voice production. We measured endotracheal phonation pressures, endoesophageal pressures, sound intensity and trans-source airflow.
We compared our prosthesis pressure drop values with *in vitro* data and found that there are some differences. We also found that the "low resistance" voice prostheses contribute up to 40% of the total pressure drop during phonation. Different tracheostoma occlusion methods did not have effect on the aerodynamics. One patient that had had a jejunal graft for reconstruction showed, not unexpectedly, extremely different aerodynamic values.
In this paper we present the average trans-source airflows, endotracheal phonation pressures, endoesophageal pressures and sound intensities for various phonatory tasks.
We were unable to define optimal airflow rates or optimal resistance values for sound production in the pharyngo-esophageal segment.

Introduction

Following total laryngectomy voice rehabilitation becomes very important. Tracheoesophageal voice (TE-voice) generally gives a better voice quality compared to esophageal voice. This has been demonstrated by various authors who used computer voice analysis to measure the voice characteristics in different voice rehabilitation methods.[1,2] An encountered problem, is the semi-periodic characteristics of the sound produced in the pharyngo-esophageal segment (PE-segment): the new sound source in voice prosthesis assisted and esophageal speech. When the sound signal is displayed onscreen it is possible to visually recognize the fundamental frequency of the semi-periodic waveforms. Once the periodic signal is manually determined, the computer will calculate the usual voice characteristics like shimmer and jitter.
One of the reasons why voice prosthesis assisted speech results in a better voice quality than esophageal speech is that the lungs supply the air needed to induce the resonance in the PE-segment. Esophageal speech relies on air swallowed into the esophagus. However, the air volume swallowed in esophageal speech is limited to approximately 75 ml a time with average airflow rates of 27-72 ml/sec., frequently resulting in a non-fluent speech.[3]
In an attempt to quantify the aerodynamics in voice prosthesis speech we built a computer setup. Our goal was to measure the airflow through the voice prosthesis and phonatory tract, measure sound pressure levels and calculate pressure drops over the voice prosthesis and PE-segment.
Key questions were: How much does the voice prosthesis contribute to the overall pressure drop of the phonatory tract?, What is the average airflow rate in voice prosthesis assisted speech as a function of the sound pressure levels?
If the aerodynamics of voice prosthesis assisted voice production are better understood it may be possible to suggest alterations in prosthetic design or surgical procedures in order to improve TE-voice, although surgical procedures are of course mainly dictated by oncological considerations.

Materials

A specially built computer setup consisting of pressure transducers, mass flow meter and sound intensity meter, was used for the acquisition of the aerodynamics. In the following the setup is described in more detail.

Computer and software.
A computer (Pentium 200 MHz) with a National Instruments 16 bit AD-DA interface card was connected to all the sensors. The software (LabVIEW 4.01, National Instruments, Texas) sampled all the unfiltered signals at 1 kHz. After the acquisition the same software was used to analyze the data. Figure 7.1 is a screen capture of the analyzing software designed for this study. The position of the sensors needed to acquire the necessary data is shown in figure 7.2.

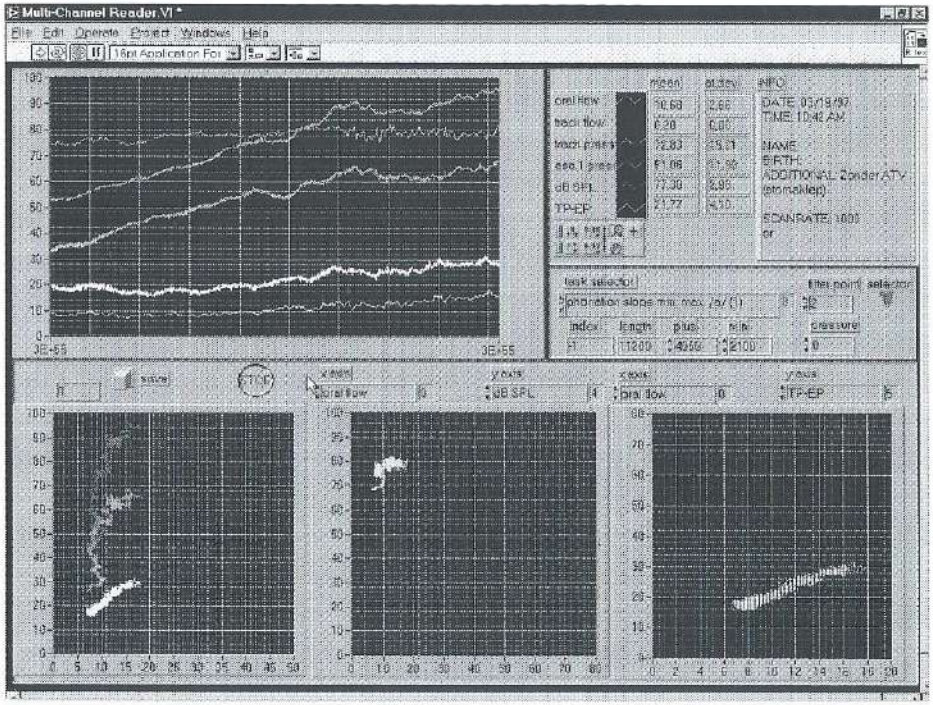

Figure 7.1: Screen capture of the data analysis software (LabVIEW) used in this study.

Tracheal pressure. The endotracheal phonation pressure is the driving force behind the airflow generated through the voice prosthesis and the phonatory tract. This measurement is needed to calculate the pressure drop over the voice prosthesis and the remaining phonatory tract. The tracheal pressure was measured using a pressure transducer (Setra Systems, Inc., Acton, MA USA) connected to the tracheostoma using a modified Blom-Singer tracheostoma valve housing.

Endo-esophageal pressure. To be able to calculate the pressure drop over the voice prosthesis and the PE-segment and remainder of the phonatory tract the endo-esophageal pressure is needed. A Mikrotip pressure transducer (Millar Instruments, Texas) was placed at the level of the voice prosthesis in the esophagus. The correct position of the pressure sensor tip was visually verified using a scope through the voice prosthesis.

Oral airflow meter. We needed to measure the oral and nasal airflow since it equals the airflow through the voice prosthesis and phonatory tract (trans-source airflow). In stead of using a pneumotachometer, which has inherent resistance to airflow, mass flow sensors were used (Sierra Instruments, California and Sensor Medics, New York) that show no pressure drop within the airflow range generated by laryngectomees during voicing and therefore do not influence the pressure recordings made.

Sound level meter. In voice recording a 30 cm mouth to microphone distance is normally used. In our measurement setup the sound would we damped by the mask and flow meter that is placed over the mouth and nose which is mandatory for the trans-source airflow recording. This would result in an inaccurate sound intensity recording. Recognizing this problem we placed a microphone into the mask itself at 5 cm distance from the mouth. By placing a microphone closer to the mouth the dB levels recorded would be significantly higher compared to a microphone place at 30 cm mouth-microphone distance. However, we calibrated the sound intensity recording in such a way that the microphone appeared to be at 30 cm

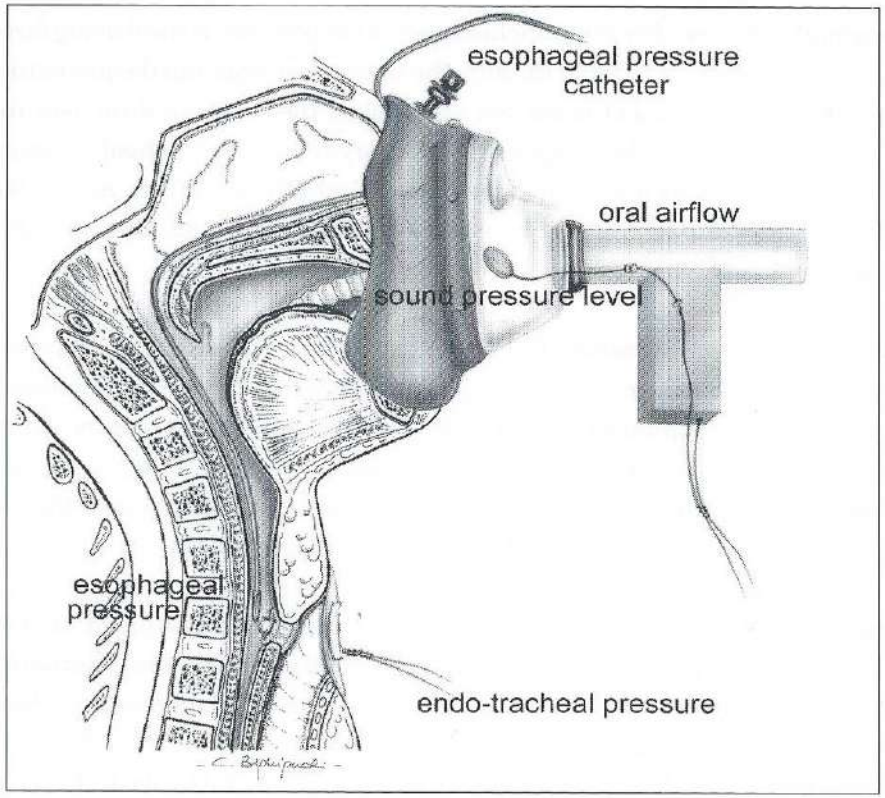

Figure 7.2: Drawing of the sensor array placement. The esophageal pressure is measured with a Mikrotip pressure transducer on a catheter through the nose with the actual sensor placed in the esophagus at the level of the voice prosthesis. Trans-source airflow is measured with a mass flow meter attached to the facemask. Sound intensity is measured with a microphone placed inside the facemask at 5 cm distance from the mouth. Endotracheal phonation pressure is measured with a pressure sensor attached to a tracheostoma valve housing.

distance from the mouth. The microphone signal was passed through the dB meter (FJ electronics, Denmark) into the computer.

All sensors were calibrated. The Mikrotip pressure catheter was calibrated in a 37°C water column before each measurement because these devices show the highest tendency to shift.

Methods

All patients had to be tracheostoma valve users in daily life since we also wanted to measure the aerodynamic effects of different stoma occlusion methods. When a laryngectomized patient came to our out patient office for oncological follow up, the patient was asked to participate.
The measurement procedure was explained to the patient and no attempt to persuade the patient was made. All laryngectomees included in this study participated on a voluntary basis. One was included in this study even though she was not a tracheostoma valve user. This patient had a jejunal graft reconstruction with a typical hypotonic voice. Table 1 is a summary of the patient data. After calibration and placement of the sensors, as illustrated in figure 7.2, the patient performed various phonatory tasks.

Table 1: Patient group data. m/f = gender, m = male, f = female. Age = current age. Tumor= tumor origin, G = glottic, SG = supraglottic, E/H = esophageal & hypopharynx. RT = radiation therapy in Gray (Gy). Operation: TL = total laryngectomy, FND = functional neck dissection, Pha & jej = laryngopharyngotomy + jejunum graft. Neurectomy = neurectomy of the plexus pharyngeus. EMG = intra-operative EMG controlled neurectomy. Myotomy = myotomy of the cricopharyngeal muscle and or constrictor muscles. Prosthesis = prosthesis used by the patient, VM = VoiceMaster, P2 = Provox 2.

mf	Age	Tumor	$_{p}$TNM	RT (Gy)	Operation	Neurectomy	Myotomy	Prosthesis
m	50	G	$T_3N_0M_0$	56	TL & FND	Yes (EMG)	No	P2
m	55	G	$T_1N_0M_0$	66	TL	Yes	Yes	VM
m	64	SG	$T_4N_0M_0$	70	TL & FND	Yes	No	P2
f	69	SG	$T_4N_0M_0$	-	TL	Yes	No	P2
m	67	SG	$T_3N_1M_0$	68	TL & FND	Yes	No	VM
m	77	SG	$T_2N_0M_0$	56	TL & FND	No	Yes	P2
m	79	G	$T_3N_1M_0$	60	TL & FND	No	Yes	VM
f	58	E/H	$T_4N_0M_0$	60	Pha & jej	n/a	n/a	VM

The patient was asked to phonate /a/ at a for him or her comfortable loudness level with manual occlusion of the tracheostoma. Consecutively, the patient was asked to phonate /a/ as loud as possible and as soft as possible. All recordings were repeated 3 times.
For the seven patients who use a tracheostoma valve in daily life, the whole recording was repeated using this valve instead of using manual

tracheostoma occlusion. Since manual occlusion requires a finger to push on the tracheostoma and a tracheostoma valve has the tendency to push away from the tracheostoma we wanted to measure whether these different occlusion methods had any effect on the pressure drop at the level of the PE-segment. In total the average duration of the recording, including the placement of the sensors, was 20 minutes.
With the data collected from these recordings we calculated the average endotracheal phonation pressure, endoesophageal pressure and airflow at comfortable, maximum and minimum /a/ phonation. The average prosthesis pressure drop is the subtraction of the average endotracheal phonation pressure and the average endoesophageal pressure.

Results

The average endotracheal and endoesophageal pressures, the phonatory airflows (trans-source airflows), sound pressure levels and voice prosthesis pressure drops for 3 different phonatory tasks during manual occlusion are shown in table 7.2. The standard deviations are in parenthesis.

Table 7.2: Summary of the average values for minimum, comfortable and maximum phonation during manual occlusion. Standard deviations are in parenthesis.

Phonation Task	Endo-tracheal pressure *cm H_2O*	Endo-esophageal pressure *cm H_2O*	Phonatory airflow *ml per second*	Sound pressure Levels *dB SPL*	Pressure drop voice prosthesis *cm H_2O*
Minimum	27 (6.5)	18 (7.8)	133 (55)	68 (6.4)	10 (3.1)
Comfort.	33 (8.7)	22 (9.5)	167 (72)	73 (5.6)	12 (3.6)
Maximum	67 (7.3)	52 (21)	267 (122)	81 (6.5)	16 (4.5)

To determine whether there is a relationship between the trans-source airflow and generated sound intensity we plotted the data (figure 7.3). Six patients show an increase in sound intensity with increased trans-source airflow. It is apparent that there is considerable variability between the patients. One patient showed an increased sound intensity with a trans-source airflow decrease.

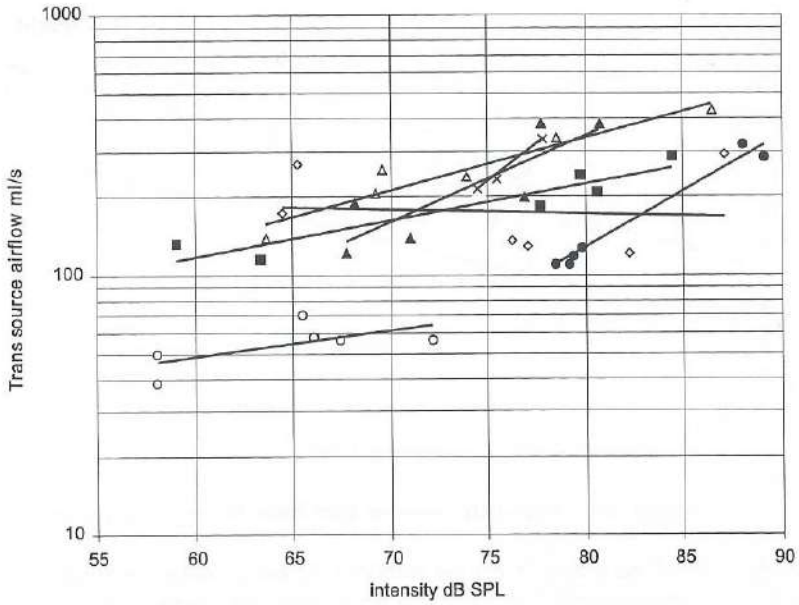

Figure 7.3: Intensity as a function of trans-source airflow. Lines are plotted for the first 7 individuals.

Comparison between* in vivo *and* in vitro *voice prosthesis data

In an earlier study, we measured the *in vitro* aerodynamic characteristics of various voice prostheses.[4] When we compare the *in vitro* aerodynamic data with the data presented in this study there are some differences. Figure 7.4 illustrates the *in vivo* measurements with a best linear curve fit. In addition the *in vitro* data is also plotted to illustrate the differences.

Voice prosthesis share in airway resistance

The overall contribution of the voice prosthesis pressure drop to the total endotracheal phonation pressure varies for different phonation tasks. The percentage of pressure drop caused by the voice prosthesis decreases as the patients talk louder. At minimal /a/ phonation the overall voice prosthesis share of the total endotracheal phonation pressure is 37%. At comfortable phonation this percentage decreases to 36% while at maximum phonation loudness its share is 24%.

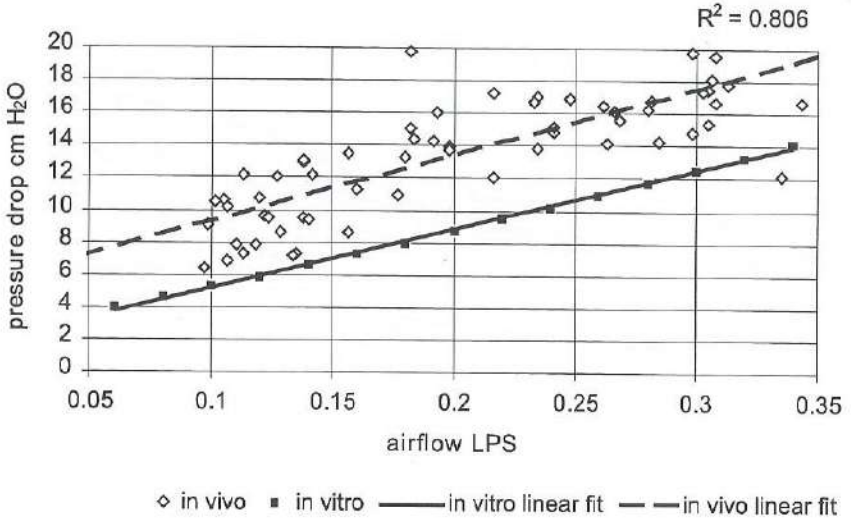

Figure 7.4: A plot of the airflow in liter per second (LPS) and pressure (cm H_2O) curves of in vitro and in vivo measurements. For the in vivo and in vitro measurements the best linear fits were used.

Aerodynamic differences in a laryngectomee with a jejunal graft

One patient in this study had a total laryngectomy in combination with a pharyngectomy with jejunum reconstruction. As expected, the average airflow through the phonatory tract is higher compared to the airflow seen in the "normal" laryngectomee. The values range from 298 ml/s for comfortable phonation up to 773 ml/s at maximum phonation. Endotracheal phonation pressures are 19 cm H_2O and 40 cm H_2O for comfortable and maximum phonation respectively. In this patient the voice prosthesis accounts for approximately 80% of the total pressure drop during phonation. Airflow resistances (table 7.3) are lower than those of the other patients. The last column of table 7.3 shows the airflow resistance of the jejunal graft, mouth and nose.

Table 7.3: Airflow resistance in laryngectomized patient with jejunal graft reconstruction. Resistance of phonatory tract includes the voice prosthesis resistance. The voice prosthesis resistance is excluded in the jejunal graft resistance column. LPS = liter per second.

Phonation Task	Flow phonatory *ml per sec*	Airflow resistance phonatory tract *cm H_2O/LPS*	Airflow resistance jejunal graft only *cm H_2O/LPS*
Minimum	368	34.6	10.9
Comfort.	298	62.6	13.1
Maximum	773	51.5	6.7

Influence of different tracheostoma occlusion methods

Seven of the patients use a tracheostoma valve on a regular daily basis. These 7 patients were measured once with manual tracheostoma occlusion and once with tracheostoma valve occlusion. We wanted to determine whether these different occlusion methods would influence the airflow and pressure drop over the PE-segment.

Table 7.4: Summary of the average values for minimum, comfortable and maximum phonation during tracheostoma valve occlusion.

Phonation task (n=7)	Endo-tracheal pressure *cm H_2O*	Endo-esophageal pressure *cm H_2O*	Phonatory airflow *ml per second*	Sound pressure levels *dB SPL*
Minimum	28.4	20.1	143	69.3
Comfort.	32.1	24.2	150	73.0
Maximum	66.0	54.2	245	80.2

When we compare the data obtained during the two different stoma occlusion methods (table 7.2 and 7.4) we do not calculate a statistical difference.

Discussion

The main advantage of tracheoesophageal voice over esophageal voice is that the lungs are the driving force behind the new voice source. As the TEP patient phonates, air passes through the voice prosthesis past the PE-segment (neoglottis) towards the mouth and nose. In the PE-segment, the

airflow induces resonance which is the new voice source. In this study we present aerodynamic data obtained from TEP speaking laryngectomees. Table 7.2 is a summary of the average values found in our study. We found an average intensity level at comfortable speech of 73 dB SPL and a intensity range of 13 dB. Robbins *et a.l*, found a mean intensity for vowel phonation of 88.1 dB SPL which seems substantially higher but needs to be adjusted before comparing it with our data.[1] They used a mouth-microphone distance half of that of ours (approximately reducing the difference by 6 dB). The intensity range they found was approximately 10 dB for /a/ phonation. For laryngeal vowel phonation, they found an average intensity of 76.9 dB SPL. Pauloski *et al.*, found a mean intensity of 74.41 for reading again at a mouth-microphone distance of 15 cm.[2]

In healthy laryngeal speakers, the average airflow during comfortable speech is approximately 200 ml/s. In our group the average airflow rate at comfortable voicing is 167 ml/s with an average endotracheal phonation pressure of 33 cm H_2O, resulting in a airway resistance of 198 cm H_2O/LPS (liter per second). The resistance of the PE-segment and remaining phonatory tract without a voice prosthesis is 132 cm H_2O/LPS. These values are much higher than the ones found in healthy subjects (on average 35.7 cm H_2O/LPS).[5] Since the airflow rates are comparable, these differences are mainly contributed to the difference of trans-source pressure drop.

The individual variations of sound intensity versus airflow or pressure drop of the PE-segment are too great to draw any definite conclusions. Figure 7.3 shows the intensity (dB SPL) as a function to trans-source airflow. One of the seven patients showed an increased intensity with a decrease of the trans-source airflow. We cannot explain this observation. The individual variations are of course dictated by the extent of the surgery, myotomy or neurectomy and radiation therapy. A considerably larger patient group is needed to define the PE-segment aerodynamics in relation to surgery extent, myotomy of the cricopharyngeal & constrictor muscles, neurectomy of the plexus pharyngeus and radiation therapy.

In vivo and in vitro prosthesis differences

Since the first introduction of a voice prosthesis researchers and manufacturers have improved designs. One of the improvements has been the reduction of voice prosthesis resistance to airflow. Nowadays, all voice prostheses are so called low resistance devices. The differences between these devices have been measured in vitro.[4,6-14] It is more challenging to measure voice prosthesis performance in the patient. It requires the cooperation of the patient and a more complex sensor array setup. Our data show that voice prostheses measurements carried out in patients have approximately a 4 cm H_2O higher pressure drop at all airflows (figure7.3). However, the difference is limited and can be explained by the following reasons.

All prostheses measured *in vivo* were not new. The average age of these devices was 6 weeks and it is well known that prosthesis resistance increases with age. The reason for this is the deterioration of the silicone by microbial attack and possibly by the wear and tear of the prosthesis due to usage. This can be verified by removing the prosthesis from the patient and measure it in a in vitro laboratory setup. In order to minimize the burden to the patient we have rejected this procedure. Another possible explanation for the difference is that *in vivo* measurements are less accurate since the small transducers are inferior to the ones used *in vitro*. Small transducers appear to have inherent inaccuracies partly because of temperature scale shift and their tiny design.

Furthermore, the voice prosthesis valve may be affected by the moist esophageal environment. A wet voice prosthesis is likely to show an increased resistance.

Voice prosthesis share in airway resistance

The share of voice prosthesis pressure drop in the total pressure drop varies with the airflow rate. At low airflow rates, like those generated during minimum and comfortable phonation, pressure drop over the voice prosthesis is approximately 37% of the endotracheal phonation pressure. At higher airflow, as observed during maximum phonation, voice prosthesis pressure drop is 16 cm H_2O at an airflow of 267 ml/sec. At these airflow rates the voice prosthesis accounts for 24% of the endotracheal phonation pressure (= total pressure drop).

During /a/ phonation the PE-segment is the narrowest part of the phonatory

tract. The physical aspects of the PE-segment are mostly dictated by surgery and radiotherapy. It has been recognized that tracheoesophageal voice rehabilitation is enhanced by surgical procedures as neurectomy and myotomy which avoid hypertonicity of the cricopharyngeal and inferior constrictor muscles. In our patient group it is apparent that the PE-segment has the greatest share of the total pressure drop especially at higher airflow rates.

Aerodynamic differences in a laryngectomee with a jejunal graft

One patient had a reconstruction with a jejunal graft and therefore has a typical hypotonic voice which is substantially worse than that of a "normal" laryngectomee. This is the only patient in this study unable to use an adjustable tracheostoma valve since the closing and opening pressures are in the range of the endotracheal phonation pressures. This is in agreement with our earlier work on tracheostoma valve aerodynamics in which we explain that the endotracheal phonation pressure needs to be higher then the opening and closing pressures of the tracheostoma valve to keep it closed during phonation.[15]

At these high average airflow rates, the maximum phonation time (not measured in this study) has to be shorter, simply because the estimated maximum phonation time is the generated airflow divided by the maximum expiratory long volume. The airflows generated during speech are substantially higher while the pressures needed to generate these flows are substantially lower.

Influence of different tracheostoma occlusion methods

The seven patients who use a tracheostoma valve in daily life were recorded twice. First, a recording with manual occlusion was made followed, by a recording using tracheostoma valve occlusion. Since manual occlusion requires a finger to push on the tracheostoma and a tracheostoma valve shows the tendency to push away from the tracheostoma we wanted to measure if these different occlusion methods had any effect on the pressure drop at the level of the PE-segment.

Patients and doctors often have the impression that vocal intensity with manual occlusion at times is higher than with occlusion with the aid of a

tracheostoma valve. This subjective observation could not be substantiated since all parameters measured in this study showed no statistical significance. This is in accordance with earlier acoustic research that showed no acoustic differences between the two occlusion methods.[2]

Conclusion

Even though tracheoesophageal voice generally results in an acceptable and usable voice quality our data clearly show that the effort needed to speak is relatively high.

We evaluated sound intensity and aerodynamic characteristics. Voice quality, however, also is determined by many other parameters such as fundamental frequency (f_0), f_0 range, phonation time are important parameters also.

The aerodynamic characteristics of voice production are determined by prosthetic factors and PE-segment tissue factors. Lowering voice prosthesis resistance decreases the effort needed for voice production. Myotomy of the cricopharyngeal and constrictor muscles and neurectomy of the plexus pharyngeus diminishes the chance of spasm and hypertonicity of the PE-segment. Unfortunately, it is difficult to predict to what extent the aerodynamic and voice characteristics are influenced by these procedures. The great variability of pharyngeal tissue quality which is dictated by the extent of the surgery and radiotherapy makes it very difficult to define the optimal PE-segment aerodynamic properties. We were unable to define optimal airflow rates or optimal airflow resistance for sound intensity production in the PE-segment.

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Chapter 8

Vocal Efficiency in Tracheoesophageal Phonation

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Submitted

Abstract

In tracheoesophageal voice, the pharyngo-esophageal segment is the new sound source or neo-glottis. Within this neoglottis aerodynamic energy is transformed into acoustic energy. The vocal efficiency is a value that expresses how efficient this energy transformation takes place.
In this paper we describe how we measured the necessary data to be able to calculate aerodynamic power and acoustic power. From these values we calculated the vocal efficiencies and compared them with normal laryngeal vocal efficiencies. We also looked at the effect of different sound intensities on vocal efficiency.
Vocal efficiency in laryngectomized patients is lower compared to laryngeal speakers. Tracheoesophageal voice requires much more effort from the patient, to phonate compared to the normal situation. For this reason we looked at the energy loss caused by the voice prosthesis and its influence on the vocal efficiency. Vocal efficiency increases with lowering the airflow resistance of voice prostheses. Apart from allowing air passage towards the esophagus a voice prosthesis needs to keep esophageal content out of the trachea. Lowering the resistance to airflow of voice prosthesis may very well diminish its other functions.

Introduction

Laryngeal voice production is an aerodynamic-myoelastic event.[1] In other words, voice production is determined by the interaction of glottal airflow, subglottic pressure and position and tension of the vocal cords. Following total laryngectomy a neoglottis or pharyngo-esophageal (PE) segment is created. Although the precise boundaries of this PE-segment are not well defined, it is the new location of voice production. Alaryngeal voice production, as is the case in tracheoesophageal (TE) voice, has been reported to be solely an aerodynamic event.[2] Researchers have stated that "there is no evidence to support the view that laryngectomized individuals are capable of altering the level of muscular activity within the PE-segment on a systematic basis to pretune, control, or influence the vibratory rate of this sphincter".[3] At a later date, researchers found some evidence for incon-sistent fundamental frequency (F_0) modulations contributed to aerodynamic-myoelastic events. However, they concluded F_0 modulation is always mediated on an aerodynamic basis and variably by additional myoelastic events.[4]
The superior TE-voice quality compared to esophageal voice quality has been demonstrated in the past.[5-8] The difference in voice quality between these two alaryngeal voice production methods is mostly contributed to the origin of the driving force. Esophageal voice production is based on swallowing air (approximately 80 ml) followed by reversing the airflow direction which induces resonance.[9] Esophageal voice production allows little intentional aerodynamic control. In TE-voice, the lungs are the driving force behind the pressure resulting in the airflow needed to induce resonance in the PE-segment. The obvious advantage is the greater air volume but also the intentional driving pressure control. The vibratory segment is supposed to be at the same level for both methods.
Voice production can be seen as a process of energy transformation. Aerodynamic power generated by the lungs is transformed into sound energy at the level of the PE-segment. This transformed energy is passed as sound through the remaining vocal tract and exits the mouth. From sound intensity recordings the acoustic power can be calculated. The efficiency of this process of energy transformation is called vocal efficiency. We describe the vocal effi-

ciency of TE-voice and compare it with laryngeal vocal efficiencies. In addition we measured the aerodynamic power loss by the voice prosthesis.

Materials

To achieve our goal of measuring aerodynamic power and acoustic power we built a computer setup. In the following section the setup is discussed in detail.

Computer and software. A computer (Pentium 200 MHz) with a National Instruments 16 bit AD-DA interface card was connected to all the sensors. The software (LabVIEW 4.01, National Instruments, Texas) sampled all the unfiltered signals at 1 kHz. After the acquisition the same software was used to analyze the data.

Endo-tracheal pressure. The endotracheal phonation pressure is the driving force behind the airflow generated through the voice prosthesis and the phonatory tract. This measurement is needed to calculate the aerodynamic power. The endo-tracheal pressure was measured using a pressure transducer (Setra Systems, Inc., Acton, MA USA) connected to the tracheostoma using a modified Blom-Singer tracheostoma valve housing.

Endo-esophageal pressure. To be able to calculate the power loss over the voice prosthesis and calculate the aerodynamic power directly below the PE-segment we had to measure the pressure at the level of the voice prosthesis in the esophagus. A Mikrotip pressure transducer (Millar Instruments, Texas) was placed through the nose in the esophagus at the level of the voice prosthesis. The correct position of the pressure sensor tip was visually verified using a scope.

Oral airflow meter. We needed to measure the oral and nasal airflow since the sum of these values is essential for the aerodynamic power calculations. Instead of using a pneumotachometer, which has inherent resistance

to airflow, mass flow sensors were used (Sierra Instruments, California and Sensor Medics, New York) which show no pressure drop within the airflow range generated by laryngectomees during voicing and therefore do not influence the pressure recordings made.

Sound intensity meter. In our measurement setup, we placed a mask with airflow sensor over the mouth and nose to record the trans-source airflow. Due to the mask the recorded sound would be damped if the microphone was placed at the usual 30 cm mouth to microphone distance. Recognizing this problem, we placed the microphone in the mask itself at a distance of 5 cm. Of course, this shorter mouth to microphone distance results in high sound intensities levels therefore we calibrated this registration to match 30 cm distance. The microphone signal was passed through the dB meter (FJ electronics, Denmark) into the computer.

All sensors were calibrated. The Mikrotip pressure catheter was calibrated in a 37°C water column before each measurement because these devices show the highest tendency to scale shift.

Methods

When a laryngectomized patient came to our out patient office for oncological follow up, the patient was asked to participate. The measurement procedure was explained to the patient and no attempt to persuade the patient was made. All laryngectomees included in this study participated on a voluntary basis. In total eight patients participated. Seven patients had a "normal" laryngectomy, one patient had a laryngo-pharyngectomy followed by a jejunal graft reconstruction. Table 8.1 shows a summary of the patient data.
After calibration and placement of the sensors, the patient performed various phonatory tasks. The patient was asked to phonate /a/ at a for him or her comfortable loudness level with manual occlusion of the tracheostoma. Consecutively, the patient was asked to phonate /a/ as loud as possible and as soft as possible. All recordings were repeated 3 times.

Table 8.1: Patient group data. m/f = gender, m = male, f = female. Age = current age. Tumor = tumor origin, G = glottic, SG = supraglottic, E/H = esophageal & hypopharynx. RT = radiation therapy in Gray (Gy). Operation: TL = total laryngectomy, FND = functional neck dissection, Pha & jej = laryngopharyngotomy + jejunum graft. Neurectomy = neurectomy of the plexus pharyngeus. EMG = intra-operative EMG controlled neurectomy. Myotomy = myotomy of the cricopharyngeal muscle and or constrictor muscles. Prosthesis = prosthesis used by the patient, VM = VoiceMaster, P2 = Provox 2.

m/f	Age	Tumor	pTNM	RT (Gy)	Operation	Neurectomy	Myotomy	Prosthesis
m	50	G	$T_3N_0M_0$	56	TL & FND	Yes (EMG)	No	P2
m	55	G	$T_1N_0M_0$	66	TL	Yes	Yes	VM
m	64	SG	$T_4N_0M_0$	70	TL & FND	Yes	No	P2
f	69	SG	$T_4N_0M_0$	-	TL	Yes	No	P2
m	67	SG	$T_3N_1M_0$	68	TL & FND	Yes	No	VM
m	77	SG	$T_2N_0M_0$	56	TL & FND	No	Yes	P2
m	79	G	$T_3N_1M_0$	60	TL & FND	No	Yes	VM
f	58	E/H	$T_4N_0M_0$	60	Pha & jej	n/a	n/a	VM

Energy calculations

Aerodynamic power was calculated as follows:

$$P_A \text{ (watts)} = P_t \times U \times 10^{-4}$$

in which P_t is the tracheal pressure (cm H_2O) and U is the average airflow in cm^3/s.

Acoustical power was calculated as follows:

$$P_R \text{ (watts)} = A \times 10^{dB\ SPL/10} \times 10^{-12}$$

In which A is the surface of the plane of the intensity measurement in m^2 and dB SPL is the sound pressure level in dB.[10]

Since the intensity measurement was calibrated as if the microphone was placed at a distance of 30 cm from the mouth the following surface calculation was used.

$$A \text{ } (m^2) = 2\pi r^2$$

We assumed that sound intensity is constant on the surface of the hemisphere facing the patient. The sound energy on the other half of the sphere was neglected. A in our setup is 0.56 m^2.

The power loss in the voice prosthesis can be calculated by subtracting the esophageal aerodynamic power from the (tracheal) aerodynamic power.

The esophageal aerodynamic power was calculated as follows:

$$P_{EA} \text{ (watts)} = P_e \times U \times 10^{-4}$$

in which P_e is the esophageal pressure (cm H_2O) and U is the average airflow in cm^3/s.

In other words, voice prosthesis power loss is:

$$P_{loss} \text{ (watts)} = P_A - P_{EA}$$

Results

Energy calculations

Table 8.2 to 8.4 were constructed using the equations described in the method section and the average airflow, pressure and intensity data from our measurements. In table 2 the power and vocal efficiency calculations for the seven "normal" laryngectomees during comfortable /a/ phonation are given.

Table 8.2: Acoustic power, aerodynamic Power and vocal efficiency during comfortable /a/ phonation.

	Vocal efficiency during comfortable /a/ phonation		
Subject	Acoustic Power (x 10^{-6} watts)	Aerodynamic Power (watts)	Vocal Efficiency (x 10^{-5})
1	4.8	0.51	0.94
2	33	0.61	5.5
3	49	0.44	11
4	9.3	0.29	3.1
5	28	0.49	5.7
6	1.9	0.81	0.24
7	20	0.70	2.9
Average	13	0.60	2.2

In table 8.3, the average acoustic power, aerodynamic power and vocal efficiency at minimum, comfortable and maximum phonation of the seven total laryngectomees are given.

Table 8.3: Average acoustic, aerodynamic power and vocal efficiency for three different phonatory tasks.

	Averages for minimum, comfortable and maximum /a/ phonation		
Phonation Task (n=7)	Acoustic Power ($\times 10^{-6}$ watts)	Aerodynamic Power (watts)	Vocal Efficiency ($\times 10^{-5}$)
Minimum	3.3	0.35	0.9
Comfortable	13	0.60	2.2
Maximum	67	1.97	3.4

For comparative purposes one patient with a jejunal graft reconstruction was measured. Vocal efficiency is dramatically worse compared to the average vocal efficiency of the "normal" laryngectomees (table 4).

Table 8.4: Acoustic power, aerodynamic power and vocal efficiency data of a patient with jejunal graft.

	Vocal efficiency during /a/ phonation (jejunal graft)		
Phonation Task (n=1)	Acoustic Power ($\times 10^{-6}$ watts)	Pulmonary Power (watts)	Vocal Efficiency ($\times 10^{-5}$)
Minimum	0.031	0.47	0.0065
Comfortable	2.2	0.55	0.39
Maximum	1.2	3.07	0.039

Discussion

During voice production aerodynamic energy is transformed into sound energy. In non-laryngectomized patients the voice production efficiency is called the vocal efficiency. Vocal efficiency is an indication of how efficient the transformation of energy takes place. Vocal efficiency is calculated by dividing the output sound power by the aerodynamic power.
The efficiency of sound production of the PE-segment (neoglottis) in the laryngectomized patient can also be calculated with the vocal efficiency equation. However, in laryngectomees the vocal efficiency is reduced by the voice prosthesis. The voice prosthesis diminishes the effective aerodynamic power but by itself does not contribute to the sound production. In

other words, the voice prosthesis causes a aerodynamic power loss during phonation. In our study, the average power loss caused by the prosthesis is 0.14, 0.22 and 0.50 watts during minimum, comfortable and maximum phonation, respectively. These values are considerable compared to the total aerodynamic power.
In figure 8.1, the vocal efficiency data from our study and that from Schutte's work on laryngeal vocal efficiency is plotted. The vocal efficiency reported for normal laryngeal speech increases with the sound intensity.[10-12] In our group of patients (n=7) an increase in vocal efficiency with increased sound intensity is also observed (figure 8.1). Patient eight, who had a jejunal graft reconstruction after laryngo-pharyngectomy, does not show this phenomenon.

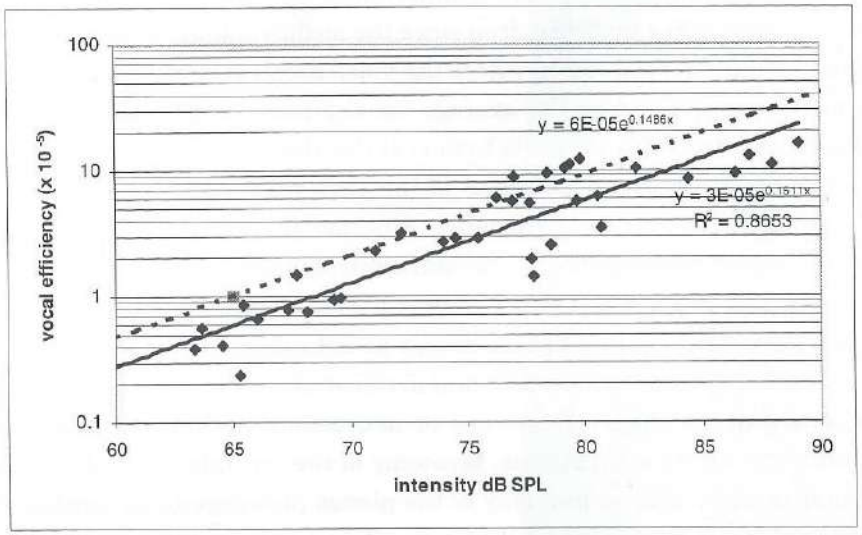

Figure 8.1: A graph of the average vocal efficiency versus average sound intensity (solid line) n=7. The dashed line (taken from Schutte pp. 93) is the average vocal efficiency in normal subjects.[10]

In our patient group, the average vocal efficiency is 2.2×10^{-5} during comfortable speech (average intensity 73.7 dB SPL). During maximum phonation the vocal efficiency increases to an average of 3.4×10^{-5} (average intensity 80.7 dB SPL) which is, as expected, considerably below the vocal efficiency of laryngeal speech (figure 8.1). Patients compensate for these low

vocal efficiencies with high aerodynamic power input. The actual average sound intensities of the "normal" laryngectomees during comfortable phonation are in the range of laryngeal sound intensities, 73 dB SPL and 76.9 dB SPL respectively.[5] In healthy laryngeal speakers the average trans-source airflow during comfortable speech is around 200 ml/s with typical endo-tracheal phonation pressures between 5 and 10 cm H_2O.[4] In our group the average airflow rate at comfortable phonation is 167 ml/s with an average endotracheal phonation pressure of 33 cm H_2O, resulting in a airway resistance of 198 cm H_2O/LPS. The resistance of the PE-segment and remaining phonatory tract without the voice prosthesis is 132 cm H_2O/LPS. These values are much higher than the ones found in healthy subjects which is on average 35.7 cm H_2O/LPS.[13] These differences are contributed to the difference of transsource pressure drop since the airflow rates are comparable.
In the hypothetical situation where the voice prosthesis would not cause a aerodynamic power loss the average vocal efficiency would be 3.6×10^{-5} (64% better) and 4.5×10^{-5} (32% better) at the above mentioned intensities. For this reason, further reduction of the airflow resistance of voice prostheses increases the vocal efficiency. Whether it is technically feasible to further reduce the resistance and still control leakage of esophageal content remains to be seen. It has been reported that aerophagia increases with a lower airflow resistance of voice prostheses.[14]
The individual voice variations found in our study are of course dictated by the extent of the surgery, myotomy or neurectomy, radiation therapy and possibly by the voice prosthesis. Myotomy of the cricopharyngeal and constrictor muscles and neurectomy of the plexus pharyngeus diminishes the chance of spasm and hypertonicity but at the same time it is difficult to predict to what extent the aerodynamic and voice characteristics are influenced by these procedures. Blom et al., found that neurectomy resulted in higher fundamental frequencies compared to a myotomy group.[8] Apart from optimizing the PE-segment for voice production, the PE-segment should allow good swallowing. These two functions are likely to be non-complimentary PE-segment functions since Pauloski et al., showed that the neurectomized patient group had significantly lower oropharyngoesophageal swallow efficiencies compared to other groups.[15]

The great variability of pharyngeal tissue quality which is dictated by the extent of the surgery and radiotherapy makes it very difficult, or maybe even impossible, to define the optimal PE-segment characteristics. A considerable bigger patient group is needed to try to define the PE-segment aerodynamics in relation to surgery extent, myotomy of the cricopharyngeal and constrictor muscles, neurectomy of the plexus pharyngeus and radiation therapy.
Ultimately, sound producing voice prostheses may be the solution to create an acoustically better and less effort requiring alaryngeal voice. Oncological treatment considerations will always overrule the for voice optimal PE-segment characteristics.

Conclusion

Our data clearly show that, although tracheoesophageal voice generally results in an acceptable and usable voice quality, the effort needed to speak is much higher than in healthy subjects. The aerodynamic power is an indication of the effort needed for voice generation. The efficiency of TE-voice production is lower compared to laryngeal voice production but does show an increase when sound intensity increases, a known phenomenon in healthy subjects. One patient in the study group had a laryngo-pharyngotomy with a jejunal graft reconstruction and showed low vocal efficiency. The effective aerodynamic power used for voicing can be increased by lowering voice prosthesis airflow resistance. Lowering the aerodynamic power loss by the voice prosthesis increased vocal efficiency and lowers the effort needed for speech.

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Summary and Conclusions
&
Samenvatting en Conclusies

Summary and Conclusions

This thesis describes the physical aspects of prosthetic tracheoesophageal voice rehabilitation in the laryngectomized patient.

There is need for an anatomic study of the tracheostoma and related structures for prosthetic design and evaluation. All common imaging techniques were inadequate either because the usefulness was low (ordinary CT-scans) or the technique would be too dangerous (silicone print of the tracheostoma). In the literature we found reports on a non-invasive technique called stereolithography that had been used on bony reconstructions. Chapter 2 describes how we used stereolithography to make 3D models of the tracheostoma and related structures. In total, we made eight soft tissue and eight air contour 3D models of eight different patients. All models show high detail although some artifacts are visible due to movement of the patient during the CT-scanning phase. Details like the voice prosthesis and an air-filled esophagus are clearly visible. These models were initially intended for the design of an endo-stomal tracheostoma valve fixation device but later turned out to be practical for voice prosthesis and measurement setup designs.

Tracheoesophageal speakers need to occlude the tracheostoma, to create a positive pressure which results in airflow through the voice prosthesis and through the phonatory tract, to speak. Normally, the tracheostoma is occluded with the hand. Requiring a hand to speak limits the patients freedom.

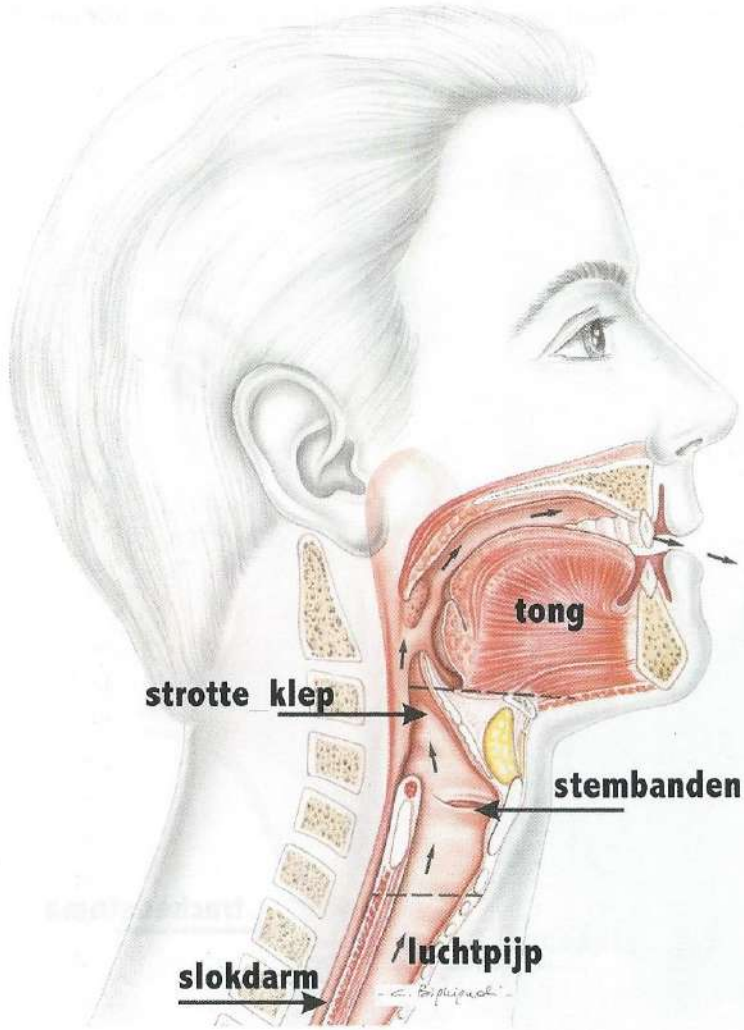
In chapter 3 we evaluate a tracheostoma valve that allows hand-free speech. The Blom-Singer Adjustable Tracheostoma Valve was introduced in 1992 and has some additional features compared to the older stoma valves. The incorporation of a heat and moisture exchanger (HME) and simple alteration of the aerodynamic characteristics are new features. Approximately, 66% of the patients are successful tracheostoma valve users, 50% of the current users notice a phlegm production decrease with HME use. Excessive phlegm production, high endotracheal phonation pressure and short leak-proof seal attachment duration are factors that negatively influence successful use.

Currently, there are three tracheostoma valves available: the Bivona

tracheostoma valve type I and II and the Blom-Singer Adjustable Tracheostoma Valve.
Chapter 4 discusses the aerodynamic differences like maximum airflow before closing, opening pressures and closing pressures and other design differences. A guideline on how to troubleshoot tracheostoma valve related problems is given.
Total laryngectomy has, apart from the implications of voice production, a great impact on the airway itself. The upper airway's air conditioning functions are lost since it is disconnected from the lower airway. For this reason the industry has developed heat and moisture exchangers that supposedly take over the lost nasal functions.
In chapter 5, we discuss how we developed a modified ISO 9360 standard to measure the efficiency of these devices. We found significant differences in performance and other physical aspects. Apart from the physical aspects we looked at costs of use and found great differences.
The endotracheal phonation pressure is determined by the airflow rate and the summation of the pressure drops of the voice prosthesis, pharyngoesophageal-segment, hypopharynx and mouth and nose.
In chapter 6, we discuss the *in vitro* aerodynamic characteristics of five voice prostheses. The measurement array is different from the ones used by others since we used a pressure controller to regulate the airflow. This resembles more the patient situation because the patient also uses pressure to regulate airflow. Using this setup, we could measure additional physical aspects like opening pressure (pre-load) (Provox voice prostheses) and inadequate valve closure Groningen Ultra Low resistance (thick).
In chapter 7, we describe a sensor array for aerodynamic and sound intensity measurement in the laryngectomized patient. The aerodynamic voice prosthesis aspects differ somewhat from our *in vitro* measurements described in chapter 6. This difference may be explained by the fact that the *in vivo* prostheses were not new. We also calculated the voice prosthesis share in total airway resistance and found that the share decreases with increased sound intensities. We could not measure any significant difference between different occlusion method namely manual or tracheostoma valve.
During voice production aerodynamic power is transformed into acoustic power. The efficiency of transformation is called vocal efficiency.
In chapter 8, we describe how we calculated the average vocal efficiencies for our patients and compared them with laryngeal vocal efficiencies. As expected, the vocal efficiencies in our patient group are lower but they do show an increased vocal efficiency with increased sound intensity.
Tracheoesophageal voice is generally regarded to result in the best alaryngeal voice quality. In many patients TE-voice does result in a usable voice but it is not as good as laryngeal voice. Fundamental frequency, dynamic range, vocal efficiency etc. are all lower than in the laryngeal speaker. The effort to speak is much higher in the alaryngeal speaker than in the normal situation. To improve alaryngeal voice production we need to further evaluate the surgical techniques and prosthetic devices.
Future optimization of surgical procedures for voice production is likely to be overruled by oncological considerations. For this reason the optimization of prosthetic devices seems to be easier and more predictable. The feasibility of sound producing voice prostheses and implantable fixation devices needs to be explored.

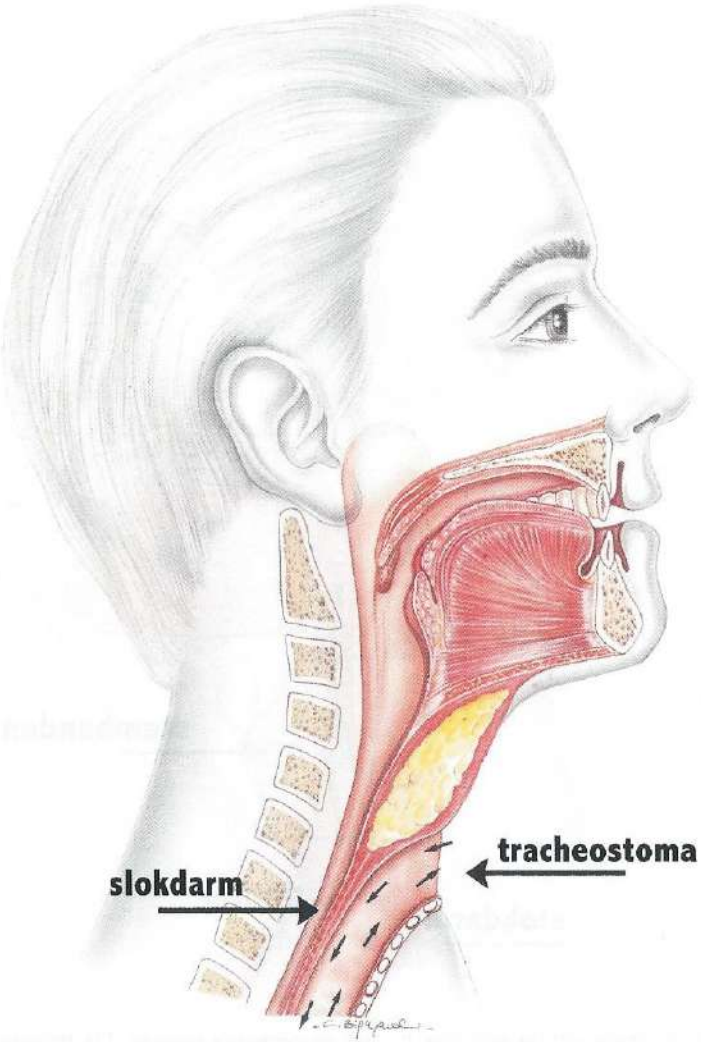
Samenvatting en Conclusies

Het strottehoofd is gesitueerd in de hals en vormt de overgang tussen de mond-keelholte en de luchtpijp (figuur S.1). In het strottehoofd zijn twee stembanden, die belangrijk zijn voor het genereren van stemgeluid.
Om diverse redenen, waaronder kankergezwellen van de stembanden, kan het noodzakelijk zijn om het strottehoofd te verwijderen ("laryngectomy", laryngectomie) en de luchtpijp direct aan de huid vast te maken ("tracheostoma"). Hierdoor verliest de persoon in kwestie niet alleen het vermogen om te spreken, maar verandert de kwaliteit van de ingeademde lucht. In de normale situatie wordt de ingeademde lucht eerst voorverwarmd, bevochtigd en gefilterd. Bij inademing via een tracheostoma worden deze drie functies niet meer door de neus gedaan, hetgeen onder andere leidt tot overmatige slijmproductie door de longen.
Sinds de eerste laryngectomie zijn er verschillende vormen ontwikkeld om stem te genereren ("voice restoration", stemrevalidatie). De beste vorm van stemrevalidatie vindt plaats door een verbinding te maken tussen luchtpijp en slokdarm ("tracheoesophageal fistula", tracheo-oesofageale fistel), zodat er lucht vanuit de longen via de verbinding in de slokdarm terecht komt en door de mond kan worden uitgeblazen. Hierdoor ontstaat er trilling in de slokdarm, hetgeen een geluid teweegbrengt. Om lekkage uit de slokdarm naar de luchtpijp toe te voorkomen moet er een eenrichtingsklepje ("voice prosthesis", stemprothese) geplaatst worden in de verbinding. Echter, de patiënt moet de tracheostoma afsluiten met een hand om een overdruk te genereren, waardoor de lucht via de verbinding naar de slokdarm stroomt en niet via de tracheostoma naar de buitenlucht.
In dit proefschrift worden de verschillende stemprotheses getest op hun fysische eigenschappen (aërodynamica) vergeleken. Tevens is er gekeken naar verschillende kleppen, die op de tracheostoma geplakt worden en de functie van de afsluitende hand overneemt. Hiervan wordt ook de aërodynamica besproken. Verder worden ook filters getest, die deels de functie van de neus overnemen ("heat and moisture exchangers", warmte-vocht wisselaars).
Het anatomisch onderzoek van de tracheostoma en haar aangrenzende structuren werd bemoeilijkt door het ontbreken van adequate imaging technieken. Gewone CT-scans geven een te weinig gedetailleerd beeld en het maken van siliconen afdrukken van de tracheostoma is ronduit een te gevaarlijke procedure. In de literatuur vonden we een non-invasieve techniek, stereolithografie geheten, die voor benige reconstructies werd



Figuur S.1: Illustratie van de anatomie bij niet geopereerde mensen. De structuren van het strottehoofd e.d. zijn aangegeven.

gebruikt. In hoofdstuk 2 wordt beschreven hoe wij deze techniek gemodificeerd hebben om driedimensionele afbeeldingen te vervaardigen van een tracheostoma met aangrenzende structuren. In totaal werden er acht 3D-afbeeldingen gemaakt van de weke delen en acht van de luchtinhoud die zij omsloten in acht verschillende patiënten. Alle gemaakte modellen zijn in detail nauwkeurig, al zijn er artefacten ten gevolge van



Figuur S.2: Anatomische illustratie waarbij het strottehoofd is verwijderd ("laryngectomy").

bewegingen van de patiënt tijdens het maken van de CT-scan. Details van de stemprothese en de lucht in de slokdarm zijn duidelijk zichtbaar. Deze modellen waren aanvankelijk bedoeld als hulpmiddel bij het vervaardigen van een endostomale bevestiging voor tracheostomakleppen maar bleken ook geschikt voor de ontwikkeling van stemprothesen en meetopstellingen. Mensen die met een stemprothese spreken moeten de tracheostoma afsluiten om luchtdruk op te bouwen waardoor lucht de stemprothese en het aanzetstuk passeert. Zij doen dit met de hand waardoor hun bewegingsvrijheid aanzienlijk beperkt wordt. In hoofdstuk 3 wordt een tracheostomaklep beschreven die spraak zoder gebruik van een hand mogelijk maakt. De Blom-Singer Adjustable Tracheostoma Klep werd in 1992 geïntroduceerd. Hij biedt de mogelijkheid om een warmte-vocht wisselaar te gebruiken en tevens de aërodynamische eigenschappen tijdens gebruik te wijzigen. Ongeveer tweederde van de patiënten gebruikt thans zo'n klep om te spreken waarvan de helft een duidelijke vermindering van slijmproductie ervaart tijdens het gebruik van de warmte-vocht wisselaar. Overmatige slijmproductie, hoge endotracheale fonatiedrukken en lekkage van lucht langs de bevestiging beïnvloeden het gebruik in negatieve zin.
In hoofdstuk 4 worden drie verschillende tracheostoma kleppen met elkaar vergeleken. Gekeken werd naar aërodynamische verschillen waaronder de maximale luchtstroom, openings- en sluitingsdrukken en de luchtweerstanden. Tevens worden veel voorkomende problemen besproken met aansluitend de voorgestelde oplossingen.
Totale laryngectomie heeft behalve de implicaties voor de spraak ook grote gevolgen voor de luchtwegen zelf. De functie van airconditioning van de hogere luchtwegen gaat verloren waarvoor warmte en vocht wisselaars zijn ontwikkeld ter compensatie van deze verloren gegane functies van de neus. In hoofdstuk 5 wordt besproken hoe wij de ISO 9360 verder ontwikkeld hebben om de effectiviteit van deze warmte-vocht wisselaars te meten. Niet alleen vonden wij grote verschillen in effectiviteit maar ook in gebruikskosten. De endotracheale fonatie druk is de som van druk vallen van de stemprothese, faryngo-oesofageale segment, hypofarynx en mond en neus als functie van de gegenereerde luchtstroom. Wij beschrijven in hoofdstuk 6 de in vitro aërodynamische karakteristieken van vijf verschillende stem-

prothesen. Onze meetopstelling verschilt met die van anderen omdat wij een drukregelaar gebruiken die de luchtstroom reguleerd, immers patienten reguleren de luchtstroom ook door middel van druk variatie. Extra eigenschappen zoals openingsdruk en klep lekkage zijn met deze opstelling te meten.
In hoofdstuk 7 wordt de meetopstelling beschreven, zoals die is gebruikt om aërodynamische eigenschappen en geluidsintensiteit bij de gelaryngectomeerde te bepalen. Verder werd berekend in hoeverre de stemprothese verantwoordelijk was voor de totale luchtweerstand. Hierbij werd gezien, dat bij toenemende geluidsintensiteit het aandeel in de totale luchtweerstand veroorzaakt door de stemprothese kleiner wordt. Er werden geen significante verschillen gevonden tussen occlusie van de tracheostoma met de hand of met de tracheostomaklep.
Het genereren van stemgeluid geschiedt door transformatie van aërodynamische energie in akoestische energie. De efficiëntie, waarin dit proces zich voltrekt, wordt weergegeven in de vocal efficiency. In vergelijking met mensen met een normaal strottehoofd verliezen de gelaryngectomeerden wat betreft efficiëntie, doch bij toenemende geluidsintensiteit zagen wij een toename van de efficiëntie, hetgeen fysiologisch is.
Hoewel tracheo-oesofageale stemrevalidatie in het algemeen beschouwd wordt als de beste vorm van stemrevalidatie, is het lang niet zo goed als stemgeving met een normaal strottehoofd met betrekking tot basisfrequentie, dynamisch bereik, vocal efficiency, enzovoorts. Bovendien kost het veel meer moeite om stem te genereren met behulp van een stemprothese dan in de normale situatie. Verdere exploratie naar wegen (operatieve procedures, stemprotheses) om spraak zonder strottehoofd te verbeteren lijkt noodzakelijk.

Echter, het verbeteren van operatieve procedures wordt beperkt door de oncologische vereisten aan deze procedure. Verdere ontwikkeling van stemprotheses en fixatiemogelijkheden is mijns inziens de aangewezen weg om een optimale stemrevalidatie te bewerkstelligen.

Appendix

Insertion of frontloading indwelling voice prothesis

Blom-Singer Indwelling Low Pressure Voice Prosthesis

The Blom-Singer Indwelling Low Pressure voice prosthesis kit consists of the low pressure voice prosthesis, inserter, loading tool, gel caps, lubricant, flushing pipets and manuals. The following section is a condensed explanation of the insertion technique. For a detailed description the reader needs to refer to the clinician's manual. The prosthesis is removed from the TEF by pulling it out with a hemostat (figure A.1).

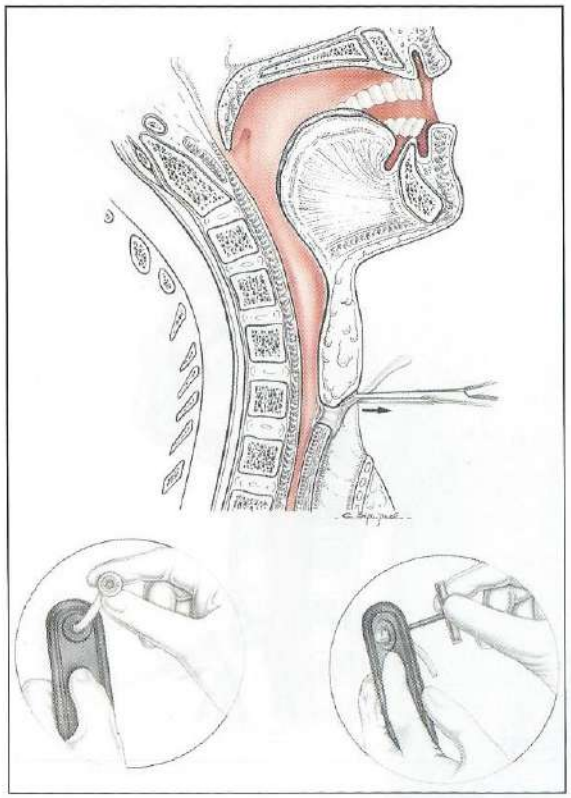


Figure A.1: Removal of the Blom-Singer Low Pressure voice prosthesis with a hemostat. Preparing the voice prosthesis for insertion using the loading tool.

The preparation of the prosthesis to make it ready for insertion is done before removing the old prosthesis or after removal of the old prosthesis followed by insertion of the 22 Fr. fistula stent to minimize the time in which leakage can occur from the esophagus towards the trachea.
The strap of the prosthesis is inserted in the center hole of the loading tool (figure A.1). It is then gently pulled in such a way that the esophageal retention collar (flange) is folded upwards in the hole. The transparent part of the gelatin capsule is placed in the groove of the loading tool over the folded retention collar. Now the prosthesis is pushed out of the loading tube in a reversed motion leaving the gelatin capsule over the forwardly

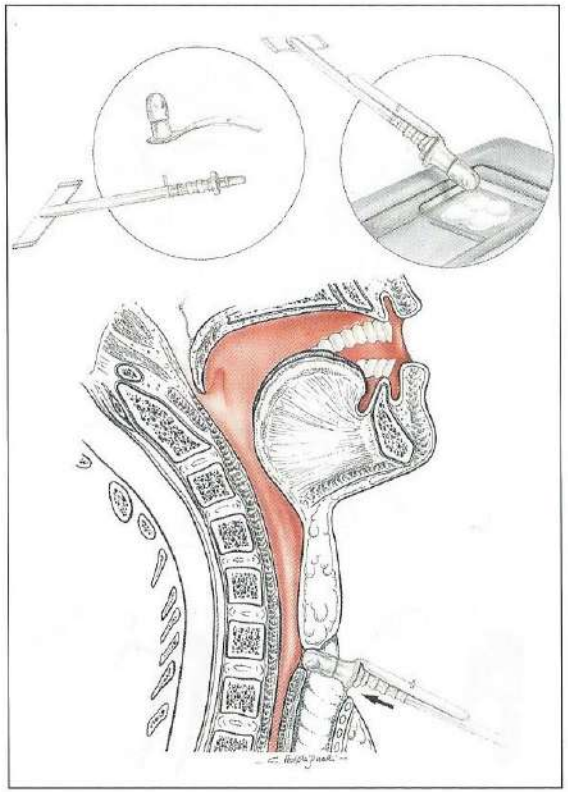


Figure A.2: Blom-Singer Low Pressure voice prosthesis with the gelatin capsule over the forwardly folded esophageal flange. The Blom-Singer voice prosthesis attached to the inserter is slightly lubricated with the lubricant gel. The prosthesis is inserted into the TEF.

folded retention collar (figure A.1). Place the prosthesis onto the inserter and attach its trap to the safety peg (figure A.2).
Directly after applying a little bit of the lubricant gel, the prosthesis is inserted into the TEF (figure A.2). Push the prosthesis so that the tracheal flange pushed against the tracheal posterior to assure complete insertion (figure A.3). After minimally three minutes the gelatin capsule will be dissolved resulting in an unfolded esophageal retention collar (letting the patient drink a glass of water can dissolve the gelatin capsule faster).
To assure proper positioning of the prosthesis, rotate the prosthesis that is still on the insertion stick (figure A.3). The prosthesis should rotate freely

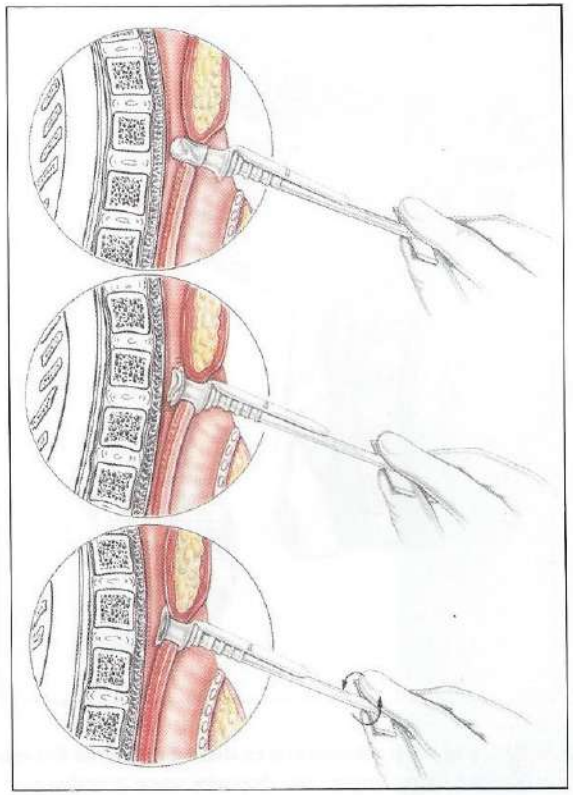


Figure A.3: Insertion of the Blom-Singer Low Pressure voice prosthesis into the TEF. Rotation of the insertion stick and thereby of the prosthesis gives an indication of a complete dissolved gelatin capsule and proper placement of the prosthesis.

within the TEF, if not so the prosthesis can be wedged inside the TEF.
When proper placement is verified the inserter stick is removed. If desired the complete expansion of the esophageal retention collar can be checked with an AP X-ray of the neck which should show a perfect circle of the radio-opaque esophageal retention collar.
The strap can be removed or glued to the peristomal skin with silicone skin adhesive (figure A.4). The insertion is ready and the patient can use the prosthesis.

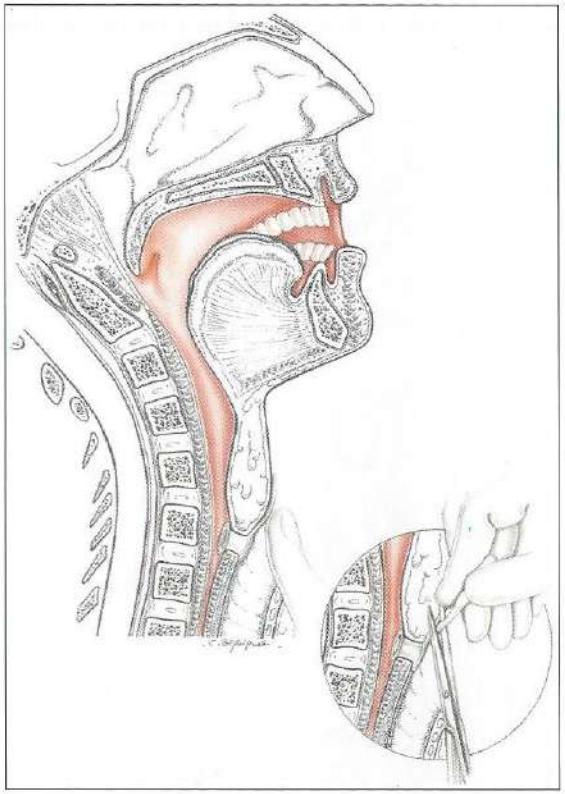


Figure A.4: Manual occlusion of the tracheostoma to shunt air towards the esophagus. Optional detachment of the strap of the Blom-Singer Low Pressure voice prosthesis.

Provox2 Voice Prosthesis

The Provox2 voice prosthesis is a low resistance indwelling medical grade silicone device. It can be inserted through the tracheostoma or through the mouth (backloading). In the following section the frontloading insertion is briefly discussed.
The Provox2 Voice Rehabilitation System consists of the prosthesis, insertion tool, cleaning brush and a manual. Refer to the manual for a complete insertion and maintenance instruction.
Removal of the old prosthesis is done by either pulling it out with a hemostat (figure A.5), or by pushing it into the esophagus after removal of the tra-

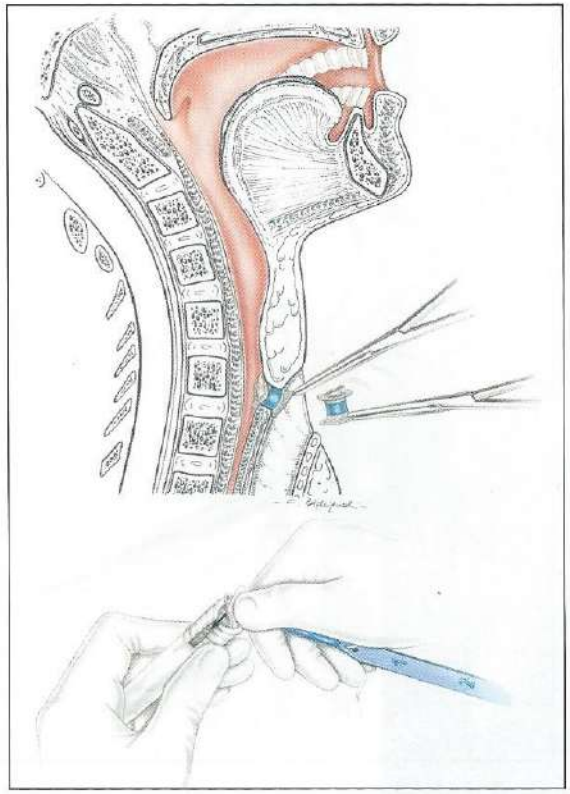


Figure A.5: Schematic drawing of removal of the Provox2 from the TEF and loading of the Provox2 into the insertion tool.

cheal flange in order to swallow it or to remove the device with a guidewire. Insertion can be done by two methods; insertion it through the tracheostoma or by insertion through the mouth (backloading). The insertion through the tracheostoma will only be discussed.

Loading the voice prosthesis into the insertion tool (figure A.5): the voice prosthesis is attached on top of the inserter after the security string is fixed into the slit of the inserter. The esophageal flange is folded into a forward direction so it can slide into the loading tube. The prosthesis will advance approximately 1 cm while a small part of the esophageal flange protrudes through the slit of the loading tube. This protruding part is then pressed

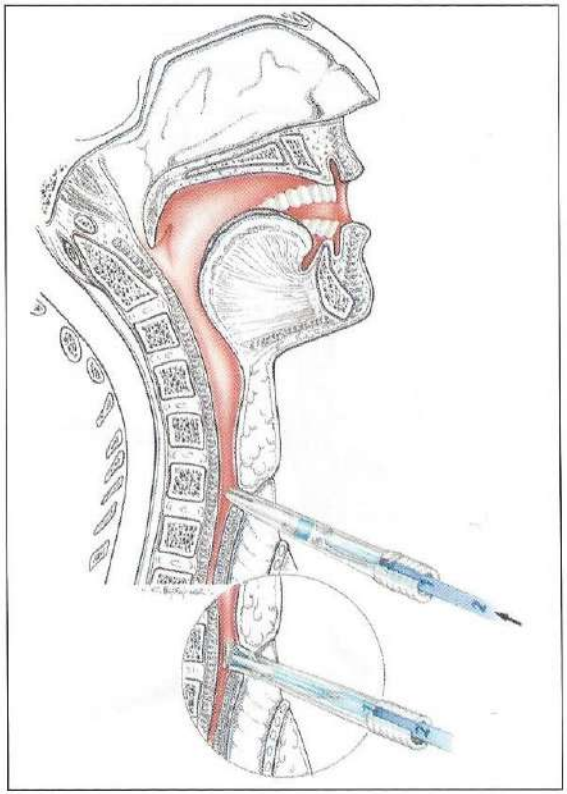


Figure A.6: The Provox2 loading tube with prosthesis inside is inserted into the TEF. The prosthesis is then pushed forward by pushing the inserter while keeping the loading tube in position.

inwards with the thumb to allow further advancement of the prosthesis and inserter in the loading tube to the mark line 1 on the inserter.

The loading tube is placed into the tracheoesophageal fistula (TEF) reaching the posterior wall of the esophagus (figure A.6). While keeping the loading tube in position the prosthesis is pushed forward with the inserter to the mark line 2. At this point the esophageal flange is expanded.

Now, the loading tube is pulled back while the voice prosthesis and inserter stay in place. By pulling the loading tube back the tracheal flange should expand thereby leaving the Provox2 voice prosthesis in its indwelling position. After having removed the loading tube over the inserter the proper

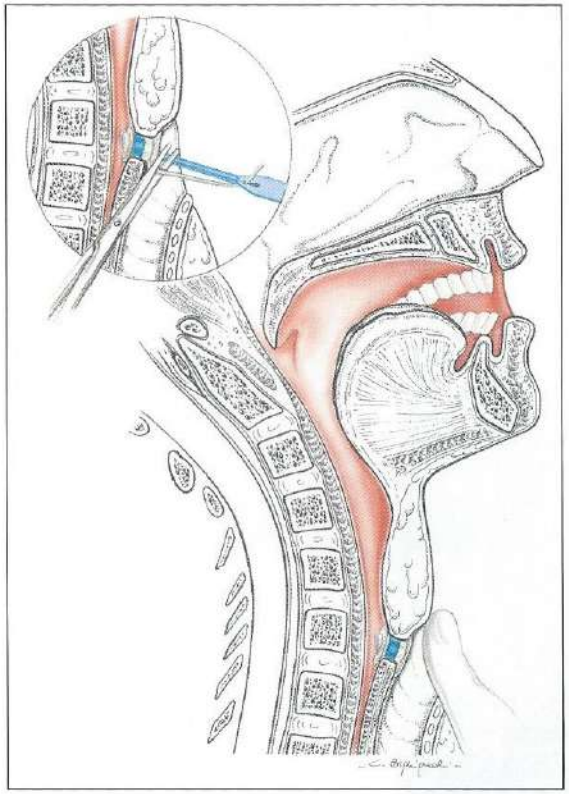


Figure A.7: The Provox2 voice prosthesis with both flanges fully unfolded while still attached to the inserter with the security strap. After checking the proper position of the voice prosthesis the strap should be cut off. On exhaling and occlusion of the stoma sound will be generated.

fixation is checked.
When the clinician is assured of proper fixation the security strap is cut off and the patient is ready to use the prosthesis (figure A.7). In the case that the tracheal flange does not unfold completely or the device is still completely in the esophagus a hemostat is needed to pull the prosthesis through the TEF towards the tracheostoma to deliver the tracheal flange. This is a minor complication but can be troublesome to those with minimal experience with backloading voice prostheses.

VoiceMaster Voice Prosthesis

The VoiceMaster voice prosthesis is a frontloading indwelling device. It consists of a Teflon or silicone ball valve, a titanium barrel and a coating made out of medical grade silicone. The VoiceMaster package consists of an inserter, cleaning tool, prosthesis, lubricant and manuals. Refer to the manuals for a complete insertion and maintenance instruction.
Important for the safe insertion of the VoiceMaster is to understand the color code of the inserter. Through a little window in the inserter the posi-

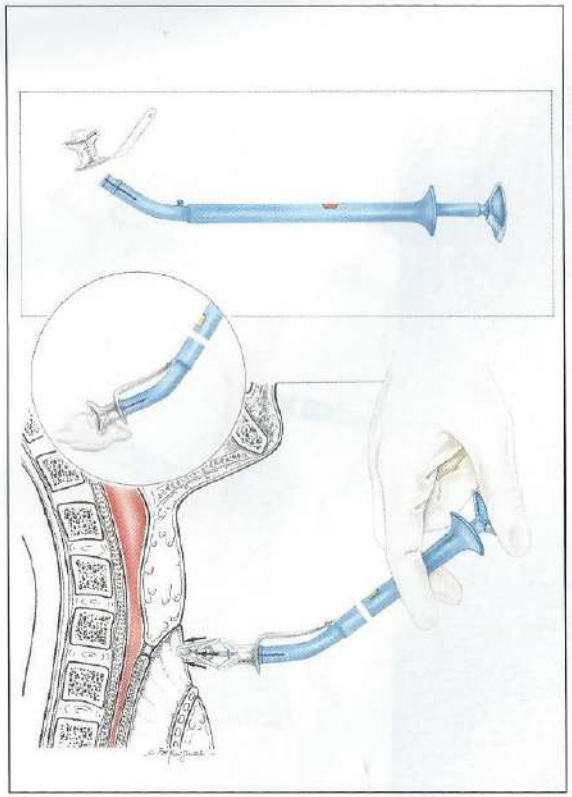


Figure A.8: A schematic drawing of the VoiceMaster voice prosthesis with its insertion tool. When the red color is visible the prosthesis is not locked onto the inserter. When the yellow color is visible the prosthesis is locked onto the inserter but not elongated. The green color indicates a locked prosthesis onto the inserter while the esophageal flange is being stretched.

tion of the plunger can be read as it is indicated by three colors. The red color indicates that the voice prosthesis is not locked onto the inserter. The yellow color indicates that the voice prosthesis is locked onto the inserter and the esophageal flange is in the normal not extended position. The green color indicates that the voice prosthesis is attached and the esophageal flange is stretched.

Removal of the VoiceMaster prosthesis can be done by reversing the insertion procedure described in detail in the section below or by pulling is out of the TEF with a hemostat.

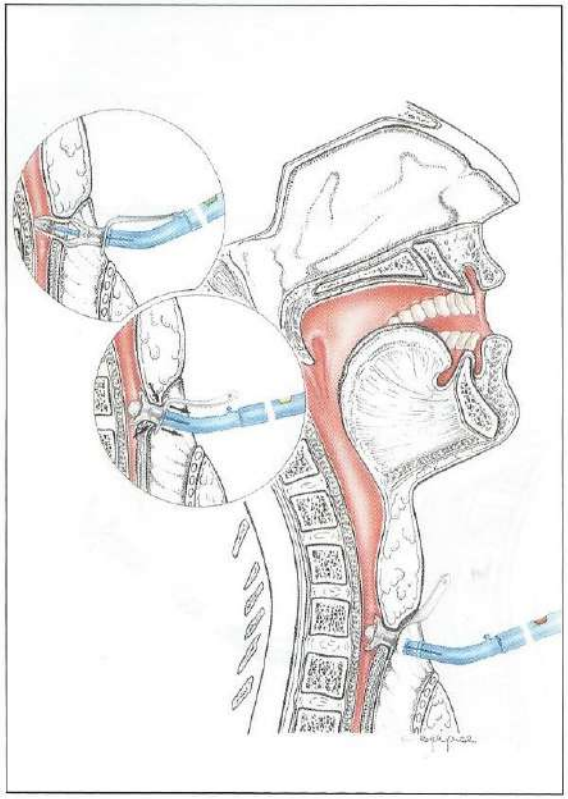


Figure A.9: When the prosthesis is fully stretched (elongated) is can be inserted into the TEF. Once the prosthesis is inserted its fixation can be checked by reversing the plunger to the yellow position followed by gently pulling (indicated by arrows in second highlight). Once proper fixation has been verified the plunger is moved back until the red color is visible followed by detachment between the inserter and prosthesis.

The VoiceMaster voice prosthesis is placed onto the inserter while the color indication is red. The safety strap is attached to the notch of the inserter (figure A.8). The plunger of the inserting tool is pushed inward until the yellow color is visible. At this point the prosthesis is locked onto the inserter. The prosthesis is then lubricated with the lubricant gel. Further advancement of the plunger will stretch the star shaped esophageal flange into a spindle shape. When the prosthesis is fully stretched (plunger pushed maximally inwards) the prosthesis is ready for insertion (figure A.8).

The elongated prosthesis is pushed through the tracheoesophageal fistula

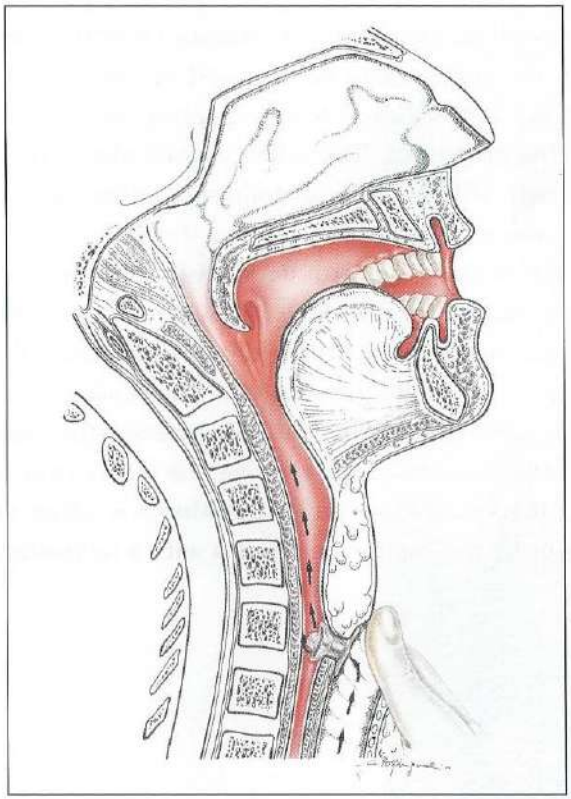


Figure A.10: Schematic drawing of the VoiceMaster voice prosthesis after insertion with the safety strap removed. Occlusion of the stoma will shunt air from the lungs towards the esophagus and sound will be generaled.

until the tracheal flange completely touches the tracheal posterior wall (figure A.9). The flexible plunger-tip with the ball valve on top will in most cases follow the esophageal contour easily.
However, when inserting the VoiceMaster voice prosthesis for the first time in a patient it is helpful to first use the 22 Fr Blom-Singer fistula stent. Using this stent allows the clinician to get informed about the direction of the fistula and slightly dilate the fistula to allow easier insertion.
Next, reverse the plunger until the yellow color is visible. At this point the prosthesis is locked onto the inserter but the esophageal flange is not stretched. Gentle pulling of the inserter allows the clinician to verify the right placement and fixation of the prosthesis. Once the clinician is sure of proper fixation the plunger can be reversed further until the red color is visible (prosthesis is not locked to the inserter) and the inserter can be detached from the prosthesis. The safety strap is also detached and can be clued to the peristomal skin with silicone skin adhesive or cut off. The insertion is complete and the patient can use the prosthesis (figure A.10).
Gluing the safety strap to the skin does give additional safety but at the same time it can hinder the use of Heat and Moisture Exchangers (HMEs) and tracheostoma valves. Since these devices are also glued to the same skin, removal of these devices increases the risk of accidental pulling of the voice prosthesis safety strap. This pulling increases the chance of dislodgment. For this reason we routinely remove the safety strap after insertion.
The removal of the VoiceMaster voice prosthesis is either done by reversing these steps or by pulling the device out with a hemostat.

Curriculum Vitae

The author was born in the Haarlemmermeer, the Netherlands, on September 19th, 1963. After graduation from secondary school (1984) he studied one year of economics at the University of Amsterdam. He switched studies in 1985 to start the medical study at the same university. He graduated in medicine in 1989 and passed the examination for medical doctor in April 1992. He started working at the ENT department of the Academic Medical Center, University of Amsterdam, on January 1st, 1993. He started as an ENT resident on August 1st 1995.

Scientific work:

Grolman W, Schouwenburg, PF, de Boer, MF, Knegt, PP, Spoelstra, HAA, Meeuwis, CA. First results with the Blom-Singer adjustable tracheostoma valve. ORL J Otorhinolaryngol Relat Spec 1995;57:165-170.

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Educational work:

He participated in programming a graphical educational computer program for general practitioners and interns.

In 1998 he wrote a chapter in a book on voice restoration following total laryngectomy: Post-laryngectomy Humidification and Air Filtration. W. Grolman, P.F. Schouwenburg. In: Tracheoesophageal Voice Restoration Following Total Laryngectomy. Editors: Eric D. Blom, Mark I. Singer & Ronald C. Hamaker; Singular Publishing Group, Inc. ISBN 1-56593-5

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Dankwoord

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Dan Prof. E.D. Blom. Dear Eric, thank you for your support and advice. The first lesson in voice rehabilitation, including actually seeing a voice prosthesis for the first time, was in Indianapolis, December 1992. After that time, every meeting with you has increased my knowledge in a most warm and friendly way. Thanks again for the trust you placed in me by asking me to write a chapter in your book on voice rehabilitation.

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Stellingen

Behorende bij het proefschrift "Physical aspects of prosthetic voice rehabilitation after total laryngectomy" te verdedigen op 29 oktober 1998 door W. Grolman, Faculteit der Geneeskunde, Universiteit van Amsterdam.

1. Aërodynamische meetopstellingen in vitro en in vivo gekoppeld aan een computer zijn noodzakelijk om de eisen vanuit de anatomische / fysiologische situatie bij gelaryngectomeerden te vertalen naar optimale fysische en prothetische kwaliteiten.

2. De in vitro bepaalde aërodynamische karakteristieken van stemprothesen zijn indicatief voor de in vivo karakteristieken.

3. Gelaryngectomeerden met een stemprothese gebruiken relatief veel pulmonale energie bij het produceren van stemgeluid.

4. Het adagium dat de weerstand van een stemprothese slechts in kleine mate bijdraagt aan de fonatiedruk is onjuist.

5. De kans op aërofagie neemt toe bij het verlagen van de stemprothese weerstand.

6. Alle gelaryngectomeerde patiënten dienen gemotiveerd te worden om op zijn minst een warmte en vocht wisselaar te proberen.

7. Zeker als de fixatie van tracheostoma spreekkleppen verder wordt verbeterd zal de toepassing daarvan -terecht- sterk toenemen.

8. Een geluidsvormende stemprothese zal een belangrijke vooruitgang in stemkwaliteit betekenen zeker als de gebruiker de toonmodulatie kan beheersen.

9. De diameter van een stapesprothese kan invloed hebben op het post-operatieve gehoor na stapedotomie. (W. Grolman et al. Eur Arch Oto, 1997)

10. Veel mensen besteden onnodig veel tijd aan het ontwerpen van een web pagina zolang ze hun URL vergeten aan te melden bij een search engine.

11. Indien kwantificering van OK produktie een uitgangspunt blijft voor het vaststellen van het budget in academische KNO afdelingen komen zowel de kwaliteit van de opleiding tot specialist als die van de academische kliniek ter discussie te staan.

PHYSICAL ASPECTS OF PROSTHETIC VOICE REHABILITATION AFTER TOTAL LARYNGECTOMY