VOICE AND SPEECH REHABILITATION FOLLOWING LARYNGECTOMY

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VOICE AND SPEECH REHABILITATION FOLLOWING LARYNGECTOMY

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STELLINGEN

1. Shunt oesophageale stemgeving met behulp van een ventielprothese is momenteel de beste methode van stem- en spraakrevalidatie voor gelaryngectomeerden.

2. Bij iedere totale laryngectomie dient een primaire tracheo-oesophageale punctie en plaatsing van een ventielprothese overwogen te worden.

3. Het verdient aanbeveling bij een totale laryngectomie een myotomie van het pharyngo-oesophageale segment te verrichten, wanneer er kans bestaat op hypertoniciteit van dit segment.

4. Voor de kleine glottische larynxcarcinomen is CO_2 laser evaporisatie een goed alternatief voor de gebruikelijke radiotherapeutische behandeling, vooral met betrekking tot de belasting van de patiënt, de stemkwaliteit, en de de kosten aspecten.

5. Het merendeel van de benigne larynxafwijkingen op glottisch niveau kan beter middels klassieke microlarynx dissectie methoden verwijderd worden dan middels CO_2 laser dissectie of evaporisatie.

6. Logopedische behandeling van stemplooiknobbeltjes bij kinderen is over het algemeen meer in het belang van de logopedist dan in het belang van het patiëntje.

7. Met de huidige ontwikkeling van de phonochirurgie met name wat betreft de thyreoplastieken, dient de inspuiting van Teflon of van andere materialen in een stemplooi niet langer beschouwd te worden als de behandeling van eerste keus bij dysfoniën op basis van een enkelzijdige larynxhelftverlamming.

8. Per-operatieve electrostimulatie van de n. recurrens en simultane registratie van het larynx-EMG zou de kans op het ontstaan van n. recurrens laesies tijdens schildklierchirurgie aanmerkelijk kunnen verkleinen.

9. Bij de huidige stand van zaken betreffende reïnnervatie procedures van de larynx moeten de positieve stemresultaten vooral toegeschreven worden aan een tonusverandering in de aangedane larynxhelft en niet aan een herwonnen mobiliteit.

10. Zolang er nog geen effectieve glottis verruimende ingreep ontwikkeld is waarbij de kwaliteit van de stem behouden blijft, dient ook een tracheotomie als alternatief met de patiënt besproken worden.

11. Een stomp larynxtrauma met aanwijzingen voor fracturen met dislocatie of met aanwijzingen voor weke delen laesies met mobiliteitsbeperking van één of beide ware stemplooien dient in de acute fase chirurgisch behandeld te worden.

12. Wordt bij patiënten, die langer dan 1 à 2 weken beademd worden onverhoopt niet voor een tracheotomie gekozen, dan moet minstens wekelijks endoscopische controle van larynx en trachea plaats vinden.

13. Het is niet wenselijk wanneer anders dan in een noodsituatie, een coniotomie als "hoge tracheotomie" verricht wordt in plaats van de meer caudaal verrichte tracheotomie.

14. De recente beschikking van de Staatssecretaris van Volksgezondheid om het aantal percutane transluminale coronaire cardio-angioplastieken drastisch te beperken, is wederom een bewijs van de monomane overheidsvisie op de gezondheidszorg. Een visie die alleen gericht schijnt te zijn op een snel ingevoerd beheersmodel en die volledig voorbij gaat aan de behoeften aan zorg.

15. Nu de belastingaftrek van kosten van congresbezoek afgeschaft dreigt te worden en er van rijkswege nauwelijks geld beschikbaar gesteld wordt voor wetenschappelijk personeel om congressen te bezoeken, dienen meer internationale congressen in Nederland georganiseerd te worden ten einde het peil van het wetenschappelijk onderzoek niet verder te laten dalen.

16. Zolang er nog typefouten voorkomen in het promotiereglement kan men in alle redelijkheid niet verwachten dat een proefschrift vrij is van typefouten.

17. Ook gelaryngectomeerden hebben stemrecht.

H.F. Mahieu

Groningen, 12 oktober 1988

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Preface

Speech is such an essential part of communication in normal human life, that it is almost impossible to imagine lacking this ability to communicate. There are people, however, who have to face a serious threat to their ability to communicate. Laryngectomees form a part of this group and the degree to which their communicational ability is handicapped, is one of the major factors determining their personal and social lives. A laryngectomee once said: 'It is very silent around me. Apparently, people think that when someone can't speak, they don't have to be spoken to as well'. Another declared: 'Sometimes people speak in a very loud, slow, and simple manner when addressing me, as if I were deaf or mentally disabled or both'.

The first aim of this study is the compilation of the various methods of voice and speech rehabilitation following laryngectomy. Therefore, this book gives a detailed survey of these voice rehabilitation methods, with emphasis on the tracheo-esophageal shunt method with a valve prosthesis in respectively Chapter II, Chapter III and Chapter IV. The development of these valve prostheses, which are inserted into a surgically created tracheo-esophageal shunt, has presented a giant step forwards in the voice and speech rehabilitation of laryngectomees.

Therefore, the second aim of the underlying study is the assessment of this newly disclosed possibility of laryngectomee rehabilitation. The main objective is to determine to which extent voice and speech rehabilitation with a valve prosthesis (the Groningen button) in a tracheo-esophageal shunt can be considered to be a good and reliable method of substitute voice production. In this respect, the early substitute voice acquisition, the substitute voice quality, and the satisfaction of the patients, achieved with this valve prosthesis in a tracheo-esophageal shunt are considered to be of importance. A comparison is made with a substitute voice production method without a tracheo-esophageal shunt. Furthermore, the major problems associated with this new type of substitute voice production are identified. The outline of the clinical study consists of a prospectively conducted evaluation of those laryngectomees, who were treated in the ENT-department of the Groningen University Hospital, with a Groningen button valve prosthesis in a tracheo-esophageal shunt. The results of this evaluation are presented in detail and the consequences are discussed in Chapter VI.

The third aim of this study is to investigate the effectiveness of two measures, which have been proposed to improve the substitute voice production of the tracheo-esophageal shunt method with a valve prosthesis. These measures consist of a pharyngo-esophageal myotomy and of prevention of deterioration of the valve prosthesis. They are discussed in Chapter IV and in Chapter V, respectively.

Chapter I

TOTAL LARYNGECTOMY AND ITS CONSEQUENCES

The early diagnosed squamous cell carcinoma which is restricted to the vocal fold, causing symptoms already when the tumor is still small and with almost no tendency of tumor spread away from the larynx are staged as T1 or T2 carcinomas (I.U.C.C. classification, 1987). These types can be easily treated by radiotherapy with a good chance (85 to 95 per cent) of cure.
Unfortunately, not all patients are diagnosed at such an early stage, either because their symptoms were ignored, or because the tumor was located elsewhere in the larynx without early symptoms. Furthermore, radiotherapy may fail to cure the disease even in an early stage. In these cases of more extended tumors staged as T3 or T4 carcinomas, or in case of recurrency after radiotherapy, total laryngectomy is the best therapy. In our department a preoperative radiation dose of 30 Gy is applied prior to the total laryngectomy, if no previous radiotherapy has been given. The indication for additional postoperative radiotherapy depends upon the peroperative findings and the histological examination of the removed specimen.
In case of tumor spread to the local lymph nodes, laryngectomy can be combined with neck dissection. In the following section the total laryngectomy procedure as performed in the ENT department of the Groningen University Hospital is described.
Furthermore, the most important consequences of total laryngectomy are discussed.

1.1 TOTAL LARYNGECTOMY

Total laryngectomy entails total removal of the larynx, including the hyoid bone superiorly and the uppermost rings of the trachea inferiorly. The remnant of the severed trachea is brought out at the front of the neck, and is sutured to the skin just above the sternum. In this way a tracheostoma is created, which guarantees an open airway.
The removal of the larynx results in the anterior dissection of the pharyngeal musculature and mucosa. The resulting defect in the anterior pharyngeal wall is closed by approximation of its edges. First the mucosa is closed and then the closed defect is reinforced by layers of pharyngeal and remaining strap muscles. This pharyngeal repair is performed meticulously to prevent fistula formation (Applebaum and Levine 1977). In this way the food passage is completely separated from the airway. Just before the operation a nasogastric feeding tube is introduced to allow postoperative nutrition. It will remain in situ for twelve days. In order to prevent local infection and fistula formation, antibiotic treatment is started two days preoperatively.
This prophylactic antibiotic treatment consists of systemic administration of cefradin (four times one and a half grams daily) and local oropharyngeal administration of a combination of polymyxin B, tobramycin and amphotericin B, either as lozenge or as paste (four times daily).
Postoperatively, the patient is not allowed to swallow and his saliva is sucked from his mouth. All nutrition is given as a liquid diet down the nasogastric tube. During this period the patient communicates by writing on a pad. All of these measures are taken in order to avoid breakdown of the pharyngeal repair. Before removal of the feeding tube, the integrity of the pharyngeal repair is tested by allowing the patient to drink a blue dye solution. If no signs of fistula formation are found, the feeding tube is removed and the patient can start with the rehabilitation program.

1.2 CONSEQUENCES OF TOTAL LARYNGECTOMY

Following total laryngectomy, the chances of being cured from the malignant disease are relatively high. Depending upon the site of the malignant lesion, its extent and whether or not locoregional metastases have occurred, the mean five years survival rates vary between 50 and 85 per cent. Consequently, many laryngectomees live a considerable number of years with the handicaps which are associated with the laryngectomized state.
Some human beings are capable of extensive adaptive behaviour, and therefore, the form and degree of disablement will vary considerably between laryngectomees. The most frequently observed and most important consequences of total laryngectomy are discussed below. These consequences must, of course, be considered and discussed with the patient before the decision to perform a laryngectomy is made. However, the actual decision to perform such radical surgery should be purely based on oncological indications, taking into consideration the physical and mental condition of the patient. Clearly the goal of this kind of oncological surgery must be total eradication of malignancy. Less radical surgical procedures which are performed to minimize the consequences of laryngectomy can comprimise this oncological principle of radical tumor excision. Therefore, the indications for less radical surgical procedures must be thoroughly scrutinized.

1.2.1 Loss of laryngeal functions

The most eminent handicap of total laryngectomy is undoubtedly the loss of vocal functions. The efforts undertaken to compensate for this loss of voice and consequent loss of speech, is the actual subject of this book.
However, even when a laryngectomee has regained his communicational ability after successful voice and speech rehabilitation, psychological and emotional problems associated with the substitute voice can, and often will, remain. The absence of sounds which normally accompany laughter and crying, is an example which supports the notion that the vehicle for emotional expression, i.e. the voice, has been radically altered following laryngectomy.
Another consequence of removal of the larynx is that glottic closure as occurs in coughing, abdominal press and lifting heavy objects is no longer possible. Severe problems resulting from this lost ability of glottic closure are, however, rarely observed (Loebell and Brahm 1950; Matzker 1955; Jakobi and Müller 1958; Diedrich and Youngstrom 1966). Apparently, compensating mechanisms enable sufficient stabilized intrathoracic pressure, even without glottic closure.

1.2.2 Loss of nasal functions

The loss of nasal air flow affects the sense of smell and, consequently, the sense of taste. Methods have been described (Damsté 1979b) to reestablish nasal air flow sufficiently to improve the sense of smell and taste.
The ability of blowing the nose is also impaired (Wirth 1972; Schultz-Coulon 1984). Sometimes laryngectomees with tracheo-esophageal shunts (2.5.2.1) can employ these shunts to effectively blow their nose. Furthermore, the filtering, warming, and humidifying functions of the nose in respiration are lost as a result of the laryngectomized state. It is our experience that loss of nasal functions present only minor discomforts for laryngectomees.

1.2.3 **Tracheostoma**

Following the loss of vocal functions, the tracheostoma is often considered to be the next most disabling consequence of laryngectomy.
The tracheostoma itself is conspicuous. Together with the sometimes excessive discharge of mucous secretions, crusting inside the tracheostoma, and coughing, it may cause embarrassment and revulsion for both the laryngectomee and his family. Pitkin (1953) even found coughing and mucus discharge to be one of the chief discomforts of the laryngectomee. Care of stoma and trachea is a recurring tedious activity for the laryngectomee or the spouse.
Inhalation of air, which has neither been moistened nor warmed may cause irritation of the tracheal mucosa. The use of sponge rubber bibs and regular instillation of saline or other solutions can be useful to diminish crusting and irritation.
Furthermore, laryngectomees should be cautioned against entry of foreign bodies into the tracheostoma. It is equally undesirable that water should be permitted to enter the tracheostoma. Therefore, shaving, bathing and showering habits must be consciously adapted (Damsté 1979b). Stoma covering is often used for both social and hygienic reasons.

1.2.4 **Swallowing**

Although disturbances of the swallowing mechanism have been reported to occur following laryngectomy, this seems to be of only minor importance in the patient's nutrition. Most laryngectomees experience no real swallowing difficulties (Sandberg 1970; Brouwer, Snow and van Dam 1979) but, pharyngeal stenosis, the development of pharyngeal pouches, and swallowing dyscoordination can occur. Food intake by means of sucking is difficult and has been reported to present problems.
In our experience laryngectomees only occasionally report swallowing disorders.

1.2.5 **Lung function**

Some authors report changes in lung function as a result of laryngectomy (Bernhardsgrütter, Löhr and Schwab 1955; Fouarge 1964; Harris and Jonson 1978; Giesen and Dorow 1978; Togawa, Konno and Hoshino 1980), others did not find these changes (Brendebach, Schmidt and Brugger 1986).
Although we did not perform lung function tests systematically, it is our general impression that our laryngectomized patients are not more prone to deterioration of lung function than other people of the same age group.

1.2.6 **Psychosocial consequences**

The psychosocial consequences of laryngectomy are often underestimated. Many different factors contribute to the psychological and social problems following laryngectomy, and these problems can in turn negativelly influence the rehabilitation process. A comprehensive discussion on this subject is worthy of, and could easily fill, a whole book. Such a discussion, however, is beyond the scope of this work. Therefore, only some of the most important psychosocial consequences of laryngectomy are mentioned here.

First of all, the psychosocial circumstances of the laryngectomee will be influenced by

the anxiety which is associated with the diagnosis and treatment of a malignancy. For a long period of time both patient and those around him, will be troubled by the question of whether or not he is really cured.
Secondly, loss of the larynx may adversely affect a patient's sense of personal worth, his family relationships, his socialization outside the family circle, and his employment. The readjustments required of the laryngectomee, and the people of his surrounding, are enormous, and in a considerable number of cases such adjustments are never achieved. In this respect a successful voice and speech rehabilitation is found to facilitate the psychosocial adjustment (Wochnik 1972; Wasilewska and Warnecka 1979; Dhillon et al 1982), but it is not enough to ensure the total rehabilitation of the laryngectomee (Barton 1965; Diedrich and Youngstrom 1966; Klinger 1971; Gilmore 1974; Watts 1975; Pfrang 1986; Pfrang et al 1986).
Therefore, it is generally recommended to include the help of other institutions besides the surgeon, the nurse, and the speech therapist, in the rehabilitation program. This additional help can be offered by social workers, laryngectomized counsellors, laryngectomee clubs, and sometimes psychologists, psychotherapists and others.
The better the patients and their families are informed about what is going to happen and what the consequences will be, the better they are prepared for the rehabilitation process, and consequently the better their chances are for adequate adjustment to the laryngectomized state.

Despite many efforts to totally rehabilitate laryngectomees a considerable number will suffer from neurotic and depressive psychic conditions (Wochnik 1972; Johnson, Casper and Lesswing 1979), vocational loss (Gilmore 1974; Savary 1977) and social isolation (Gilmore 1974; Savary 1977; Wasilewska and Warnecka 1979; Brouwer, Snow and van Dam 1979; Dhillon et al 1982). It is therefore, essential that all people who are involved with treatment and rehabilitation of laryngectomees realize that their responsibilities towards the laryngectomee do not end, when a total cancer eradication and successful voice and speech rehabilitation has been achieved.

Chapter II

VOICE PRODUCTION AND VOICE REHABILITATION PROCEDURES FOLLOWING LARYNGECTOMY

The most disabling consequence of laryngectomy is generally considered to be the loss of vocal function. It is therefore hardly surprising that ever since the first laryngectomies performed by Watson in 1866 (Alberti 1975) and by Billroth in 1873 (Gussenbauer 1874), methods have been sought to restore the voices of laryngectomees.
In the more than hundred years that have passed, several methods of substitute voice production have been developed and these will be discussed in the next chapters.
Voice production can be considered to be the generator part of the speech mechanism for normal laryngeal speakers as well as for laryngectomees. In order to appreciate the problems associated with laryngectomee voice production, we must first consider normal laryngeal voice production.

2.1 NORMAL LARYNGEAL VOICE PRODUCTION

In normal laryngeal phonation the source of energy for voice production is the steady stream of air from the lungs on exhalation. The airstream can be made audible by setting it into rapid vibration by vocal fold action. The actual sound generation in the larynx is dependent upon the subtle interaction of aerodynamic forces during expiration and myoelastic forces of the vocal fold. The vocal folds are both in the median position during phonation. The loosely attached, and therefore very flexible mucosal lining of the vocal folds, is brought into motion by the expiratory air, thus creating a mucosal wave. This mucosal wave opens and closes the glottis periodically, thus causing a periodical interruption of the outwards moving column of air, which in turn results in sound. For a good laryngeal sound production the biomechanical properties of the epithelial lining of the vocal folds are very important. This explains the severe voice problems that can arise when even a small part of the vocal fold mucosa has been damaged.
The vibrating air can be heard as a buzz. The frequency of this buzz rises when the vibration rate of the vocal folds and their mucosa increases. The character of the vocal buzz is modified by the vocal tract's acoustical properties. The vocal tract is the part of the airway situated above the larynx and consists of pharynx, mouth and nose. It serves as a resonator. The acoustical properties depend upon the internal shape of the vocal tract. During speech this shape is continually altered by moving the tongue and lips etc. These movements enable the production of the different sounds of speech, by alteration of the acoustical properties of the vocal tract.
The mechanism just described is used for producing voiced speech sounds. Two methods are available for producing unvoiced speech sounds. In one, the vocal tract is constricted at some points along its length. The air stream passing through the constriction becomes turbulent, and sounds like a hiss. This is the fricative noise produced when pronouncing sounds like /s/ or /sh/. The other method is to stop the flow of air momentarily by blocking the vocal tract with the tongue or the lips, and then suddenly releasing the air pressure built up behind this block. This method is used to make sounds like /p/, /k/ and /t/, some of the so-called plosives. These plosives play an important role in one of the methods of substitute voice production: the esophageal voice (Chapter III).

The two methods described for producing unvoiced speech sounds are independent of vocal fold activity. Whichever technique is used, the resonance of the vocal tract still modifies the character of the basic sounds produced by hiss, plosion, or vocal fold vibration.

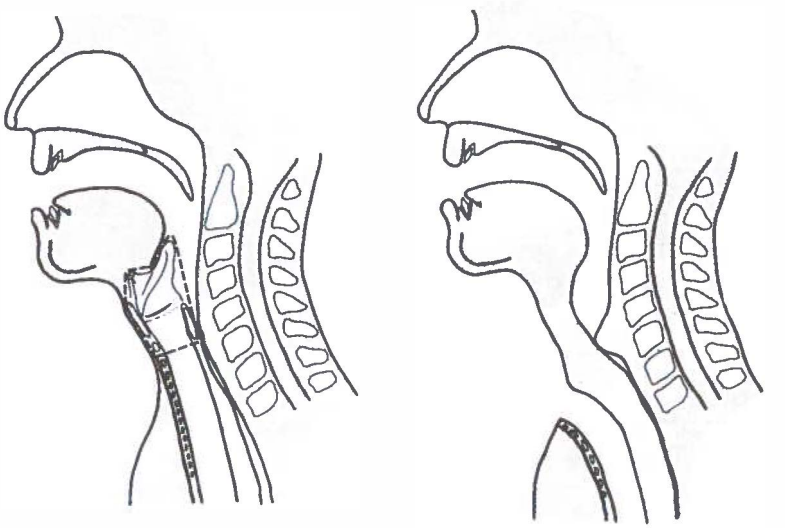
2.2 ANATOMY AFTER LARYNGECTOMY WITH REGARD TO VOICE PRODUCTION

The anatomy is essentially changed by laryngectomy (Fig. 2.1):

1. The larynx, including the vocal folds, is removed.
2. The lower respiratory tract is separated from the vocal tract and from the upper digestive tract. The laryngectomee breathes through a tracheostoma.

The direct connection of the vocal tract with the upper digestive tract remains unaltered.

Fig. 2.1



Anatomy before and after laryngectomy.
Left: before laryngectomy. Total laryngectomy resection lines are marked.
Right: after laryngectomy. Complete separation of airway and digestive tract. Tracheostoma for respiration.

After laryngectomy, the patient is not only deprived of the vibrating sound source (the vocal folds), but also the energy source for voice production (air stream from the lungs) is no longer connected to the vocal tract. The vocal tract itself is not essentially changed by the laryngectomy, so that the normal articulatory mechanisms are not hampered. Articulatory characteristics like dialect are unaltered. Therefore, 'speech rehabilitation' is not a correct phrase in the strict sense; the laryngectomee doesn't have to learn to speak all over again, but has to develop a new sound source and a new energy source in order to acquire a substitute voice. This new sound source must be connected to the vocal tract, so that the basic sound can be modulated into speech. Furthermore, the new sound source must be connected to the energy source.

Available substitute sound sources are:

1. Mechanical sound sources.
2. Non-mechanical sound sources, using anatomical structures for sound production.

Anatomical structures which can act as sound source are:
a. specially created or surgically altered anatomical structures;
b. the pharyngo-esophageal (P-E) segment, a normal anatomical structure situated in the upper digestive tract, just below the vocal tract. The part of the P-E segment which is the actual sound generating vibratory body is called the pseudoglottis and produces the esophageal voice (Chapter III);
c. normal anatomical structures situated in the oropharynx and mouth, which are situated high in the vocal tract. These structures enable the production of pharyngeal and buccal voice.

Electric power or pneumatic power can be used as power sources. Electric power for some mechanical sound sources, and pneumatic power for both mechanical and nonmechanical sound sources. Pneumatic power requires supply of air, for which there are two possibilities:
1. Expired air from the lungs. This requires the creation of a new connection between the respiratory tract and the vocal tract. Thus expired air can be used as a power source again, just as in normal laryngeal phonation;
2. An air supply other than the respiratory tract. Of course this air supply must be connected to the alternative sound source.

The differences between the above mentioned substitute sound sources are not only of a physiological nature. The quality of the resulting substitute voice, and the patient's acceptance of the methods used, differ so much, that separate discussions are required to understand the respective advantages and disadvantages.
The principles of mechanical sound sources will be outlined in section 2.4 and some examples will be discussed.
The specially constructed or altered sound sources consist of a large group of varying surgical procedures. The principles and some examples of these procedures will be discussed in section 2.5.
Since the esophageal voice which is produced by the P-E segment is considered to be the most readily available, most used, and best substitute voice, this method will be discussed in detail in Chapter III.
The oropharynx and the mouth, used as a sound source, are of minor importance. But in order to give a complete review of all possible methods of alaryngeal voice production, the buccal and pharyngeal method will be briefly discussed here.

2.3 PHARYNGEAL AND BUCCAL VOICE PRODUCTION

Pharyngeal and buccal voice production are rarely used as substitute voices for laryngectomees (Damsté 1958; Diedrich and Youngstrom 1966; Gardner 1971) and are generally considered to be unpractical and undesirable methods of alaryngeal speech (Damsté 1958; Dinville 1961; Weinberg and Westerhouse 1971, 1973; Torgerson and Martin 1976).
The power source is formed by air which is trapped in an air reservoir in the oropharynx.

2.3.1 Mechanism of pharyngeal phonation

Air is pushed outwards from the oropharynx, which serves as an air reservoir. The root of the tongue pressed against the posterior pharyngeal wall, together with the palate, the fauces and sometimes the upper lateral pharyngeal walls function as sound sources. In this situation only a small part of the vocal tract can be used to modulate the produced

sound and the tongue is not fully free to function as an articulator. Therefore, it is not surprising that Damsté and Moolenaar-Bijl (1960), and Weinberg and Westerhouse (1973) report that the intelligibility is markedly reduced in pharyngeal speech production.

2.3.2 **Mechanism of buccal phonation**

In this method of phonation an air reservoir is created between the upper jaw and the cheek (van Gilse 1949). The sound source is formed between the upper jaw, the teeth and the cheek. Thus even a smaller part of the vocal tract is available for modulation, than in pharyngeal phonation. Here also markedly reduced intelligibility has been reported (Weinberg and Westerhouse 1971).

2.3.3 **Comment on pharyngeal and buccal phonation**

In both the pharyngeal and the buccal mechanism of phonation the air reservoir is very small, requiring frequent interruptions of voice production. The resulting voice in both methods is often referred to as 'frog-like' or 'Donald Duck speech' and is generally associated with a high pitch (Damsté 1957; Edels 1983), although Weinberg and Westerhouse (1973) reported a case in which the pitch was comparable with that of esophageal voice production.

Pharyngeal voice production is less rare than buccal voice production, and can be found in laryngectomees training for esophageal voice production (Damsté 1958), when they are not able to bring air through the P-E segment down to the air reservoir in the esophagus (Chapter III). Hypertonicity of the P-E segment can be the underlying cause. Damsté (1957) has reported that the site of the sound source can descend from a high pharyngeal level to the usual pharyngo-esophageal level, following bougisation of the P-E segment. This results in a better substitute voice.
Both the pharyngeal and the buccal method of voice production should be discouraged, because these methods result in a substitute voice which is inferior to esophageal voice production, and, furthermore, the use of these methods can interfere with the acquisition of esophageal voice (Chapter III).

2.4 **MECHANICAL SOUND SOURCES**

Numerous mechanical vibration sources have been developed which, internally or externally applied, set the air in the vocal tract in vibration. These vibration sources are either powered by airpressure, in most cases expired air coming out of the tracheostoma (pneumolarynges), or they are battery powered (electrolarynges).

2.4.1 **Pneumolarynges**

The pneumolarynges can be divided in neck-types and mouth-types.

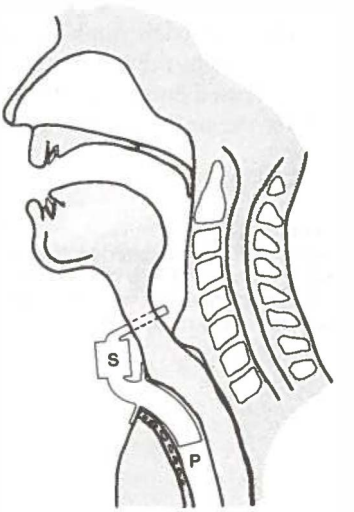
2.4.1.1 **Neck-type pneumolarynges**

The neck-type pneumolarynx (Fig. 2.2) is a sound generator containing device with a connection both to the respiratory tract and the hypopharyngeal part of the vocal tract. In the connecting tube a membrane or reed is situated, which is the actual sound

generator. The expired air flows through the connecting tube and sets the membrane or reed into vibration. The air vibrations are then led into the vocal tract through a pharyngeal opening. In contrast to the early days of laryngectomy, when the pharynx was left open, at present this requires a surgically created pharyngo-cutaneous fistula.

Fig. 2.2

Neck-type pneumolarynx.
The power source (P) is the expired air from the lungs. The sound source (S) is formed by a reed or membrane. The sound is led, through a pharyngeal opening, into the vocal tract for further modulation.



The first mechanical sound source for laryngectomees, developed by Leiter in 1873 and modified by Billroth's assistent Gussenbauer in 1874, was such a pneumolarynx. Caselli made a modification in 1879 which was successfully used for 38 years by one of his patients (Holinger 1975). Roswell Park published an identical method in 1886.
With the advent of closure of the pharynx defect, transmission of external sound through a pharyngeal opening was no longer possible until Shedd and co-workers (1972, 1974a, 1974b, 1975, 1980a) revived the concept by creating a pharyngo-cutaneous fistula especially for this purpose. They initially developed this method for patients who had undergone total pharyngo-laryngectomy, a group of patients who rarely develop serviceable esophageal speech (3.1.6).
Neck-type pneumolarynges have many disadvantages (Shedd 1978; Taub 1980). The creation of a pharyngo-cutaneous fistula can be a very difficult operation, especially in patients who have been previously irradiated or have undergone radical neck dissection. Major arteries and nerves can be endangered, during the operation or later by erosion. Carotid hemorrhage has been reported (Taub and Bergner 1973; Yousuf and Novotny 1976). The connection of the device to the tracheostoma and the pharyngo-cutaneous fistula can be difficult, and can lead to skin necrosis or leakage of food and saliva. The devices require frequent maintenance and cleaning, they are large and conspicuous and last, but not least, the resulting voice sounds monotonous and mechanical (Weinberg, Shedd and Horii 1978).
Even though the more recent model described by Schoendorfer and co-workers (1979), which is smaller and partially internal, may have overcome some of the described disadvantages, the neck-type pneumolarynges are presently seldom used. Reviews of

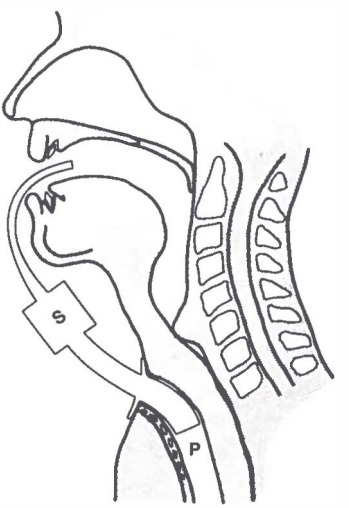
these methods were presented by Blom and Singer (1979), Shedd and Weinberg (1980b), and Vuyk (1985).

2.4.1.2 **Mouth-type pneumolarynges**

The mouth-type pneumolarynx (Fig. 2.3) is a device containing a sound generator with connection to both the respiratory tract and the oral part of the vocal tract. A membrane or reed is situated in the connecting tube just as in the neck-type pneumolarynx . The air vibrations are not led through an opening in the pharynx, but through a tube which is held in the corner of the mouth, or passed through the nose into the naso pharynx. No surgically created entrance into the vocal tract is required, which is clearly an advantage over the neck-type pneumolarynx.

Fig. 2.3

Mouth type pneumolarynx.
The power source (P) is the expired air from the lungs. The sound source (S) is formed by a reed or membrane. The sound is led through a tube into the mouth for further modulation.



Numerous types and modifications of mouth-type pneumolarynges have been developed. One of the first descriptions of such a device for laryngectomees was given by Stoerk in 1887, presumably inspired by Czermak. Czermak is credited with the development of the first known mechanical sound source, which was used for substitute voice production in a tracheotomized girl suffering from complete laryngeal stenosis in 1859 (Green 1943). Hochenegg (1892) described a modification which did not use expired air, but was powered by an apparatus employing bellows. The bellows were held between the arm and the side of the body and could thus be compressed to supply air. In 1930 Riesz described what was to become the first mechanical sound source commercially available on a large scale: a prototype of the Western Electric reed-types 1A and 2A (Barney 1958).
Other examples of mouth-type pneumolarynges are the Tokyo artificial larynx (Mueller and Kupperman 1973; Weinberg and Riekema 1973; Nelson, Parkin and Potter 1975) and the Dutch-made type of van Hunen/Memacon (Diedrich and Youngstrom 1966). The Tokyo artificial larynx has been reported to be significantly more acceptable for

listeners than some other devices (Bennett and Weinberg 1973).
The mouth-type pneumolarynges do not have the surgery related disadvantages mentioned for the neck-type of pneumolarynx, but otherwise they have similar disadvantages such as the rather monotonous sound and the conspicuousness of the device. Furthermore, the laryngectomee has to learn to speak with a tube in his mouth, unless the sound conducting tube is lead through the nose to the nasopharynx.
A review of these devices has been given by Blom (1978) and Lowry (1981).

2.4.2 **Electrolarynges**

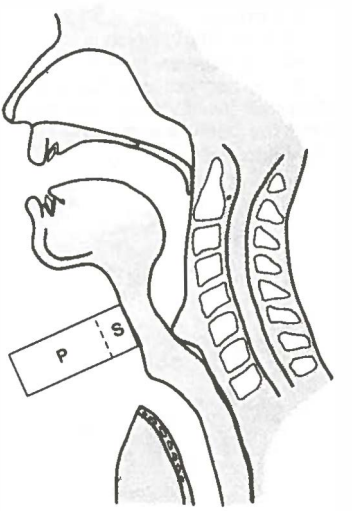
The electrolarynges generate vibrations by means of an electromagnetic mechanism similar to that of a loudspeaker. They can also be divided into neck-types and mouth-types. Both types can be subdivided into externally and internally applied devices.

2.4.2.1 **Neck-type electrolarynges**

The vibrations generated by the *externally applied neck-types of electrolarynges* (Fig. 2.4) are transmitted to the soft tissue of the neck and floor of the mouth. When the device is firmly pressed against the skin, the air in the pharynx and oral cavity is set into vibration.

Fig. 2.4

External neck-type electrolarynx.
The power source (P) is a battery. The sound source (S) is an electromagnetic vibrator. The vibrations are transmitted through the soft tissues of the neck and set the air in the vocal tract in vibration, where the sound is further modulated.



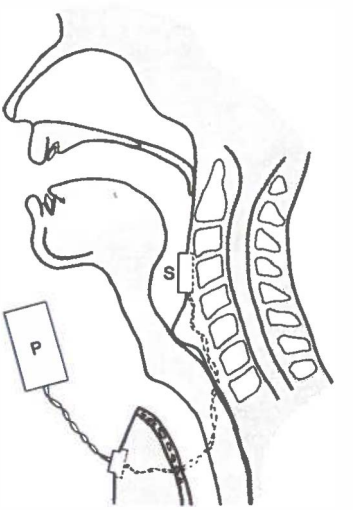
The Western Electric Electrolarynx and the Servox Electrolarynx (Oticon) are examples of externally applied neck-types of electrolarynges. Intensity and pitch levels are preset in these devices. The Servox with variable pitch adjusted to the Dutch speech-intonation pattern is a new development. The pitch variation is manually controlled (van Geel 1983). However, the laryngectomee must be musically gifted and have a certain

knowledge of linguistics in order to profit from this device (Greven 1984). Hippel and Krause (1987) recently described a pitch adjustable device, using motion sensitive controls which are attached to the wrist. Pitch regulation is thus achieved with gesticulations which normally accompany speech. The lack of intonational contrast in speech produced with non-pitch variable electrolarynges was demonstrated by Gandour and Weinberg (1982, 1983, 1984).
All externally applied neck-type electrolarynges have the drawback that proper placement against the skin can be difficult, especially in necks with much scar tissue or postsurgical swelling shortly after the operation. Therefore, one device has been modified in order to enable usage both as a mouth-type and as a neck-type (Zwitman and Disinger 1975).
Most externally applied neck-types of electrolarynges are hand-held, which is another drawback. Therefore, Brusis and Hassheider (1976) described a device which is pressed unto the neck with a strap. Controlling this device still requires manipulations by hand, but the controls can be held out of sight, for instance in a pocket.
The most important drawback, of all electrolarynges is that the substitute voice sounds monotonous and mechanical.
Reviews of these electrolarynges have been presented by Gardner and Harris (1961), Lebrun (1973), Blom (1979a), and Dworkin and Banton (1982).

Internally applied neck-types of electrolarynges (Fig. 2.5) are implanted in the pharyngeal part of the vocal tract.

Fig. 2.5

Internal neck-type electrolarynx.
The power source (P) is a battery, which is connected to a connector device which is implanted in the skin. This connector device in its turn is connected to an electromagnetic vibrator, which is implanted in the pharynx and which functions as sound source (S).



Such devices have been described by Rogers, Frederickson and Bryce (1975, 1976), Griffiths, Frederickson and Bryce (1976), Young et al (1980), and Frederickson, Charles and Bryce (1980). The use of these devices has remained limited to a small number of patients, probably as a result of the surgical implications and problems concerning the

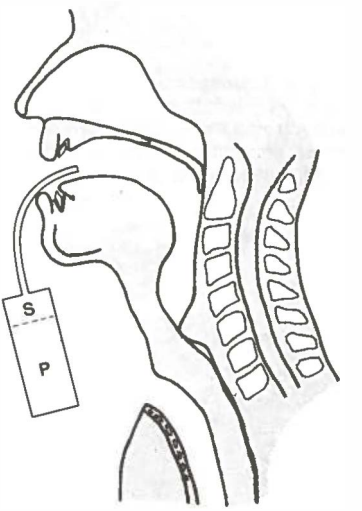
control of the device. These devices are less conspicuous than the externally applied neck-type electrolarynges.

2.4.2.2 **Mouth-type electrolarynges**

A well-known example of the *external mouth-type electrolarynx* (Fig. 2.6) is the Cooper-Rand Electrolarynx. This hand-held instrument basically consists of a battery powered pulse generator, connected to a tone generator. Sound is directed into the mouth by a plastic tube. Various similar devices are available, with or without varying pitch and intensity.

Fig. 2.6

External mouth-type electrolarynx.
The power source (P) is a battery. The sound source (S) is an electromagnetic vibrator. The sound is led through a tube into the mouth for further modulation.



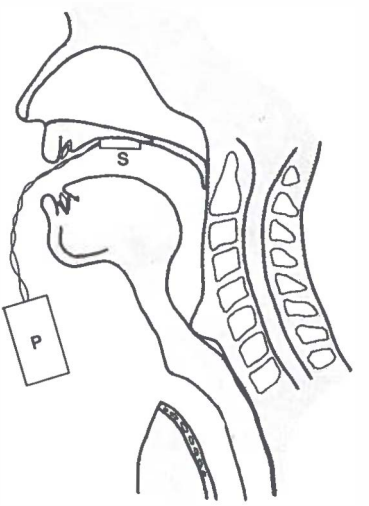
The major drawbacks of this device are the mechanical characteristics of the voice and the conspicuousness. This last problem can be overcome with modifications such as the Pipa de Tichoni and the Danapipe, in which the electromagnetic vibrator is hidden in a pipe. The stem of the pipe leads the sound to the oral cavity. The devices are controlled by switches in the pipe.
Most of the externally applied mouth-type electrolarynges are hand-held which is a serious drawback. Modifications were developed to overcome this problem. McRae and Pillsbury (1979) described a device fitted in the frame of spectacles.
Reviews on electrolarynges are presented by Gardner and Harris (1961), Lebrun (1973), Blom (1979a), and Dworkin and Banton (1982).

Another alternative is presented by the *internally applied mouth-type electrolarynges* (Fig. 2.7). In these models the vibrator is placed on a dental plate on the hard palate (Tait and Tait 1959; Cooper and Millard 1959; Lowry et al 1982). Connection to the batteries outside the mouth prove to be a problem with these devices. An interesting attempt to solve this problem was made by Pichler (1961) who transmitted electrical energy by an induction loop around the neck to a miniature speaker located in an upper

denture. A similar principle was applied later by Goode (1975) who placed the energy-transmitter unit externally on the cheeck. Zwitman, Knorr and Sondermann (1978) used rechargeable batteries placed in the denture. Most devices are controlled by hand-held switches. The wireless device described by Pichler, however, is controlled by a 'speech-contact plug' situated in a tracheal canula. This plug is, probably mechanically, activated by a 'speech-respiratory reflex' which, according to Pichler, is the learned behaviour of a speaker to start phonation with an expiratory movement. This behaviour is said to be more apparent in laryngectomees in the early stages of the rehabilitation period. Later this concept was modified by using a thermistor placed near the tracheostoma. The sound source is then activated when warm expiratory air passes the thermistor (Schultz-Coulon, Pichler and Grunzke 1982; Pichler, Schultz-Coulon and Grunzke 1983).
Reports on actual use of the intra-oral electrolarynx devices are sparse.

Fig. 2.7

Internal mouth-type electrolarynx.
The power source (P) is a battery. The sound source (S) is an electromagnetic vibrator which is placed in a denture, and which sets the air in the mouth into vibration, where it is further modulated.



2.4.3 **Comment on mechanical sound sources**

Generally, the mechanical sound sources are considered to be inferior to other methods of substitute voice production, and the choice of using them early in speech rehabilitation has proved to be a controversial issue (Lueders 1956; Diedrich and Youngstrom 1966; Lauder 1968, 1970; Wirth 1972; Green, Atkinson and Watson 1974; Goldstein 1978; Duguay 1978; Berry 1978; Gates, Ryan and Lauder 1982; Salmon 1983; Edelman 1984). Some clinicians, fear from a psychological point of view, that it will interfere with the development of esophageal voice (see Chapter III). Other drawbacks are clearly associated with the monotonous quality of the produced voice. Often the laryngectomees consider the sound to be alien; they cannot associate it with their 'own' voice. Furthermore, the conspicuousness of most devices draws too much unwanted attention to the laryngectomee. The surgical complications associated with the neck-type pneumolarynges make these devices an even less desirable form of

laryngectomee voice rehabilitation.
Some mechanical sound sources, however, are still used if other voice rehabilitation methods have failed. In such cases, we prefer an externally applied neck-type electrolarynx, such as the Servox or intonable Servox, because the use of these devices is not associated with surgical complications, and is relatively well-accepted by patients.

2.5 SURGICAL VOICE REHABILITATION

As described above, the first efforts towards vocal rehabilitation of laryngectomees have been undertaken using mechanical sound sources, some of which are still occasionally used with success.
Another line of development consists of surgical efforts to achieve laryngectomee voice production. These surgical procedures have one or more of the following objectives:
- to preserve as much functional tissue as possible during the laryngectomy procedure (the so-called partial, and subtotal laryngectomies),
- to create a new phonatory organ, (the so-called neoglottis procedures),
- to recreate a connection between the physiological power source – the air in the lungs and airways – and the vocal tract (the so-called shunt procedures),
- to fully reconstruct laryngeal functioning, not only the phonatory function, but also the complicated regulation of the cross-roads of airway and digestive tract (some of the reconstruction procedures).

The development of these surgical procedures was initiated by a report presented at the meeting of the American College of Surgeons in 1927 by Beck, who demonstrated.....

...'a remarkable case of pseudo-voice. The patient had taken a violent dislike to the MacKenty artificial larynx, although he was an expert in its use. He carefully considered his case and then passed an icepick, which he had heated red hot, through the opening of his trachea in the neck upward and backward until it reached the hypopharynx. He repeated this heroic procedure on two more occasions and subsequently a permanent fistula between the tracheal orifice in the neck and the hypopharynx remained. By placing his thumb on the tracheal orifice and making an expiratory effort with his chest, he was able to force a blast of air through the small fistula into the hypopharynx' (cited after Guttman 1932).

Guttman, who attended this meeting, was so inspired by this report, that he tried to reproduce the procedure under surgical control with a diathermic needle (1932, 1935). Although substitute voice was readily acquired, all the fistulas thus created by Guttman eventually closed spontaneously, because of the lack of an effective device to keep them open (Goldstein and Price 1987). Guttman's work was transiently forgotten until Conley and co-workers revived the concept in 1958.
Since then, surgical voice rehabilitation efforts revived. Most of these techniques consist of the creation of a shunt between the airway and the upper digestive tract. Because the upper digestive tract and the vocal tract are continuous, the above described shunt reconnects the power supply for voice production (air from the lungs) to the resonator (the vocal tract).
This connection between power source and resonator, alone, is not sufficient to produce voice. A sound generator must also be present to produce the basic vocal sound. Therefore, numerous surgeons have tried to surgically construct a neoglottic structure to act as a sound generator. Indeed most of their patients were able to phonate. This, however, was not always the product of a surgically constructed, sound producing,

neoglottis. Only a few surgeons were in fact able to construct a structure which was actually capable of generating sound. Most, however, like Guttman, entered the digestive tract just below the level of the so-called pseudoglottis. This structure is situated in the esophagus entrance and can act as a sound generator, which produces the esophageal voice (Chapter III). Thus no real surgical neoglottis had been constructed but just a shunt which connected the power supply to the sound generator.
It is difficult to differentiate between the multiplicity of surgical procedures which have been developed in order to vocally rehabilitate the laryngectomee. Description of all of these procedures is beyond the scope of this work.
Since partial laryngectomy procedures mostly result in relatively minor voice problems, and voice restoration is the main topic of this book, only the voice rehabilitation procedures for subtotal (2.5.1) and total laryngectomies (2.5.2) will be discussed.

2.5.1 **Surgical voice rehabilitation procedures for subtotal laryngectomies**

A subtotal laryngectomy is a type of operation which preserves some structures that can be used to reconstruct a functional 'neoglottis' for voice production. The actual sound generator in this type of neoglottic reconstruction is considered to be one of the following structures:
1. the created 'neoglottic' structures;
2. the anastomosis connecting the respiratory with the digestive and vocal tract;
3. pharyngeal structures.

The connection between airway and vocal tract is mostly situated above the level of the P-E segment, so that structures of this segment cannot contribute to the sound production.

In addition to voice production, some procedures also have the objective of avoiding the creation of a permanent tracheostoma. A procedure, aimed at total restoration of laryngeal function, inevitably requires the preservation or creation of a large anastomosis between the respiratory tract and the vocal tract, with sufficient lumen to guarantee respiration. Such a large anastomosis bears a considerable risk of massive aspiration. Both aspiration and a compromised airway often prevent decanulation of these patients, so that they end up with a permanent tracheostoma after all.
Other techniques are aimed at voice restoration alone and therefore require only a small anastomosis between the respiratory and vocal tract. In such cases a patent airway is maintained through a permanent tracheostoma. Although the small anastomosis reduces the chances of aspiration, this still presents the major problem of such procedures.

Procedures as described by Mozolewski and co-workers (1972, 1975, 1980), Iwai and Koike (1973, 1975), Stallings (1977) and Pearson and co-workers (1980, 1981, 1985) are examples of subtotal laryngectomies with a permanent tracheostoma to maintain the airway. Mozolewski and Pearson both construct a myomucosal tube, using piriform sinus mucosa and one of the arytenoids. Iwai and Koike use parts of the thyroid cartilage to reconstruct the larynx which is lined by mucosal flaps from the hypopharynx. Stallings uses one of the arytenoids, and free cartilage and tendon grafts, for his reconstruction technique.

Procedures aimed at restoration of all laryngeal functions – deglutition, respiration, and phonation without a permanent tracheostoma – are for example the reconstructive

laryngectomy as described by Hofmann-Saguez (1954), the reconstructions as described by Conley (1962) and the cricohyoidpexy procedures as described by Majer and ieder (1958, 1959, 1971, 1972, 1973). Hofmann-Saguez resected the larynx anteriorly, preserving the cricoid and sometimes one of the arytenoids. The dorsal parts of the thyroid cartilage and the hyoid bone were also preserved. The vocal folds, ventricular folds, epiglottis and one or both of the arytenoids were resected. A stent was inserted in place of the resected laryngeal structures. No actual reconstruction was performed. The stent was removed after several months. Hofmann-Saguez did not report aspiration problems. Phonation and respiration without a tracheostoma was achieved by all fifteen patients.
Conley described a reconstruction following subtotal laryngectomy in which at least one arytenoid, the dorsal part of the vocal fold on the same side and the cricoid had been preserved. The resected part of the glottic structures was reconstructed with skin flaps from the neck, which were formed into new vocal folds. Although actually developed for reconstruction following hemilaryngectomy, nine successful reconstructions following subtotal laryngectomy have been reported (Brodnitz and Conley 1967).
In the cricohyoidpexy procedure the cricoid is at least partly preserved and is sutured to the hyoid bone, which is also preserved. Many modifications of the cricohyoidpexy procedure have been reported, among others by Sekula (1967), Labayle et al (1971, 1972, 1973, 1974, 1980), Traissac et al (1973, 1976), Alajmo (1974, 1976), Piquet et al (1974a, 1974b, 1976, 1980), Savary (1975a, 1975b), and Teatini and Staffieri (1979).
Variations of cricohyoidpexy procedures, also aiming at total restoration of laryngeal function, are for example cricoglossopexy procedures as described by Jonesco (1978) in which the remnant of the cricoid cartilage is sutured to the base of the tongue and thyrotracheopexy procedures as described by Hofmann-Saguez (1950, 1951), Bartual and Roquette (1978) and Calearo and Teatini (1978). In the thyrotracheopexy procedures the glottic and subglottic structures are excised, while the supraglottic structures are preserved. The upper remnant of the thyroid cartilage is sutured to the trachea.
In most above mentioned procedures, preservation of one arytenoid, the cricoid plate and sometimes even the ipsilateral recurrent nerve has been advocated to diminish postoperative problems with deglutition and aspiration (Alajmo 1976, Staffieri 1979).
Complications are in part dependent upon the extent of the surgery and previous irradiation and involve the already mentioned major problems of aspiration and securing a sufficient airway. Furthermore, deglutitional problems and stenosis of the anastomosis, resulting in poor voice production, are frequently encountered (Labayle 1973; Traissac et al 1973, 1980; Alajmo 1974, 1976; Pardes 1974; Pardes, Traissac and Vazel 1974; Sisson et al 1978; Dietzel 1979; Mozolewski et al 1979; Sisson and Goldman 1980).

2.5.2 **Surgical voice rehabilitation procedures for total laryngectomies**

Total laryngectomy is a type of operation which leaves no laryngeal structures that can be used for reconstruction of a neoglottis. Furthermore, preservation of a connection between respiratory tract and vocal tract is often not feasible, and therefore other methods of surgical voice restoration have been developed. The following methods will be discussed:
- shunt methods, using a tracheo-pharyngeal or tracheo-esophageal shunt,
- 'neoglottic' reconstructions after total laryngectomy,
- larynx transplantation,
- implantation of an artifial larynx.

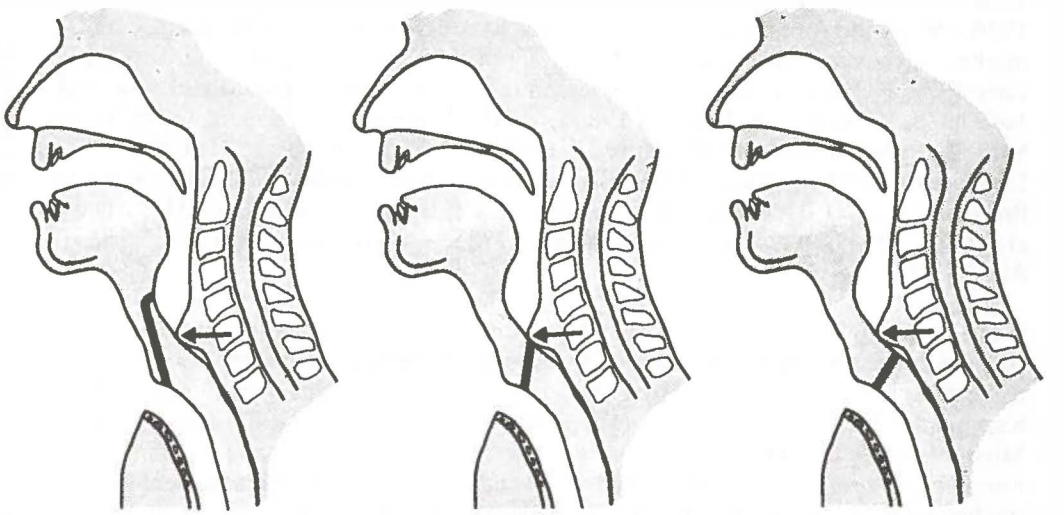
2.5.2.1 **Shunt methods**

The tracheo-pharyngeal or tracheo-esophageal shunt methods are the most widely used techniques of surgical voice restoration following laryngectomy. These shunt methods basically are modifications of the method presented by Guttman.
The energy source in all shunt methods is expiratory air. When during expiration the tracheostoma is occluded, either by a finger or a valve mechanism, the air flows from the trachea through the shunt. Subsequently, the air either enters the vocal tract, above the level of the P-E segment (high pharyngeal shunt), or the upper digestive tract, at or below the level of the P-E segment (low pharyngeal or esophageal shunt). At the level of the sound generator the air stream is set into vibration which is further modulated in the vocal tract. A good regulation of the air stream can be achieved, because expiration is under voluntary control. The air supply is rather similar to the air supply in normal laryngeal phonation and the whole pulmonary air reservoir is available for voice production.
Several classifications can be made with regard to these shunt methods. In the literature these methods are usually differentiated according to the fact whether the shunt is an internal shunt or an external shunt. 'Internal' refers to inside the body and 'external' refers to outside the body. The latter requires a connecting tube and a pharyngo-cutaneous fistula. Internal shunts can be constructed using skin, tracheal mucosa, hypopharyngeal mucosa, tracheal cartilage, venous grafts, enteric grafts, or by a simple puncture of the tracheo-esophageal wall.
Another differentiation often encountered in the literature is based on whether or not a one-way valve prosthesis is inserted into the shunt to prevent leakage from the upper digestive tract into the airway.

Determination of the structure that will act as a sound generator depends upon the level at which the shunt enters the vocal tract or the upper digestive tract. Therefore, a differentiation between three levels is made (Fig. 2.8):
1. High tracheo-pharyngeal shunts;
2. Low tracheo-pharyngeal shunts;
3. Tracheo-esophageal shunts.

One of the first descriptions of a high tracheo-pharyngeal shunt has been given by Briani (1952), who made an external shunt with a connecting tube from the tracheostoma to the created pharyngo-cutaneous fistula.
In 1958 Damsté described a case of a young man with a laryngeal stenosis and a small pharyngo-cutaneous fistula located just above the tracheostoma. A small connecting device placed between the fistula and the tracheostoma enabled an excellent substitute voice production.
With initial success Lockhart (1962) experimented with external shunts entering the digestive tract on different levels, but local inflammation and recurrency of tumor prevented a sufficient follow-up period of his patients.
With initial succes Lockhart (1962) experimented with external shunts entering the digestive tract on different levels, but local inflammation and recurrency of tumor prevented a sufficient follow-up period of his patients.
To overcome the difficulties presented by leakage from pharyngeal contents through the connecting tube into the tracheostoma, the use of valve prosthesis in external shunts has been reported by several authors (Taub and Spiro 1972; Zeitzer and Hays 1972; Edwards 1974, 1975, 1980; Taub 1974, 1975, 1980; Mohran 1975; Sisson et al 1975a,

Fig. 2.8



Levels of internal shunts between airway and digestive tract.
Left: high tracheo-pharyngeal shunt entering pharynx above the level of the pseudoglottis (example: Asai's technique).
Middle: low internal tracheo-pharyngeal shunt entering pharynx at the level of the pseudoglottis (example: Staffieri's technique).
Right: internal tracheo-esophageal shunt entering the esophagus just below the pseudoglottis (example: Guttman's technique; most tracheo-esophageal puncture techniques).
The pseudoglottis is marked by an arrow.

1975b; Graham and Edwards 1977; McConnel et al 1977. The hazards and problems associated with such an external shunt have already been pointed out (2.4.1.1). It should be mentioned, however, that the location of the pharyngo-cutaneous fistula as described by Edward, Sisson, and McConnel is in a surgically safe area, distant from the major vessels.

An extremely high situated internal shunt with an indwelling tube has been described by Barton (1966). The shunt extended from the tracheostoma to the floor of the mouth, where the shunt entered the vocal tract underneath the tongue. Substitute voice production was successfully achieved and leakage through the shunt was prevented by covering the opening of the tube with the tongue.

Asai (1960, 1966, 1972) described a three staged internal high tracheo-pharyngeal shunt procedure using a skin-lined shunt without a valve prosthesis. This method has been extensively used and modified (Miller 1967, 1968, 1971, 1974, 1975; Karlan 1968; Minnigerode 1968, 1969, 1972; Montgomery and Toohill 1968; Porres and Mersol 1968; Kitamura et al 1970a, 1970b, 1970c, 1974; Putney and Bagley 1970; Maurer 1971, 1973; McGrail and Oldfield 1971; Turnbul et al 1971; von Schulthess 1971; Abu-Jaudeh 1972; Bryce 1972; Marshall 1972; Montgomery 1972; Frederickson, Bryce and Williams 1973; McGrail 1975; Rasche 1976; Woods and Pearson 1980; Yamamoto 1980; Minnigerode, Arnold-Schneider and Polyzoidis 1988). In this first group, in which the shunts enter at high pharyngeal level, the sound source is most likely formed by the shunt orifice in the pharynx (Tarnowska, Jach and Mozolewski 1982). It is also possible that pharyngeal mucosal structures and the tongue-base contribute to the basic sound production.

In the last decade the procedures resulting in an internal low tracheo-pharyngeal shunt as described by Staffieri (1969, 1973, 1974, 1980), Staffieri et al (1978), Amatsu (1978, 1980, 1985), and Amatsu et al (1986a, 1986b) have been widely applied, adopted and modified (Maurizi, Nardi and Rosignoli 1977; Draf 1978a, 1978b, 1981; Griffiths and Love 1978; Heermann 1978a, 1978b; Sisson et al 1978, 1980; Zietek, Mozolewski and Jach 1978; Rudert 1979; Griffiths 1980a, 1980b; Leipzig 1980; Leipzig, Griffiths and Shea 1980; McConnel and Whitmire 1980; Calearo and Caroggio 1981; Gatti, Lucchinetti and Thinakkal 1981; Hall and Arnesen 1981; Kuske 1981; Novak 1981; Bretlau et al 1982; Hybasek 1982; Tiwari et al 1982; Unger et al 1982, 1985; Algaba et al 1983, 1984, 1985; Cerenko and Padovan 1985; Taniguchi et al 1985; Vuyk 1985; Algaba 1987).

Conley and co-workers (1958, 1959) described an internal tracheo-esophageal shunt constructed from esophageal mucosa or from an autogenous vein graft. These techniques have been modified by Calcaterra and Jafek (1971), Komorn et al (1973), Komorn (1974, 1975), Calcaterra (1975), Saito et al (1977), Li (1985) and Strome, Mustoe and Kelly (1986).
Ehrenberger et al (1985a, 1985b) and Grasl et al (1985) described an internal tracheo-esophageal shunt created by interposition of a jejunal graft.
These constructions of tracheo-esophageal shunts form the basis for the simple tracheo-esophageal puncture techniques which are used in combination with internally situated valve prostheses (Chapter IV).

In the second and third group the low tracheo-pharyngeal and tracheo-esophageal shunts end at or below the level of the P-E segment. This is usually the site of the pseudoglottis, the generator of the esophageal voice. Therefore, it seems logical that these shunt methods also employ the pseudoglottis as the main sound source (Chapter III).
Zwitman and Calcaterra (1973) are credited to have first noticed that the voice produced with a tracheo-esophageal shunt is similar to esophageal voice produced by the pseudoglottis. This suggests that the sound source is identical in both methods. This notion was further substantiated by Zwitman's cinefluoroscopic analysis of speakers with tracheo-esophageal shunts, which revealed a similar pseudoglottis as was found in esophageal speakers. That the substitute sound source is formed by the pseudoglottis, is presently not only generally accepted for the tracheo-esophageal shunt methods, but also for the low tracheo-pharyngeal shunt methods (Hlava et al 1982; McCurtain et al 1982; Novak et al 1982; Vuyk 1985; Wetmore et al 1985b; Traissac et al 1986b; own observations). The physiology of voice production with the low tracheo-pharyngeal and tracheo-esophageal shunt techniques will further be discussed in the chapter on esophageal voice.

The different levels at which the shunts enter the vocal tract or the digestive tract and consequently the place where the substitute sound source is located, have consequences for the quality and pitch of the voice. As a rule voices produced at high pharyngeal level have a breathy quality and are higher pitched than the voices produced at a lower level, which generally have a rather low pitch (Nichols 1969; Snidecor 1969a, 1975; Curry, Snidecor and Isshiki 1973; Tarnowska, Jach and Mozolewski 1982; Evans and Drummond 1985).
From a theoretical point of view voices produced at the lower level are to be preferred, because in these cases the resonator (vocal tract) is virtually unaltered and can be used

over its entire length for acoustic modulation of the basic sound.

2.5.2.2 **Problems associated with shunt methods**

All of the above-mentioned shunt techniques result in a substitute voice production which is superior to the voice produced with mechanical sound sources and superior to the esophageal voice production without a shunt (Chapter III). The shunt techniques, however, frequently are associated with a number of drawbacks (Pardes 1974; Pardes, Traissac and Vazel 1974; Pinel, Trotoux and Beutter 1976; Nitze 1978; Sisson et al 1978, 1980; Klor et al 1981; Czigner 1982; Graner et al 1982; McConnel and Teichgroeber 1982; Grünbacher 1983; Vuyk 1985; Vuyk, Tiwari and Snow 1985a, 1985b; Klima and von Ilberg 1986; Minnigerode, Arnold-Schneider and Polyzoidis 1988). The most important drawbacks are:

1. leakage of food or fluids through the fistula from the esophagus into the trachea, resulting in aspiration;
2. obstruction, stenosis and spontaneous closure of the shunt, resulting in poor or absent speech production.

Several techniques have been developed to prevent aspiration. Montgomery and Lavelle (1974) tried to regulate the opening of the shunt with a myoplasty using the sternocleidomastoid muscle. Amatsu et al (1986b) used two esophageal muscle flaps in an effort to gain some control over opening and closing of the shunt. Heermann (1978a, 1978b) created a valve with homogeneous cartilage in order to close the shunt during the swallowing act. Ghosh (1977, 1985) created a neo-epiglottis to protect the shunt outlet in the esophagus. Despite all these efforts good voice without aspiration was not always achieved.

Some studies have suggested that leakage from the digestive tract through the shunt is associated with high intraluminal pressures in the esophagus during the act of swallowing (Mann, Laniado and Schumann 1980), and with upper esophageal dysfunction (Vuyk 1985).

The aspiration problems often left no other alternative than surgical closure of the shunt, despite the good voice result.

As a result of these drawbacks, the initial enthusiasm for the above-mentioned shunt methods subsided, and presently only a few surgeons still use them. Most of the drawbacks have been overcome by one of the more recent developments in laryngectomee voice rehabilitation: the development of silicone one-way valve prostheses which are introduced in the internal tracheo-esophageal shunts. Because of the importance of this development and it's reportedly good rehabilitation results, these prostheses will be discussed separately in Chapter IV.

2.5.2.3 **Surgical reconstruction after total laryngectomy**

Most surgical reconstruction techniques used after total laryngectomy are derived from the techniques described for the reconstruction after subtotal laryngectomy (2.5.1). It should be noted that efforts towards reconstruction by direct anastomosis of the trachea and the pharynx increase morbidity. Nevertheless, many tracheohyoidpexy procedures, which are extended versions of the cricohyoidpexy technique, have been described.

Serafini (1967, 1969, 1970, 1972, 1980) described a tracheohyoidpexy technique aimed at total restoration of laryngeal functions (respiration, deglutition and phonation). Most of his patients were able to phonate postoperatively but permanent

decanulation was only achieved in a few of them. Some authors reported good results with Serafini's technique or with modifications (Arslan and Serafini 1970, 1972; Arslan 1972, 1975; Gignoux et al 1972; Lange and Beck 1974; Scola, Fernandez-Vega and Bachiller 1974; Swaminathan, Jefferis and Rush 1977). Others reported far less favourable results (Guerrier 1970; Vega and Galvez 1972; Traissac et al 1973, 1980; Claverie 1974; Guerrier et al 1975; Vega 1975; Sisson et al 1978; Vega and Scola 1980; Schumann, Laniado and Majora 1981). Claverie (1973) even abandoned the concept of fixation of the trachea to the hyoid bone and attempted to construct a neoglottis from pharyngeal mucosa.

A totally different surgical reconstruction technique has been presented by Lapidot and co-workers (1965), also in an effort to restore all laryngeal functions (respiration, deglutition and phonation). This reconstruction consisted of three techniques:

1. The upper part of the trachea was narrowed by resection of an anterior wedge in the upper tracheal rings;
2. A neo-epiglottis was constructed with a superior-based flap of the anterior wall of the cervical esophagus;
3. Bilateral posterior-based flaps of pharyngeal mucosa were sutured to the anterior wall of the narrowed trachea to form 'vocal folds'.

Postoperatively the airway was, however, compromised by edema and a permanent pharyngeal airway never was established.

Brandenburg and co-workers (1980, 1985) presented a rather similar reconstruction in which they used the first two techniques described by Lapidot, but instead of creating 'vocal folds' with pharyngeal mucosa flaps, they narrowed the upper part of the trachea lumen even more by placing a mattress suture in the posterior tracheal wall. A patent airway was guaranteed by a tracheostoma. Successful reports were given for ten of the thirteen patients.

Tanabe, Honjo and Isshiki (1985) employed a modification of the first technique described by Lapidot. Successful rehabilitation has been reported for seven of the eight patients.

Grossenbacher and Fisch (1978) described a three staged technique aiming at total restoration of laryngeal functions. They utilized a deltopectoral flap and autogenic or allogenic cartilage to reconstruct the larynx. Only one of their thirteen patients achieved both a patent airway and an adequate voice.

Stallings and co-workers (1979, 1980a, 1980b) presented a technique utilizing tendon and rib grafts in the immediate reconstruction of the larynx. The thyroid cartilage was reconstructed by grafts of rib-cartilage. The 'vocal folds' were reconstructed with autogenous tendon grafts from the arm, leg, or neck. These grafts were anteriorly and posteriorly attached to the midline of the reconstructed larynx. A tracheostoma was still required. Stallings (1980a) has reported three patients who have undergone this reconstruction technique. In all of these patients successful phonation and deglutition has been achieved.

Rush and co-workers (1979) employed skin flaps to form new 'vocal folds' and to construct a neoglottis. Respiration was guaranteed by a tracheostoma. They reported six patients, all without aspiration problems.

Recently, Herrmann (1986, personal communication) employed the pharyngoesophageal musculature to create 'vocal folds' at the level of the P-E segment. This last technique, however, still requires the use of a one-way valve prosthesis in an internal tracheo-esophageal shunt, as well as a permanent tracheostoma.

Similar to the reconstructive procedures described for the subtotal laryngectomies, the

anastomosis between airway and vocal tract is located above the level of the P-E segment in most reconstructive procedures after total laryngectomy. The potential sound generating structures are therefore also the same as described previously for the reconstructive procedures after subtotal laryngectomy:

1. The created 'neoglottic' structures;
2. The anastomosis between airway and vocal tract;
3. Pharyngeal structures.

2.5.2.4 **Larynx transplantation**

Another effort towards surgical voice restoration for laryngectomees was made by Kluyskens and co-workers (1969, 1970), who performed the first human larynx transplantation in 1969. Although much research had been done on larynx transplantations in animals (Boles 1966; Ogura et al 1966, 1970; Yagi 1966; Silver, Liebert and Sam 1967; Takenouchi et al 1967), several authors (Daly 1970; Tucker 1975; Pearson 1979) have criticized the procedure undertaken by Kluyskens. The final outcome of the operation performed by Kluyskens proved to be a failure: The patient died of recurrent tumor, possibly induced by the immunosuppressive treatment (Kluyskens and Ringoir 1970a, 1970b; Tucker 1975; Pearson 1979). Since that time – to our knowledge – no other human larynx transplantations have been performed.

2.5.2.5 **Implantation of an artificial larynx**

Thus far none of the studies concerning the implantation of a total artificial larynx, which enables deglutition, respiration, and phonation, have successfully passed the experimental stage (McCall and Whitacker 1962; Ogura, Shumrick and Lapidot 1962). Efforts in this direction continue and progress seems promising. Herrmann, Hammer and Grevemeyer (1986) have succeeded in implanting a valve mechanism in baboons, which enables respiration and deglutition without aspiration. Phonation can be achieved after simultaneous implantation of an other one-way valve prosthesis in a tracheo-esophageal shunt (Chapter IV).
Permanent closure of the tracheostoma in such procedures bears the obvious risk of suffocation in case of malfunction of the artificial larynx. An artificial larynx must therefore always be easily removable and replaceable. Much additional research is required before successful implantation of an artificial larynx in humans may be expected.

2.5.3 **Comment on surgical voice rehabilitation methods**

The surgical voice rehabilitation methods generally result in good substitute voice production. Surgical complications, leakage of pharyngeal contents through shunts with subsequent aspiration, and inadvertent spontaneous closure of many shunts, however, have limited the use of these methods. Only a few authors reported acceptable success rates.
The recent development of the silicone valve prostheses which are introduced into an internal shunt, have eliminated most of the above-mentioned problems. These prostheses will be discussed in Chapter IV.
Reviews of surgical voice restoration methods are given by Dworkin and Sparker (1980), Shedd and Weinberg (1980b), Steiner (1980), Jahnke (1982), Smith (1982), Singer (1983), Atkinson (1984), Calcaterra (1985), Evans and Drummond (1985) and

Vuyk (1985).
In most shunt methods (low tracheo-pharyngeal shunts and tracheo-esophageal shunts) the basic sound is generated by the pseudoglottis, which is situated in the P-E segment. Therefore, these shunt voice rehabilitation methods can be seen as employing the esophageal voice.
In most reconstructive procedures after subtotal or total laryngectomy, the pharyngeal aperture of the anastomosis with the airway is situated high in the pharynx. Just like the high tracheo-pharyngeal shunt methods these anastomoses are situated above the level of the pseudoglottis and the substitute voice produced, therefore, is not the esophageal voice. In the next chapter the physiology of esophageal voice production and the different methods by which this substitute voice can be achieved, will be discussed.

Chapter III

ESOPHAGEAL VOICE

Most people are familiar with the sound accompanying belching, when air is expelled from the esophagus and escapes through the mouth. Already at the end of the past century and early in this century it has been reported that the sound accompanying belching could be used as a substitute voice for laryngectomees (Struebbing 1888; Gottstein 1900; Gutzmann 1909). Fränkel (1893) is credited with first locating the source of the 'pseudovoice' at the opening of the esophagus into the hypopharynx. The term 'esophageal speech' was coined by Seeman at a meeting of the Laryngological Society in Vienna in 1919 (Damsté 1958), also suggesting an active role of the esophagus in this type of voice production. Later Seeman's extensive research substantiated this active role of the esophagus (1920, 1922, 1926, 1958, 1961, 1967). In belching the esophageal sound is usually produced rather involuntary and uncontrolled. The laryngectomee has to learn to acquire voluntary control of this method of sound production in order to use it as a substitute voice. Thus, some are able to produce good, intelligible speech by using the acoustical properties of the vocal tract to modulate this belching or esophageal sound.
Just as in other methods of substitute voice production, two factors are essential for esophageal voice production:
1. a sound source
2. an energy source.

Unlike the previously described substitute voice production methods, the energy source is not readily available for esophageal voice production (with the exception of the shunt esophageal voice). Therefore, a relative large part of this chapter deals with the supply of air, which serves as an energy source. But first of all the sound source or pseudoglottis will be discussed.

3.1 PSEUDOGLOTTIS: THE SOUND SOURCE

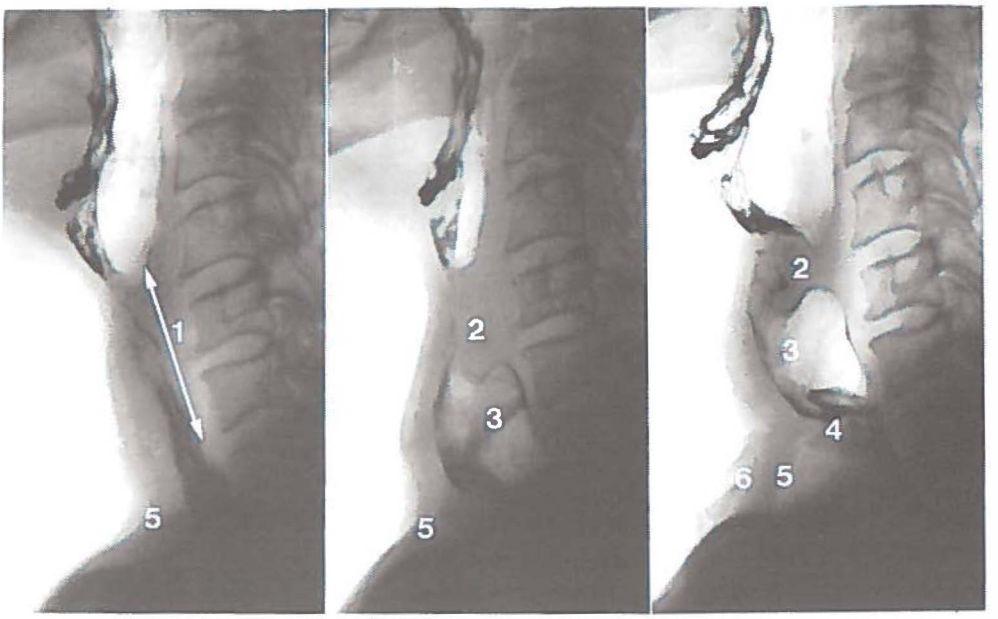
Throughout the years there has been much discussion concerning the nature, location, and physiology of the structures producing esophageal sound. With a large variety of research methods, investigators have tried to disclose the origin of esophageal voice production. Several aspects of these investigations and diverging opinions of some authors are discussed below.

The actual sound source is generally considered to be the so-called pseudoglottis*[1], a structure situated in the pharyngo-esophageal or P-E segment (figures 3.1 and 3.2). Although some authors (Micheli-Pelligrini 1957; Brewer 1975) dispute the active role of the pseudoglottis in esophageal voice production, the widely accepted physiological theories and basic knowledge of voice production do not support their scepticism. The myoelastic-aerodynamic theory of voice production by Van den Berg (1958) and the so-called body and cover voice production theory by Hirano (1977), both described for

*[1]: The meaning of the word 'pseudoglottis' has been controversial. Some authors use this term to describe any structure capable of acting as a sound source for substitute voice production, while others use it to describe the specific structure which produces the esophageal voice. In this book the term is used in the latter meaning.

laryngeal phonation, can also be held valid for esophageal voice production. Both theories involve the vibrating action of certain structures, especially the mucosa, and tension adjustments of these same structures by elasticity and muscular control during phonation.

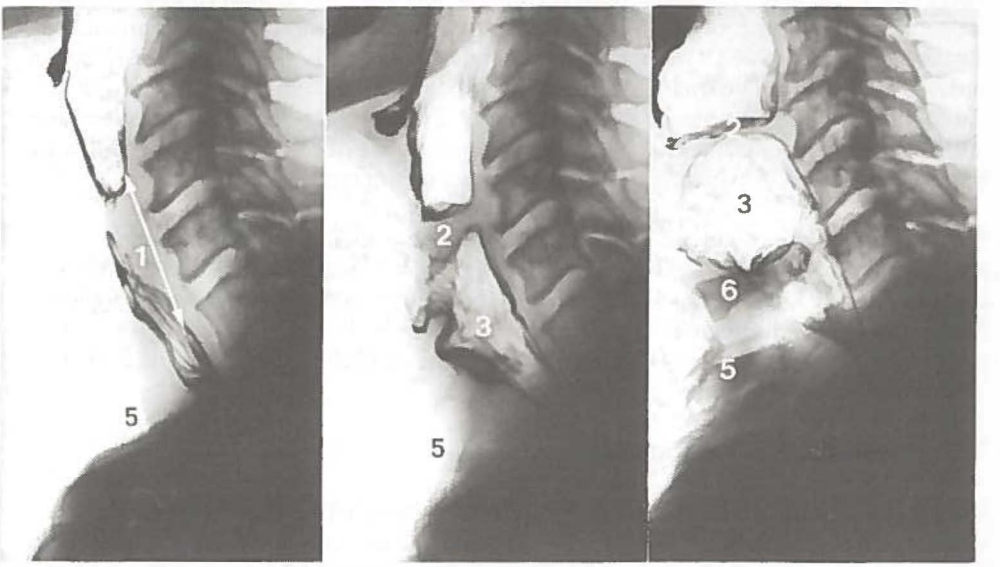
Fig. 3.1



Fluoroscopic imaging of the P-E segment of a laryngectomee (with good substitute non-shunt and shunt esophageal voice) during:
Left: rest (just after swallowing)
Middle: non-shunt esophageal phonation
Right: shunt esophageal phonation.
Note that the structures involved in non-shunt and shunt esophageal voice production are identical. The configuration of the pseudoglottis and the air reservoir are slightly different during non-shunt and shunt esophageal phonation (due to different aerodynamic circumstances).
1 = P-E segment, 2 = pseudoglottis, 3 = air reservoir, 4 = valve prosthesis in shunt, 5 = tracheostoma, 6 = finger occluding tracheostoma.

That the pseudoglottis is indeed the vibrating body producing the esophageal voice was already suggested by the fluoro-stroboscopic examinations of Brankel (1954). This is, furthermore, supported by recent electroglottographic studies (Lecluse, Tiwari and Snow 1981; Schutte 1983; Motta et al 1985), radiographic studies (Novak et al 1982), stroboscopic studies of the P-E segment in esophageal voice production (Hirose 1983; Brandenburg, Bless and Salinsky 1985; Traissac et al 1986b; own observations), and ultrasonic pseudoglottis imaging studies (Böckler et al 1988).
The role of muscular control of the pseudoglottis during esophageal voice production has been demonstrated by electromyographic studies (Shipp 1970; Pruscewicz, Obrebowski and Woznica 1982).

Fig. 3.2



Fluoroscopic imaging of the P-E segment of another laryngectomee (with a good non-shunt and an excellent shunt esophageal voice) during:
Left: rest (just after swallowing)
Middle: non-shunt esophageal phonation
Right: shunt esophageal phonation.
Note that the configurations of the pseudoglottis and the air reservoir during non-shunt and shunt esophageal phonation differ as a result of different aerodynamic circumstances. Nevertheless the same structures are involved in both phonation methods.
1 = P-E segment, 2 = pseudoglottis, 3 = air reservoir, 5 = tracheostoma, 6 = fingers held to the side of the neck during stoma occlusion.

3.1.1 **Anatomical location of the pseudoglottis**

In non-laryngectomized subjects sometimes a 'hypopharyngeal bar' situated at the level of the esophagus entrance can be radiologically demonstrated, either during deglutition (Clements et al 1974; Augustiny, Wolfensberger and Brühlmann 1984) or during a Valsalva test (Templeton and Kredel 1943; Lindsay, Morgan and Wepman 1944). Templeton and Kredel, as well as Lindsay, Morgan and Wepman, observed the same hypopharyngeal bar in a laryngectomee during phonation. Thus, proof has been obtained that this structure, which is held responsible for the alaryngeal voice production, is also present in normal subjects and is situated in or near the esophagus entrance.
Most authors agree that the pseudoglottis is situated at a level between the fourth and sixth cervical vertebra in the majority of patients, and that it is identical with the esophagus entrance (Hoople and Brewer 1954; Schlosshauer and Möckel 1955; Vandor 1955; Van den Berg 1956; Robe et al 1956; Damsté 1958; Decroix, Libersa and Lattard 1958; Landeau 1961; Precechtel 1961; Kytta 1964; Diedrich 1968; Robe 1969; Salmon

1979a; Taptapova 1979). To avoid discussion on whether the pseudoglottis is situated just in or just above the esophagus, the term pharyngo-esophageal (P-E) segment is often used to describe the region where the pseudoglottis is located.
There is general agreement that both the dorsal and the ventral pharyngo-esophageal wall contribute to the formation of a pseudoglottis, either separately or in combination (Brankel 1957; Damsté 1958; Schlosshauer and Möckel 1958; Fumeaux 1961; Vrticka and Svoboda 1961; Diedrich and Youngstrom 1966). Motta and co-workers (1959) also observed contributions of the lateral walls. This observation is in agreement with our own observations and also with the functional state of the P-E segment following laryngectomy (3.1.4) which can be regarded as a sphincter muscle.

The location of the pseudoglottis can be a factor of influence on the quality of esophageal voice production. In this respect a high situated pseudoglottis is usually considered to be less desirable. It should be noted that in some patients no pseudoglottis can be observed radiologically (for example fig. 5.3), although they are capable of esophageal voice production (Vandor 1955; Böhme and Schneider 1960; Diedrich and Youngstrom 1966; Mahieu et al 1987).

3.1.2 **Shape of the pseudoglottis**

Several investigators have thoroughly studied and categorized the radiologically assessed lengths and shapes of pseudoglottides in efforts to relate these parameters to the success of voice rehabilitation. Such correlations have been reported by some of these investigators (Robe et al 1956; Schwab 1956, 1957; Damsté 1957, 1958; Schlosshauer and Möckel 1958; Damsté and Lerman 1969; Bentzen 1976). Others did not find significant correlations between speech skill and length or form of the pseudoglottis (Hodson and Oswald 1958; Kirchner et al 1963; Diedrich and Youngstrom 1966).
Vrticka and Svoboda (1963) state that the shape of the pseudoglottis, hypopharynx and esophagus is conditioned primarily by the type and extent of surgery. They observed no essential change in this shape during the rehabilitation period of seventy laryngectomees (the observation period varied: two-thirds of the laryngectomees were observed for less than one year, none for more than two years). They concluded from this study that training does not alter the shape of the pseudoglottis. Tachiiri and co-workers (1972) concluded from their radiological study that the shape of the pseudoglottis can vary extremely between individuals.
Despite the controversies in the earlier literature, most clinically working researchers still share the opinion that fluoroscopic assessment is important especially for determining causes of failing esophageal voice rehabilitation (Blom 1979b; Damsté 1979; Perry 1983; Perry and Edels 1983, 1985; Mahieu and Annyas 1985; Cheesman, Holden and Perry 1986; Zenner and Herrmann 1986a; Mahieu 1987; Mahieu et al 1987). In our department, fluoroscopic assessment is one of the routinely performed examinations in failing or impaired esophageal voice rehabilitation. It is our experience that massively shaped pseudoglottides are associated with a poor esophageal voice.

3.1.3 **Composition of the pseudoglottis**

In a combined study of radiological findings and autopsy reports Torres and co-workers (1984) demonstrated that the 'hypopharyngeal bar' in the P-E segment consists of hypertrophy of the cricopharyngeus muscle. Cremer and Pau (1978, 1979) also

performed a histological study of 'folds' in the hypopharynx-esophagus region of laryngectomees. They found a circumscribed hypertrophy in the innermost circular muscle fibres of the uppermost part of the esophagus. The authors, however, doubted if the 'folds' were active in esophageal voice production. Their conclusions were only based on two autopsies.
Initially the pseudoglottis has been described as being primarily formed by the cricopharyngeal muscle (Negus 1938; Hoople and Brewer 1954; Robe et al 1956; Van den Berg, Molenaar-Bijl and Damsté 1958; Damsté 1958; Van den Berg and Moolenaar-Bijl 1959; Seeman 1961; Levin 1962).
However, Diedrich and Youngstrom (1966) found the pseudoglottis to be 21 to 29 millimeters in length, using cinefluoroscopic measurements, while anatomical studies have shown that the cricopharyngeal muscle ranges only from 10 to 12 millimeters in length (Batson 1955). Anatomical and radiological studies in non-laryngectomized subjects by Zaino and co-workers (1967, 1970) showed that the pharyngo-esophageal sphincter is not only formed by the cricopharyngeal muscle but also by the uppermost circular esophageal musculature. This is in agreement with manometric studies (Dey and Kirchner 1961; Reichbach and Winans 1970; van Overbeek 1977; Welch et al 1979a, 1979b), which demonstrated that fibres of the upper esophageal musculature, the cricopharyngeal muscle*[2] and the lower constrictor pharyngeal musculature all contribute to the pharyngo-esophageal sphincter mechanism. Van Overbeek reported a mean pharyngo-esophageal sphincter length of 27 millimeters, with a range of 15 to 40 millimeters in fifteen normal subjects.

Since both the location and the length of the pharyngo-esophageal sphincter approximately coincide with the location and the length of the pseudoglottis it may be assumed that the pharyngo-esophageal sphincter and the pseudoglottis are formed by the same structures.
Consequently, it can be stated that the pseudoglottis is formed and controlled by more muscles than the cricopharyngeus muscle alone. This concept is presently shared by most investigators in this field (Shipp 1970; Martin 1979; Zwitman 1979).

We can conclude that, in most cases, the pseudoglottis is composed of the musculature which is normally present in the P-E segment – the cricopharyngeal muscle, lower pharyngeal constrictor muscle and the muscle fibres of the upper esophagus – and the mucosa covering these structures.

3.1.4 **Changes in the P-E segment due to the laryngectomy procedure**

In most cases, the pseudoglottis is situated at the level between the fourth and sixth cervical vertebrae. This is also the level where normally the larynx is situated. It is therefore understandable that surgical manipulations during the laryngectomy in this area account for a large variety in pseudoglottis morphology and behaviour. Muscle fibres within the P-E segment can be cut or removed. Damage to the innervation will occur. It can be expected that, without adequate innervation, no voluntary control over the P-E segment can be achieved later on. Furthermore, a reduction in tactile and kinaesthetic sensation as a result of inadequate innervation may exert negative influence

*[2]: The difference in clinical and anatomical definitions of the cricopharyngeal muscle is an additional problem in the discussion concerning the composition of the pseudoglottis, as has been pointed out by van Overbeek (1977).

on the coordination and tonicity adjustments, required for esophageal phonation. After closure of the pharyngeal defect, suturing of the remaining musculature will inevitably result in some crossing of muscle fibres. Therefore, changes in the organisation of muscle groups may be expected. According to Precechtel (1958) and Simpson and co-workers (1972) closure techniques of the pharynx in the P-E segment are critical with regard to voice rehabilitation. They advocate a careful multilayer closure, including the cricopharyngeal muscle, over the pharyngeal mucosal repair. Hiroto and co-workers (1974), however, report the opposite: the cricopharyngeus muscle should not be tightly closed but rather left unsutured, in order to avoid postoperative stricture of the P-E segment, and consequently impaired esophageal voice production. Cheesman and co-workers (1986) also state that a multilayer muscular closure is most inappropriate for subsequent voice rehabilitation since it can result in a hypertonic P-E segment (3.1.5).
Decroix and co-workers (1958) stressed the importance of preserving as much as possible of the innervation of this area. Herrmann (1986a) also carefully identifies and preserves the innervation of the P-E segment in order to achieve better substitute voice results. Contrary to those advocating preservation of innervation, Singer and co-workers (1986) have recently described a selective neurectomy of the P-E segment innervation, as an alternative to P-E segment myotomy (5.5). They reported excellent voice rehabilitation results with this method. However, on theoretical grounds, neurectomy seems to be a less desirable procedure, because of the subsequent loss of coordinated tonicity adjustments in the P-E segment.

It should be noted that the anatomic alterations produced by laryngectomy functionally result in a complete annular and pure muscular constrictor behaviour of the upper esophageal sphincter or P-E segment (Gates 1980). In a non-laryngectomized subject there is a marked axial asymmetry in the upper part of the upper esophageal sphincter, with antero-posterior accentuation of peak pressures (Winans 1972; Welch et al 1979b). This annular behaviour of the upper esophageal sphincter in laryngectomized subjects may be important in regulation of tonicity in the P-E segment prior to, and during, esophageal phonation (3.1.5). Together with the damaged innervation of the P-E segment, such an annular sphincter behaviour may explain the reported high incidence of laryngectomees with spasmodic activity of the P-E segment during esophageal phonation (Perry and Edels 1985; Cheesman et al 1986). These problems obviously occur in spite of the lower resting pressures registered in the high pressure zone (HPZ) of the P-E segment of laryngectomees.
Manometric studies were consistent in finding that the HPZ of the P-E segment consisted of significantly lower resting pressures in laryngectomees than in normal subjects. Dey and Kirchner (1961) even concluded that normal sphincteric closure was totally absent in laryngectomees, which, however, was not substantiated by other studies.
Using electromyography, Lauerma and co-workers (1972) studied the muscle activity of the P-E segment in normal and subtotal supraglottic laryngectomized dogs. They found a coordination of the musculature in the swallowing action of normal dogs, including an inhibition of the cricopharyngeus muscle. After subtotal supraglottic laryngectomy, the cricopharyngeus muscle no longer showed this normal inhibition of activity during deglutition, but seemed to go into spasmodic contractions, concurrently with contractions of other muscles. After performing a cricopharyngeal myotomy, the cricopharyngeus muscle showed the same inhibition as was seen in the normal situation. Manometric studies also demonstrated relaxation and coordination problems in the

upper esophageal sphincter of laryngectomees (Sandberg 1970; Duranceau et al 1976; Hanks et al 1981; Vuyk, Klinkenberg-Knol and Tiwari 1986). Using X-ray studies, Schobinger (1958) found a spastic cricopharyngeus muscle in 25 per cent of a group of laryngectomized patients. This situation was related to complaints of dysphagia; voice rehabilitation results were not taken into account.
Although most of the above-mentioned studies were performed in rest and during swallowing to investigate deglutition following laryngectomy, it is likely that the reported dyscoordination and spasmodic contractions of the musculature in the P-E segment can also have negative effects on esophageal voice production.

3.1.5 **Activity of the P-E segment with regard to esophageal phonation**

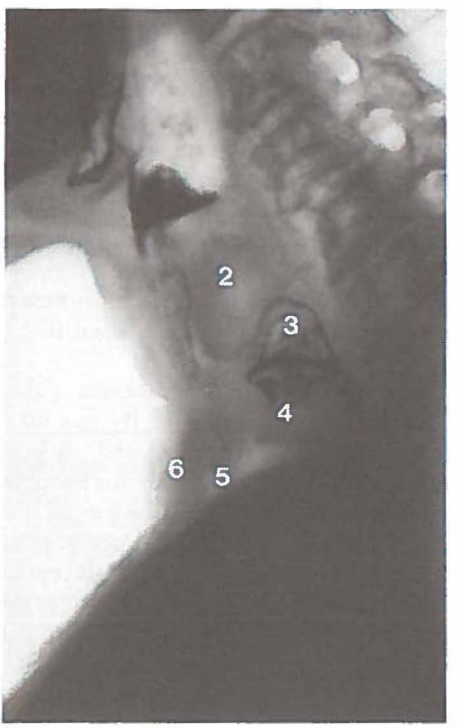
In normal laryngeal subjects, the P-E segment only opens when the upper esophageal sphincter relaxes early in the deglutitive sequence, to allow the passage of the bolus, or during belching.
Brunner (1952) found that increased air pressure in the hypopharynx often results in a spastic contraction of the cricopharyngeal muscle. He concluded that an important function of the cricopharyngeal muscle is to prevent the influx of air into the esophagus. Therefore, increased air pressure in the hypopharynx, and a bolus in the hypopharynx, seem to have opposite effects upon the upper esophageal sphincter. This mechanism can interfere with the intake of air for esophageal voice production (3.2).
A similar reflex mechanism can be found following the intake of air in the esophagus. In normal individuals distention of the esophageal wall has been found to result in elevation of intraluminal pressures in the P-E segment (Creamer and Schlegel 1957; Schutte 1980). Following it's intake for esophageal phonation the air is accumulated in the esophagus, which may also result in a distention of the esophageal wall.

The resulting reflectory pressure rise in the P-E segment may prevent the release of air from the esophagus. Therefore, it is important for the laryngectomee to gain voluntary control over the P-E segment, so that sufficient relaxation can be achieved to allow both the intake and the release of air for esophageal voice production. Furthermore, voluntary control over the P-E segment is important for proper tonicity adjustment of the P-E segment, required for good esophageal voice production.
A coordinated interaction of the P-E segment musculature must be realized in order to regulate this mechanism of relaxation for intake and release of air, and the simultaneous adjustment of tonicity for the onset and sustenance of esophageal voice production.
Electromyographic studies by Shipp (1970) supported the notion of active and coordinated P-E segment musculature during esophageal voice production. In a comparison of adequate and inadequate laryngectomized speakers he found that the ability to contract the musculature differentially during the intake and the release of air, during phonation, was more characteristic of proficient speakers. No typical or modal muscle pattern could be detected in all of his eighteen subjects, which may be explained by interindividual variations in voicing method, consistent with varying postoperative anatomy and physiology.
In manometric studies Vuyk and co-workers (1986) observed marked derangements in upper esophageal sphincter relaxation and coordination in eight out of sixteen patients with a Staffieri 'neoglottis'. They found this incomplete relaxation and dyscoordination to be a determinant of inefficient phonation. The sound source in the 'neoglottis' speakers is essentially the same as that in esophageal voice production. In both situations the pseudoglottis can be considered to be the sound source (Novak et al 1982).

Many investigators have shown interest in assessing the relationship between the tonicity of the pseudoglottis and development of esophageal voice production. The generally held opinion is that both hypotonicity and hypertonicity negatively influence esophageal phonation. Damsté (1958) has speculated that lack of tonicity within the P-E segment may result in a situation, in which the pseudoglottis does not provide enough resistance to the air, which is expelled from the esophagus during phonation. This resistance is considered an essential factor in the mechanism which sets the air into vibration, especially at the onset of phonation. Therefore, lack of tonicity may result in a poor esophageal voice. The tonicity, and consequently the pseudoglottis resistance, can also be excessively high (fig. 3.3), thus hindering or even preventing, the expulsion of air (3.2.1) through the P-E segment downward to fill the air reservoir, is also hampered (Damsté 1959; Landeau 1961).

Fig. 3.3

Fluoroscopic imaging of a laryngectomee with a hypertonic P-E segment during shunt esophageal phonation. The resulting substitute voice is poor and has a pressed and hyperfunctional quality. This laryngectomee required a high intratracheal air pressure to phonate with the shunt esophageal method. He never achieved phonation with a non-shunt method. Phonation with the shunt method requires a lot of energy and often gives him a headache. The maximal phonation time is short, the phonation often abruptly stopping, shortly following its onset.
Note that the pseudoglottis is a very massive structure when compared to figures 3.1, 3.2 and 3.4. The air reservoir is small.
2 = pseudogottis, 3 = air reservoir, 4 = valve prosthetis in shunt, 5 = tracheostoma, 6 = finger occluding tracheostoma.



Pruscewicz and co-workers (1981, 1982) studied the activity of the cricopharyngeus muscle during esophageal speech, using manometric and electromyographic methods. They found a correlation between the subpseudoglottic pressure required for air expulsion, and the amplitudes of the electromyographic recordings. A hypertonic P-E segment (high electromyographic amplitudes) was found to require a high subpseudoglottic pressure to let the air pass outwards. A relaxed P-E segment (small electromyographic amplitudes) was found to coincide with a low subpseudoglottic pressure required for air expulsion and subsequent phonation.
Many manometric studies failed to demonstrate a correlation between tonicity of the P-E segment and esophageal voice acquisition, (Damsté 1958; Van den Berg and

Moolenaar-Bijl 1959; Salmon 1965; Crouch 1974).
With more modern manometric techniques Winans, Reichbach and Waldrop (1974) and Kelly, Adamovich and Roberts (1981) were able to distinguish between good and poor esophageal speakers, on the basis of resting upper esophageal sphincter pressures. Better speakers had lower pressures. Their findings were, however, not substantiated by other recent studies (Collo, Weihrauch and Foerster 1977; Roed-Peterson, Jorgensen and Larsen 1979; Welch et al 1979a; Salmon 1979b; Mathis, Lehman and Shanks 1983).
It should be noted that manometric measurements performed during a 'static' phase, at rest, or during a 'dynamic' deglutition phase may be totally different from the situation during the 'dynamic' phase which is associated with the intake of air, and with esophageal phonation (Zinner and Flesher 1972; Blom 1979b). This difference between the situation during phonation, during swallowing and in rest, is illustrated by the absence of a correlation between subpseudoglottic pressures required for sustained phonation, and manometrically assessed post-deglutitive and resting pressures, in a group of Staffieri speakers (Vuyk 1985).
Many authors stress the importance of a proper tonicity in the P-E segment for good esophageal voice production. Probably, they mean the tonicity during air intake and esophageal phonation. However, most of them measure the tonicity during deglutition and in the resting state.
Despite all controversies, the consensus seems to be:
A hypertonicity, or inability of sphincter relaxation, both associated with a high resistance of the P-E segment, hampers the intake of air, the expulsion of air, and the vibratory movements of the pseudoglottis.
A hypotonicity allows an easy intake and expulsion of air, but due to the lack of resistance, hardly any or no vibration at all will be generated in the pseudoglottis.

Several methods were developed to determine the resistance of the P-E segment for air intake or air expulsion. Damsté, Van den Berg and Moolenaar-Bijl (1956), Seeman (1958, 1961), and Vrticka, Gunderman and Petrik (1965) described methods to determine the resistance of the P-E segment for air intake. They used a manometer which was attached to a Politzer balloon with olive. The olive was placed in a nostril, while the other nostril was occluded and the mouth was closed. Subsequently, air was pressed from the balloon into the pharynx and (if sufficient pressure was obtained) through the P-E segment into the upper part of the esophagus. Thus the pressure required to overcome the resistance of the P-E segment during the intake of air could be measured. High pressures were found to be correlated with poor or no esophageal voice acquisition.
As early as 1953 Legler described an insufflation test to assess the resistance of the P-E segment for air expulsion. This test was almost identical to the test which was later described by and named after Taub (1973). During the insufflation test a rubber catheter is passed through the nose into the upper part of the esophagus. When air is insufflated through this catheter, it either passes upwards through the P-E segment, producing esophageal sound, or it passes downwards to the stomach if the P-E segment is too tight to allow the expulsion of the air.
Brankel (1954) combined this insufflation test with fluoroscopic and fluoro-stroboscopic examinations.
In 1957 Van den Berg described the connection of a manometer to the catheter to measure the pressure required for air expulsion. This technique of bringing air below the pseudoglottis can also be used during the training for esophageal voice production

(Dinville 1961, de Vleeshouwer 1971). Insufflation tests are still widely used to determine the ability for developing esophageal voice (Blom, Singer and Hamaker 1985, 1986; Perry and Edels 1985; Singer and Blom 1985a; Cheesman, Holden and Perry 1986; Mahieu 1987).
To avoid or treat the *hypertonic* situation, which is considered to be the most frequent cause of failure in esophageal voice acquisition, a myotomy of the P-E segment is advocated by several authors (5.5). Such functional pharyngeal surgery with the objective of regulating the tonicity of the P-E segment, can presently be considered as one of the most important topics in laryngectomee voice rehabiliation. Alternative methods in order to treat the hypertonic state of the P-E segment include bouginage (Damsté 1975) and speech therapeutic approaches such as relaxation methods, for instance the chewing method (Klinger and Martin 1971). The practical use of these alternative methods, however, seems to be rather small.
Correction of the *hypotonic* situation can easily be accomplished by exerting external pressure on the P-E segment through the skin. This can be accomplished digitally (Damsté 1975; Davis 1981; Perry 1983; Cheesman, Holden and Perry 1986) or by specially developed devices, which are strapped to the neck (Grisius, Moore and Simpkins 1974; Shanks 1983). Also surgical procedures such as the sternocleidomastoid muscle swing operation have been described for this purpose (Montgomery and Lavelle 1974). Such manipulations for increasing the resistance of the P-E segment are sometimes recommended to increase the loudness and intelligibility of esophageal voice. Duguay (1979) stressed the important fact that external pressure should be applied after air intake and not prior to air intake. Therefore, digitally applied external pressure seems to be the most appropriate method. Furthermore, Duguay hypothesizes that externally applied pressure does not correct the hypotonic state, but prevents bulging or ballooning of the P-E segment.

3.1.6. **Substitute voice production without P-E segment**

Patients whose carcinoma requires partial or total resection and reconstruction of the P-E segment in addition to the laryngectomy usually encounter greater difficulty in substitute voice acquisition, than laryngectomees whose P-E segment has been preserved.
The problems which can be encountered in the voice rehabilitation of patients after pharyngo-laryngectomy or even more extended surgery are based on the following aspects:

1. Absence of elastic tissue, within the reconstructed P-E segment, which can vibrate adequately for sound production.
2. Failure to achieve voluntary control over the reconstructed P-E segment. This results in failure of coordination, relaxation and tonicity adjustment, which is required for air intake and air release prior to phonation, and for onset and sustaining of the phonation itself.
3. Loss of tactile and kinaesthetic sensation in the reconstructed P-E segment, interfering with the above-described process of learning to gain voluntarily control and to adjust the tonicity of the reconstructed P-E segment.
4. Elimination or reduction of the air reservoir (3.2) in the upper esophagus.

Since these patients no longer have a P-E segment and pseudoglottis, the structures used for the reconstruction (gastric structures, other enteric structures, muscle or skin flaps) will have to form a substitute pseudoglottis. Therefore, these patients do not produce an esophageal voice in the strict sense. Only a few of them are reported to achieve a

substitute voice without the aid of a shunt (Lall and Evison 1966; Wertz, Keith and DeSanto 1973; Shedd et al 1974, 1975; Damsté 1975, 1979; Vizel1976; Weinberg, Shedd and Horii 1978; Richardson 1981; Meyer and Brupbacher 1983; Logemann 1983; Lamprecht 1986). The quality of the substitute voice seems to depend upon the type of reconstruction. Schechter and co-workers (1987) found that gastric pull-up reconstructions resulted in relatively good substitute voices without a shunt. This in contrast to their regional flap reconstructions or free jejunal grafts.
Many more laryngo-pharyngectomees acquired substitute voice with tracheo-esophageal or tracheo-gastric shunt methods (Draf 1980; Logemann 1983; Krespi, Sisson and Wurster 1984; Saito et al 1984; Cheesman, Holden and Perry 1986; Herrmann 1986b; own observations). Ehrenberger and co-workers (1985a, 1985b, 1986) reported good phonatory results with a tracheo-pharyngeal shunt of an interposed jejunal graft. However, a tracheo-pharyngeal shunt with interposition of a colonic graft has been reported to give a poor phonatory result (Vergnolles, Sauvage and Descottes 1982). The fact that substitute voice acquisition following laryngo-pharyngectomy is only occasionally successful without a shunt, but is mostly successful with a shunt, suggests that the air intake is more hampered by the absence of a P-E segment than is the sound generation itself. However, the quality of the shunt substitute voice is generally not as good as that of the laryngectomee with a preserved P-E segment is.

3.1.7. Conclusions concerning the role of the P-E segment in esophageal voice production

All studies seem to substantiate that the pseudoglottis, as part of the P-E segment, is responsible for the esophageal voice production. The vibrating pseudoglottis sets the air into vibration. The vibrating air (= sound) is modulated into speech by the vocal tract. To generate these vibrations, air is required not only as a medium in the P-E segment and the vocal tract but also as a source of energy.
The anatomical and functional situation in the P-E segment determines to a great extent whether or not the laryngectomee will learn to use the esophageal voice, and what the quality of the resulting substitute voice will be. This not only concerns the role of the pseudoglottis as a vibrating sound source but also the role of the P-E segment as an inlet of air, in those methods of esophageal voice production in which air is not brought into the upper part of the esophagus through a shunt (swallowing, inhalation or injection method: 3.2.1).
A good sound will be produced when:
- the pseudoglottis can accomplish a good periodical occlusion of the P-E segment,
- the pseudoglottis has elastic properties, which enable a short opening phase, so that only a small amount of air will pass through the P-E segment during each periodical opening,
- the pseudoglottis is supple enough to vibrate and allow vibration of its mucosal cover,
- sufficient innervation is preserved to allow voluntary control over the P-E segment, consequently enabling coordination, relaxation and tonicity adjustments of this P-E segment,
- the tactile and kinaesthetic sensation in the P-E segment is sufficient to allow coordination and tonicity adjustment of this P-E segment,
- the tonus in the P-E segment during esophageal phonation is neither too high nor too low, and can be adjusted to different aerodynamical circumstances which occur during the onset and duration of esophageal phonation,

- the P-E segment allows sufficient intake of air.

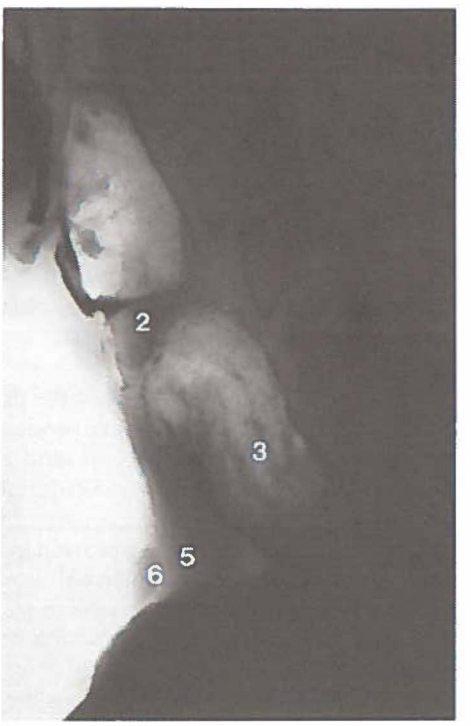
The last item brings us to the second prerequisite for esophageal voice production: the air supply which is used as a source of energy. How can the air be brought into the esophagus, below the P-E segment?

3.2. **AIR SUPPLY: THE ENERGY SOURCE**

The energy source of esophageal voice production is the reservoir of air in the upper part of the esophagus (fig. 3.4).

Fig. 3.4

Fluoroscopic imaging of a laryngectomee phonating with the shunt esophageal method. Note the large air reservoir.
2 = pseudoglottis, 3 = air reservoir, 5 = tracheostoma, 6 = finger occluding tracheostoma.



Pressurization of this air results in a rise in subpseudoglottic pressure, and consequently in a more or less periodic escape of air outwardly, through the periodically opening and closing system of the pseudoglottis and its mucosal cover. As Snidecor (1969c) correctly states, the fundamental act in learning esophageal voice is twofold: the charging intake and releasing expulsion of air from the esophagus. The most difficult aspect of this two-sided problem is that of getting air into the esophagus, the so-called air intake. In the older literature it was often believed that the stomach (Kallen 1932, 1934) or the hypopharynx (Ragaglini, Teramo and Micheli-Pellegrini 1956) served as an air reservoir for esophageal phonation. More recent studies, however, demonstrate that the air reservoir is situated in the esophagus, mainly in it's upper part (Van den Berg 1957; Van den Berg, Moolenaar-Bijl and Damsté 1958; Hodson and Oswald 1958; Damsté 1958; Schlosshauer and Möckel 1958; von Kamieth 1959; Motta, Preofazio and Acciari 1959; Vrticka and Svoboda 1961, 1963).

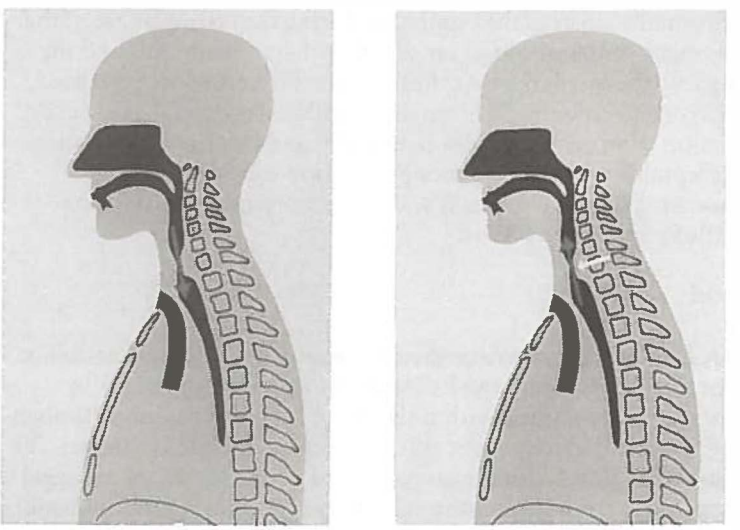
The air containing capacity of the entire esophagus has been estimated to be 60 – 70 milliliters, when fully inflated (Van den Berg, Moolenaar-Bijl and Damsté 1958). However, the esophagus is not fully inflated for esophageal phonation. Estimation of the amount of air available for use after one air charge with the injection method (3.2.1.3) or inhalation method (3.1.1.2) is about 15 to 25 milliliters (Van den Berg, Moolenaar-Bijl and Damsté 1958; Snidecor and Isshiki 1965). Mean air flow rate values during continuous esophageal phonation using injection or inhalation air charging methods, range from 27 to 72 milliliters per second (Isshiki and Snidecor 1965). Therefore, it is easy to understand why frequent successive air charges are required during esophageal speech performance. In contrast, the air reservoir in the lungs of laryngeal speakers contains 3500 to 4000 milliliters of air, of which at least 1500 to 2000 milliliters are available for phonation.

3.2.1 **Air intake**

To fill the air reservoir in the esophagus four different methods can be distinguished:
1) swallowing method
2) inhalation method
3) injection method
4) shunt method

The air which is used for sound production in the first three listed methods is not respiratory air, but air which must be passed downward from the oral and pharyngeal cavities, through the P-E segment, into the esophagus. Subsequently, it must be redirected upward from the esophagus and pass through the P-E segment in order to initiate the sound production (fig. 3.5).

Fig. 3.5



Non-shunt esophageal phonation.
Left: the intake of air (gray arrow) into the esophageal air reservoir.
Right: the expulsion of air (gray arrow) from the air reservoir generating esophageal sound by interaction with the pseudoglottis (white arrow).

As already mentioned (3.1.5) the tonus and anatomy of the P-E segment have a major influence on these air intake methods. In addition, Klinger (1970) suggests that tongue movements lend a mechanical assist in opening the P-E segment, thus facilitating the intake of air with these methods.
In the shunt method expired pulmonary air is used, just as in normal laryngeal voice production. In this method the intake of air is not influenced by the P-E segment.
The different methods of air intake are discussed below.

3.2.1.1 **Swallowing method**

When using the air intake method described by Gottstein in 1900, the esophagus is filled with air by swallowing actions. This swallowing method is generally considered to be an undesirable technique of filling the air chamber in the esophagus (Froeschels 1951; Seeman 1958; Diedrich and Youngstrom 1966; Isshiki 1969; Salmon 1979a; Heuillet-Martin and Cornubert 1982; Edels 1983). It is an uneconomical method and has several disadvantages. The speech is interrupted too long during the air intake, and is also conspicuous because of the swallowing actions which are often accompanied by undesired movements of head and neck. The air is often not redirected upward through the P-E segment, but passes downward to the stomach, because the act of swallowing initiates a peristaltic wave pattern along the esophagus. Furthermore, the swallowing actions cannot be repeated as frequently as is required for serviceable speech.

3.2.1.2 **Inhalation method**

This air intake method which is sometimes called aspiration method, has been described by Seeman in 1920, and is still advocated and used by many speech therapists. The method consists of filling the air reservoir in the esophagus by means of a quick respiratory inhalation. The negative intrathoracic pressure, associated with inspiration, is also transmitted to the esophagus. This results in an even lower pressure than the negative pressure which normally exists in the esophagus during the resting phase. If the P-E segment relaxes and opens simultaniously, air will flow from the mouth and the nose through the pharynx into the esophagus. As the pressure differences are equalized, the P-E segment closes, leaving air contained within the insufflated esophagus ready for esophageal sound production (Van den Berg, Moolenaar-Bijl and Damsté 1958). With this method good and acceptable esophageal voice production can be achieved. However, problems concerning hyperventilation and respiratory overexertion have been described (Isshiki 1969; Snidecor 1969b).

3.2.1.3 **Injection method**

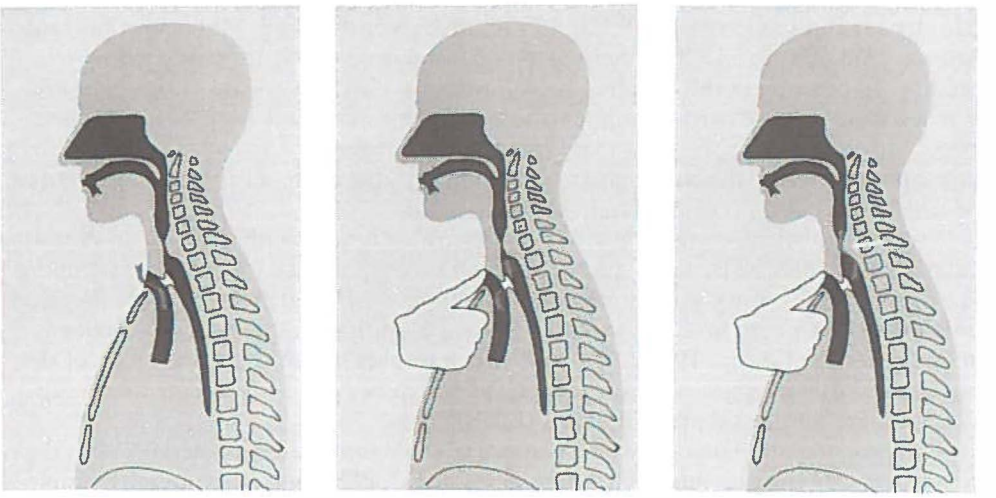
In this air intake method, for the first time extensively described by Moolenaar-Bijl in 1951, the air is pushed or injected through the P-E segment into the esophagus by increasing the pressure of the air contained within the oropharyngeal cavity. Although various methods have been described to achieve this, the basic principle is similar. The escape routes – the oral and nasal ports – for the air contained within the oropharyngeal cavity, are closed by respectively the lips, and the velopharyngeal closing mechanism. Subsequently the size of the oropharyngeal cavity is reduced. When the enclosed air is thus sufficiently pressurized to overcome the resistance of the P-E segment, the air will pass into the esophagus. Relaxation of the P-E segment will favorably influence this passage of air.

The movements of the mouth associated with the above described sequence of events, is identical with the articulation of certain consonants, especially /p/, /t/ and /k/ (Moolenaar-Bijl 1951, 1953a, 1953b, 1953c, 1979; Van den Berg, Moolenaar-Bijl and Damsté 1958; Damsté 1958). These plosive consonants, which are produced by building up pressure in the oropharynx followed by a sudden release of this pressure, form a natural way of teaching patients to use this air intake method. The preparing speech movements for these consonants are slightly exaggerated and air is injected into the esophagus before the consonant is pronounced. This method is often referred to as the consonant injection or plosive injection method.
Another method of injecting air into the esophagus has been described by Diedrich and Youngstrom (1966): The air in the oropharynx is compressed by a piston or pumping type of action of the tongue. This method is known as the glossal press, glossopharyngeal press, or tongue pump injection method. Several modifications have been described, among others by Gately (1977). The time which elapses between the beginning of the movements of air injection and voice onset, i.e. the latency period, is less for consonant injectors than for glossal press injectors (Edels 1983).
Some authors mention a noise which can occur while filling the air reservoir with the glossal press injection method. It has been described as 'klunking', 'thumping', 'pump', or 'clump' (Diedrich and Youngstrom 1966; Snidecor 1969b). A study by Gunn and co-workers (1979) disclosed that 'klunking' is one of the most frequently occurring perceptual characteristics of esophageal speech. According to Salmon (1979a) this 'klunking' noise, may be the result of too much air, which is injected too fast, with too much tension in the P-E segment. Because it occurs immediately prior to an utterance, some authors describe 'klunking' as a distraction rather than a direct interference to speech (Hyman 1979). This is substantiated by a recent study in which no correlation between 'klunking' and a judgement of overall esophageal speech proficiency could be established (Knox et al 1987). Others, however, are convinced that 'klunking' does interfere with intelligibility (Shanks 1979c; Martin, Salmon and Shanks 1981).

3.2.1.4 **Shunt method**

In this method the air reservoir under the P-E segment is filled with air, which is shunted from the respiratory tract. The surgical aspects of various shunt methods have been described in 2.5.2. As previously pointed out (2.5.2.1) the pseudoglottis can only be employed as the primary sound source, if the shunts enter the vocal or digestive tract at or below the level of the P-E segment (low tracheo-pharyngeal shunts and tracheo-esophageal shunts). Thus, these shunt methods are per definition methods which produce esophageal voice.
In all shunting methods occlusion of the tracheostoma is required to bring air beneath the sound generating structures. On exhalation, the air pressure rises in the trachea and consequently the air will flow through the shunt into the air reservoir in the upper part of the esophagus (fig. 3.6). This mechanism of air intake has several advantages over the previously described methods: first of all, this shunt method of air supply, using expired air, is almost identical to the physiological energy source in laryngeal voice production, and requires little or no respiratory adjustments. This makes the shunt method of esophageal voice production easy to learn.
Secondly, the amount of air available for esophageal voice production is equal to that available for normal laryngeal phonation (3.2).

Fig. 3.6



Shunt esophageal phonation (in this example with valve prosthesis situated in the shunt).
Left: the intake of air (gray arrow) into the lungs during inspiration.
Middle: occlusion of the tracheostoma during expiration, air flowing (gray arrow) through the shunt (and the valve prosthesis) into the esophageal air reservoir, immediately followed by,
Right: the further expulsion of air (gray arrow) through the pseudoglottis (white arrow) generating the esophageal sound.

Compared to the air intake methods which do not use respiratory air, this enables a longer sustained phonation and consequently a more fluent speech, since fewer interruptions are required for filling the esophageal air reservoir.
For a better understanding of the substitute voice producing mechanisms the term *non-shunt* esophageal voice will be used in contrast to *shunt* esophageal voice. In this sense non-shunt esophageal voice is the esophageal voice, which is produced by the inhalation, the injection, and the swallowing methods of air intake, and shunt esophageal voice is the esophageal voice produced with the shunt method.

3.2.2 **Air expulsion**

Once the air is contained in the air reservoir beneath the P-E segment, it will have to be pressurized and redirected upward through the P-E segment in order to supply the air and energy required for generating vibration, and subsequent sound production, in the P-E segment.
This expulsion of air can be achieved by complex mechanisms. Although these mechanisms are difficult to understand due to their complexity, they are apparently of such a physiological nature, that most laryngectomees seem to manage them without effort. The air expulsion mechanisms alone will seldom be the cause of failing esophageal voice acquisition. This in contrast to the air intake methods which, with the exception of the shunt method, can be difficult to learn and therefore often interfere with esophageal voice acquisition.
Different mechanisms of air expulsion can be applied, depending upon the method of air intake used. Because the air expulsion mechanisms for the non-shunt air intake methods are more or less comparable, they will be discussed together. The air expulsion

mechanism for the shunt air intake method is quite different and will therefore be discussed separately.

3.2.2.1 **Air expulsion following the non-shunt air intake methods**

An increase of pressure within the esophagus is required in order to redirect air upward through the P-E segment. Several mechanisms contribute to this pressure rise. Furthermore, during the escape of air through the P-E segment, the pressure in the air reservoir cannot be allowed to drop, because this would stop the phonation. The maintenance of an adequate amount of subpseudoglottic air pressure requires a delicate balance between the air flow resistance offered by the P-E segment and the force of air expulsion.

The most detailed description of the complex mechanism of air expulsion has been given by Van den Berg, Moolenaar-Bijl and Damsté (1958).
Five mechanisms may come into action:

1) A voluntary active contraction of the striated muscles of the upper part of the esophagus.
2) A direct compression of the region of the cardia by the diaphragm.
3) A passive increase of esophageal pressure by the decrease of the volume of the lungs during expiration. At the end of a maximal expiration, this increase can attain very high values, as the tissue itself is then compressed.
4) A passive behaviour of the non-muscular components of the wall of the esophagus.
5) A passive increase of the esophageal pressure by expiratory movements of the thorax. This effect becomes extremely important with a filled esophagus, during loud speech or with a strong effort to speak, when a local distention of the esophagus into the trachea gives rise to a high air flow resistance.

The third and fifth mechanism are dependent upon the fact that the esophagus is a structure which is situated inside the thorax. Consequently intrathoracic pressure changes, due to respiration, result in similar pressure changes in the esophagus.
As described by Van den Berg the fourth and fifth mechanism are the most important factors for maintaining the pressure in the esophagus, required for esophageal voice production.
The fourth mechanism, the elastic property of the wall of the esophagus, is an important factor, especially in the injection air intake method, in which the air is pressed through the P-E segment into the upper esophagus. The resulting pressure rise in the upper esophagus, is only present for a very short time, and is higher in the injection method than in the inhalation method of air intake. Furthermore, since the latency period between air intake and onset of phonation is longer in the inhalation method, the effective pressure rise in the esophagus due to the fourth mechanism will have already decreased by the time that air expulsion and esophageal phonation can start. According to Van den Berg and co-workers (1958) and Damsté (1958), the fourth mechanism alone is enough to guarantee expulsion of air, if the plosive injection method of esophageal voice production is used at normal conversational loudness level.
The fifth mechanism, referred to by Damsté as 'the alveolar pressure in expiration', is used when air intake is performed with the inhalation method or when, with the injection air intake method, higher subpseudoglottic pressures are required, such as for loud or high pitched phonation. This mechanism is also employed by beginners who still have a poor control of the pseudoglottis, and who generally let a long interval elapse

between air intake and phonation onset. The fifth mechanism also plays the major role in air expulsion following the undesirable swallowing method of air intake.
The intra-esophageal pressure rise due to the fifth mechanism can be described as follows: rapid expiration results in a high airway resistance in the bronchi and bronchioli, leading to a rise in alveolar pressure and thus a rise in intrathoracic pressure and esophageal pressure. According to Damsté, a Bernoulli effect may contribute to the increase of air resistance in the respiratory tract during expiration.
Van den Berg also mentions the coughing mechanism which results in high pressures in the esophagus. This can be considered as an extreme form of the fifth mechanism in combination with a contraction of the abdominal and neck muscles, which limits and eventually reduces the space available for trachea and esophagus.
The rapid and strong expiration which is required for an intra-esophageal pressure rise due to the fifth mechanism, is often accompanied by stoma noises, caused by the high volume velocity of the air passing through the tracheostoma. These noises can seriously interfere with the intelligibility of the esophageal voice production. Shipp (1967) demonstrated that excessive stoma noise negatively influences the acceptability judgement of esophageal speech.
It is very important that the high esophageal pressures required for esophageal voice production are passively produced, no active high alveolar pressure being necessary, as a high alveolar pressure would obstruct the circulation of the blood, forcing the patient to stop after a few seconds (Van den Berg, Moolenaar-Bijl and Damsté 1958). Therefore, the fourth mechanism is to be preferred for maintaining the necessary subpseudoglottic pressure during phonation. This implicates that the injection method is to be preferred over the inhalation method of air intake.
Several authors, however, advocate a combination of inhalation and injection air intake methods (Diedrich and Youngstrom 1966, Isshiki 1969, Snidecor 1969b, Salmon 1979a, Edels 1983). Since there is probably no esophageal speaker who exclusively uses only one of the non-shunt air intake methods, an integration of methods seems to take place automatically.

We prefer to use the plosive injection method as the basis of non-shunt esophageal voice rehabilitation. There is a consensus that the swallowing method should be avoided, because of its ineffectiveness and because it compromises the acquisition of the other non-shunt air intake methods.

3.2.2.2 **Air expulsion following the shunt method**

Air expulsion in the shunt method can be considered to be largely identical to the normal air expulsion in laryngeal voice production, i.e. respiratory expiration. When the tracheostoma is occluded during expiration, the air pressure in the trachea rises, resulting in an air flow through the shunt into the esophageal air reservoir, in which consequently a pressure rise occurs. The air pressure in the esophageal air reservoir depends mainly upon: the force of expiration, the air flow resistance of the shunt, the elastic property of the air reservoir, and the air flow resistance of the P-E segment. Since expiration can be voluntarily controlled, fine adjustment of the subpseudoglottic air pressure, required for air expulsion and phonation, can be achieved. Obviously, the air flow resistance offered by the shunt has an important influence on the relationship between intratracheal and subpseudoglottic air pressure.
The five mechanisms responsible for the air expulsion in the non-shunt methods of air intake (3.2.2.1), may contribute to the air expulsion in the shunt method. However, they

seem to be of minor importance with the possible exception of the fourth mechanism. The elastic property of the esophageal wall comprising the fourth mechanism can be considered to be of importance for the maintenance of the pressure in the esophageal air reservoir during phonation. The contribution of the other mechanisms is probably limited to the obstruction of air flow to the lower esophagus, thus preventing an escape of air towards the stomach. The functional obstruction of the lower esophagus is supported by the intrathoracic pressure rise due to the expiration effort with occluded tracheostoma. The contribution of the distal esophageal sphincter in preventing the air to pass into the stomach is probably neglectable (3.3.1.1).
Not only the amount of air which is available for esophageal phonation is larger when a shunt method is being used, but also the expulsion of air can be regulated finer, than with the non-shunt methods of esophageal voice production. This contributes to a better esophageal speech fluency, which sometimes even resembles normal laryngeal speech, and to a better quality of esophageal voice due to a better regulation of the aerodynamic situation in and just below the P-E segment.

3.3 **Difficulties in the acquisition of esophageal voice**

Why do some laryngectomees fail to develop esophageal voice, while others seem to manage it with little effort? Obviously some do not want to learn, but others just aren't able to learn, despite good motivation and high intelligence, among other factors.
Essentially, all problems of acquiring esophageal voice are related to the fact(s) that the laryngectomee lacks the ability or facility:
1) to fill the esophageal air reservoir,
2) to redirect the air from the esophageal air reservoir upwards,
3) to maintain the required subpseudoglottic air pressure,
4) to regulate the tonicity of the P-E segment according to the requirement for esophageal sound production.

The causes of this lack of abilities or facilities are categorized by Duguay (1979) and involve:
1) physiological and anatomical factors
2) psychological and sociological factors (which we prefer to distend to: 'patient related factors')
3) speech therapy related factors.

He adds a fourth category to cover those laryngectomees who fail to acquire esophageal voice, without an apparent reason. Unlike the laryngectomees involved, this fourth category speaks for itself and will not be further discussed.
It stands to reason that several factors may co-exist. There are major differences in the percentages and causes of failing esophageal voice acquisition between the various method of air intake. Since the swallowing method is regarded to be obsolete, this method will not be taken into consideration. Because the problems concerning the acquisition of esophageal voice with the inhalation method and injection method are almost the same, and most laryngectomees employ a combination of these methods, they are discussed together (3.3.1).
Problems associated with esophageal voice acquisition using a shunt method will be discussed separately (3.3.2).

3.3.1 **Failing esophageal voice production in non-shunt methods**

Until very recently, the non-shunt esophageal voice was generally regarded to be the most desirable form of laryngectomee speech rehabilitation, and some people still hold this opinion. The reported numbers of laryngectomees who have successfully acquired this type of substitute voice production varies greatly. A review of the literature shows that the number of laryngectomees who fail to attain satisfactory proficient non-shunt esophageal speech, ranges from 14 per cent (Hunt 1964) to 76 per cent (Gray and Konrad 1976; Schaefer and Johns 1982). The average estimates place the amount of non-shunt esophageal speech failures at approximately one-third (McGall 1955; Putney 1958; Bisi and Conley 1965; Lauder 1969; Kitzing and Toremalm 1974; Van de Calseyde et al 1975; Watts 1975; Salmon 1979b; Shumann, Laniado and Carstens 1981; Berger 1982;Kiwasaki 1983; Natvig 1983a). These results are derived from retrospective studies.
Using prospectively obtained data, Gates and co-workers (1982a) found that 74 per cent of the laryngectomees fail to acquire non-shunt esophageal speech. When those who did not attempt to learn are excluded, the failure rate is 66 per cent.
From our own prospectively obtained data we were able to report no more than 17 per cent failures of non-shunt esophageal voice acquisition (Bors, de Boer and Schutte 1984).
The variations in the reported success rates of non-shunt esophageal voice acquisition will undoubtedly be influenced by different definitions of successful voice rehabilition and by methodological differences in research design. This can, however, not be held solely accountable for the large differences in the reported success rates. Therefore, other factors, such as those categorized by Duguay (3.3), must be held responsible for these variations.

3.3.1.1 **Physiological and anatomical factors**

Dysfunction of the P-E segment is considered to be the major physiological problem in non-shunt esophageal voice production, especially with regard to the air intake procedures. The consequences of dysfunction of the P-E segment for the injection and inhalation air intake methods, for the air expulsion mechanisms, for the aerodynamic factors regulating the subpseudoglottic air pressure and for the vibratory, sound producing mechanisms, have already been pointed out extensively (3.1.5, 3.1.6, 3.2.1, 3.2.2), and will not be further discussed here. There are, however, also other physiological factors which can interfere with the inhalation and injection esophageal voice production. In the first place, those interfering with the air intake mechanisms will be discussed.

Factors related to air intake
Damage to the lingual or hypoglossal nerve as may occur during laryngectomy accompanied by neck dissection, will impair oral tactile and kinaesthetic sensation and tongue movements. This may hamper injection air intake methods, either by interfering with closure of the oral port, or by interfering with the tongue movements required for the injection of the air into the esophageal air reservoir. Studies concerning the influence of laryngectomy on tongue strength (Dworkin, Hartman and Keith 1980) and concerning the tongue strength in neck-type electrolarynx speakers (Hartman and Dworkin 1980) showed that tongue strength was not reduced in proficient non-shunt esophageal speakers, and was significantly reduced in electrolarynx speakers. The

authors concluded that the method of alaryngeal speech which is used will influence the tongue strength. It is more likely, however, that reduced tongue strength has a negative effect on esophageal voice acquisition, and will consequently lead to the use of an electrolarynx. Noll and Torgerson (1967) found a correlation between a specific pattern of tongue movement and esophageal speech quality, a finding which stresses the importance of the tongue in non-shunt esophageal voice acquisition.
Damage to the mandibular branch of the facial nerve may also interfere with adequate closure of the oral port. Damage to the vagus nerve or other causes of velopharyngeal insufficiency may interfere with adequate closure of the nasal port (Berlin 1964). Furthermore, ill fitting dentures can interfere with the injection method of air intake (Diedrich and Youngstrom 1966; de Vleeshouwer 1971). In situations as summarized above, techniques involving inhalation, rather than injection, as the prime method of air intake may allow avoidance of problems in esophageal voice acquisition.
For the inhalation air intake technique an optimal pulmonary situation is required for esophageal voice acquisition.

Factors related to air expulsion
Problems concerning air expulsion which interfere with non-shunt esophageal voice acquisition occur far less frequently than problems associated with the intake of air. Wolfe and co-workers (1971) suggest that incompetence of the distal esophageal sphincter may interfere with esophageal voice acquisition. They postulate that air cannot be retained in, and consequently cannot be expelled from, an esophagus with an incompetent lower sphincter. A similar hypothesis has been presented by Frith and Montague (1985), who suggest that some food products (chocolate, coffee, ice cream, milk) may have a negative influence on esophageal voice production, because these products cause a decrease in lower esophageal sphincter pressure. Considering the five mechanisms involved in air expulsion (3.2.2.1), an active contribution of the distal esophageal sphincter, however, seems to be unlikely. This is supported by the fact that Winans and co-workers (1974) and Mathis and co-workers (1983) found no differences in lower esophageal sphincter pressure between proficient and non-proficient esophageal speakers. Furthermore, Mathis and co-workers found no correlation between anamnestic signs of gastroesophageal reflux and esophageal speech proficiency. Nevertheless, it seems quite likely that during esophageal voice production some air will pass downwards into the stomach instead of upwards through the P-E segment. It is a well known fact that laryngectomees more often experience both flatulence and belching than they did before the laryngectomy (Diedrich and Youngstrom 1966; Samuel and Adams 1976a; Shanks 1979b). Furthermore, several radiological studies (Weihs 1958; Schlosshauer and Möckel 1958; Diedrich and Youngstrom 1966; Schabel and Stanley 1981) demonstrated an increase of air contained in the esophagus and the stomach following esophageal voice production. Samuel and Adams (1976a) found poor esophageal speakers to have significantly more air contained in their stomachs than good esophageal speakers. This suggests a correlation between poor technique of esophageal voice production and air passing down to the stomach. Another study, concerning factors associated with air expulsion, performed by Samuel and Adams (1976b), suggests that problems in air expulsion can arise due to a dyscoordination of diaphragmatic ascent and P-E segment relaxation. However, considering the mechanisms of air expulsion, the contribution of the diaphragm, seems to be only of minor importance.

Factors related to radiotherapy
Obviously, a negative effect of radiotherapy on esophageal voice acquisition may be expected, as a result of the loss of elasticity of the P-E segment and esophageal air reservoir. However, the results of studies in which the effect of radiation therapy on non-shunt esophageal voice acquisition has been investigated, are controversial. Theiner (1967) and Gates and co-workers (1982b, 1982c) found a significant different non-shunt esophageal voice acquisition rate, depending on the fact of whether the patients were irradiated postoperatively or not. The highest number of laryngectomees who acquired esophageal voice was found, as could be expected, in the postoperatively non-irradiated group. Gates and co-workers even found postoperative irradiation to be one of the factors by which they were able to predict the acquisition of non-shunt esophageal speech. Hunt (1964), Brouwer, Snow and van Dam (1979), Richardson (1981) and Schaeffer and Johns (1982), however, found no relation between voice acquisition and radiotherapy.

Anatomical factors
Anatomical abnormalities such as strictures, pouches or diverticuli located in or above the level of the P-E segment may also interfere with esophageal voice acquisition (Damsté 1958, 1975, 1979; Diedrich and Youngstrom 1966; Damsté and Lerman 1969; Simpson, Smith and Gordon 1972). These configurations in the pharynx may hamper both the intake and expulsion of air, especially when air, or mucus and saliva, is trapped in the pouches. Furthermore, if esophageal sound can be produced in such cases, the resulting voice often has a 'wet' and 'bubbly' quality. Nayar and co-workers (1984), however, found no correlation between the presence of hypopharyngeal pouches and esophageal voice acquisition.

Surgery related factors
The relationship between the surgical technique of laryngectomy and esophageal voice acquisition has the interest of many investigators. All agree that surgical procedures which interfere with the function of the P-E segment will have a negative influence on esophageal voice acquisition. The laryngo-pharyngectomies and laryngo-pharyngo-esophagectomies are the most extreme examples of this group (3.1.4, 3.1.5 and 3.1.6). In addition, some authors also found other correlations.
Vrticka and Svoboda (1961), Shames, Font and Matthews (1963), Simpson, Smith and Gordon (1972), Sopko and Faust (1977) reported results, suggesting that total or partial preservation of the hyoid bone, with intact strap-muscles, result in better esophageal voice acquisition. Diedrich and Youngstrom (1966), however, did not find such correlations. Robe and co-workers (1956, 1969) and Putney (1958) concluded that the types of surgery alone, excluding surgery of the P-E segment, does not determine the speech result.

Additional anatomical and physiological factors such as recurring fistulas, neurological disorders, and recurrent malignancy have been mentioned as causes of failing esophageal voice acquisition. Although objective data are not available to support most of these assertions, logic prevents an argumentative reaction.

3.3.1.2 **Patient related factors**

The patient related factors of age, sex, hearing acuity, psychological, and sociological factors are discussed. Other factors are not considered, because they seem to be too far

fetched, too controversial or too obvious.

Age

Damsté (1958) discussed the adverse influence of old age on the development of intelligible non-shunt esophageal speech. Many authors reported that older age diminishes the chances of successful non-shunt esophageal voice acquisition (Svane-Knudsen 1960; Moolenaar-Bijl 1963; Shames, Font and Matthews 1963; Smith, Rise and Gralnek 1966; Kitzing and Toremalm 1970; DiBartolo 1971; Gardner 1971; Pfau 1974; Van de Calseyde et al 1975; Natvig 1983c; Brusis and Schöning 1984). Frank (1973) pointed out that older laryngectomees require a greater number of speech therapy sessions to acquire intelligible non-shunt esophageal voice. Schaeffer and Johns (1982) found that in a group of 357 laryngectomees, the mean age of laryngectomees who acquired non-shunt esophageal speech was 6 years younger than the mean age of laryngectomees who did not acquire non-shunt esophageal voice. However, others found no significant correlation between age and non-shunt esophageal voice acquisition (Hunt 1964; Berlin 1965; Diedrich and Youngstrom 1966; Theiner 1967; Simpson, Smith and Gordon 1972; Gilchrist 1973; Brouwer, Snow and van Dam 1979; Kelly, Adamovich and Roberts 1981; Breuninger 1982; Gates et al 1982b, 1982c).

Sex

Gates and co-workers (1982c) reported no significant difference in the acquisition of non-shunt esophageal voice production between male and female laryngectomees. Dabul and Lovestedt (1974) found a slightly better non-shunt esophageal voice rehabilitation in females. Putney (1958) and Gilchrist (1973), however, found that men were more adept at developing non-shunt esophageal voice than women.
The number of female laryngectomees involved in most studies is so small that no clear notion can be obtained as to whether the laryngectomee's sex is indeed a factor influencing esophageal voice acquisition.
The female laryngectomee's situation is, however, generally regarded as differing from the male laryngectomee's situation. The low pitch associated with esophageal voice production is often considered to be not feminine and this seems to be one of the factors why some female laryngectomees have additional adjustment problems (Gardner 1966, Shanks 1979a, Stack 1979). Despite the low pitch however, the esophageal voice produced by female laryngectomees differs significantly from the esophageal speech produced by male laryngectomees (Weinberg and Bennet 1972) and listeners are generally able to identify the sex of the esophageal speaker (Weinberg and Bennet 1971).

Hearing acuity

Numerous authors have either surmised or reported evidence to indicate that acquisition of esophageal speech is related to audiometrically assessed acuity of hearing (Hoople and Brewer 1954; Svane-Knudsen 1960; Berlin 1964; Greene 1964; Diedrich and Youngstrom 1966; Martin, Hoops and Shanks 1974). Apparently, adequate hearing is necessary in order to monitor the esophageal voice and speech, and also the loudness level of stoma noise. Consequently, laryngectomees who demonstrate hearing impairment should receive auditory rehabilitation to improve their chances of esophageal speech acquisition.

Psychological and sociological factors

Laryngectomy has a tremendous impact on a person and requires enormous

psychological adjustments. It is generally accepted that these psychological adjustments are an important factor, which influences non-shunt esophageal voice acquisition. Data from several investigations can be interpreted to indicate that specific factors such as higher intelligence, higher educational level, favorable self-concept, good body-image, high achievement level, less depression and lower levels of anxiety are related to good non-shunt esophageal speech development (Stoll 1958; Fontaine and Mitchell 1960; Shames, Font and Matthews 1963; Bisi and Conley 1965; Amster, Love and Menzel 1972; Keith, Ewert and Flowers 1974; Kitzing and Toremalm 1974; Dabul and Lovestedt 1974; Pfau 1975; Spiecker-Henke 1978; Gates and Hearne 1982d, Natvig 1983a).
Shames and co-workers (1963) and Goldstein and Salmon (1978) stated that non-shunt esophageal speakers can be psychologically differentiated from speakers using a mechanical sound source, who can be regarded to be failed esophageal speakers.
Stoll noted that the outgoing extrovert person has the best chances of non-shunt esophageal voice acquisition. Furthermore, Stoll concluded that a patient's motivation is the most important factor which determines non-shunt esophageal voice acquisition. The importance of motivation has been confirmed by the studies of Gilchrist (1973) and Goldstein and Salmon (1978). Anxiety and depression, due to fear of cancer recurrency and of postoperative functioning, were found to have negative effects on non-shunt esophageal voice acquisition. Stoll cited evidence which showed that fear increases spasms of the esophagus and tension in the P-E segment. In contrast, relaxation occurs under suggestions which incite emotions of enthusiasm, elation, security, happiness and contentment. This relationship between fear and poor non-shunt esophageal voice production has been substantiated by a questionnaire study of Diedrich and Youngstrom (1966). Eighty per cent of the laryngectomees reported poorer speech when they were emotionally upset, and the same percentage spoke better when they were relaxed.
Unfortunately, many patients face loss of employment after laryngectomy, which may result in a depressed and despairing state. There is tremendous stress upon patients who need verbal skill in their work, to acquire speech quickly postoperatively. Such a mental stress can interfere with non-shunt esophageal voice acquisition, but it can also have a positive effect due to the stimulated motivation to learn to speak quickly. Volin (1980) noted a correlation between employment and non-shunt esophageal substitute voice acquisition: patients who were working at the time of admission to the hospital to undergo a laryngectomy were more likely to speak postoperatively. Probably this can again be accounted for by motivation.
Gardner and Harris (1961) emphasized that success or failure in substitute voice acquisition often depends on the attitude of the partner towards the laryngectomee's handicap and efforts to talk.

Because of the negative influence of fear and anxiety on esophageal voice production, it is important to identify the periods in which the laryngectomee is particularly at risk to be emotionally upset or depressed.
Sanchez-Salazar and Stark (1972) mentioned four specific periods of crisis for the laryngectomee:

1) being told that an operation is required,
2) just after the operation, while still in the hospital,
3) coming home after discharge from the hospital,
4) a few months after the operation, when the favoured status is lost and everything has settled back into routine.

The last three periods coincide with the period of esophageal voice development and can interfere with its learning process.

In the numerous studies in this field only Gates and Hearne (1982c) claim to be able to predict non-shunt esophageal speech acquisition. The interaction of factors such as: postoperative physical performance status, preoperative phonation duration, postoperative dysphagia, site of lesions, patient income and postoperative radiation therapy, apparently allowed correct prediction of successful acquisition of non-shunt esophageal speech in 85 per cent of the cases, and correct prediction of failure to acquire speech in 96 per cent of the cases.
Shanks (1979b) clearly exhibits a different point of view when he states: 'If his (the laryngectomee's) desire to talk is strong enough and there is an opportunity to learn, he can learn by one means or another'.
Although not so intended, the conclusions of Gates and co-workers and the statement of Shanks may be interpreted to represent somewhat dangerous points of view on esophageal voice acquisition, which can result in discontinuation of teaching esophageal speech. If too many negative factors are present both laryngectomee and therapist may believe that the laryngectomee will not learn to speak anyhow. This can easily become a self-fullfilling prophecy. According to the statement made by Shanks, a laryngectomee who cannot learn to use the esophageal voice is apparently not willing to learn. Then the question as to whether or not speech therapy should be continued in such cases, can be raised far too easily and quickly. Furthermore, the value of such statements and of efforts to predict esophageal speech acquisition is of limited practical use, since expectations towards the acquisition of esophageal voice production should never be a factor in determining whether a laryngectomy should be performed or not. Such decisions should be purely made on medical oncological indications, with consideration of the physical and mental condition of the patient. Once the operation is performed, each laryngectomee should be approached with positive expectations concerning his ability to develop esophageal voice.

3.3.1.3 **Speech therapy related factors**

Without going into the ability of speech therapists to teach injection or inhalation esophageal voice, there are several other speech therapy factors which have a strong influence on the acquisition of a substitute voice. The most important factors are the time available to teach, and the moment at which speech therapy can start. There seems to be a consensus that speech therapy should start as early as possible, in order to achieve the best voice rehabilitation result (Moolenaar-Bijl 1953c, 1979; Fontaine and Mitchell 1960; Godfrey and Bagshaw 1962; Shames, Font and Matthews 1963; Bagshaw 1967; Kelly, Adamovich and Roberts 1981; Edels 1983).
Some authors even advise to start training preoperatively with instructions in belching, aided by the use of carbonated drinks (McGall 1943; Pitkin 1953). McGall reported significant differences in esophageal voice acquisition rates between preoperatively trained and preoperatively untrained laryngectomees.
The reports are slightly controversial concerning the required number of speech therapy sessions and how long speech therapy should be continued. Amster, Love and Menzel (1972), Brouwer, Snow and van Dam (1977), and Kelly, Adamovich and Roberts (1981) concluded that more speech therapy did not result in better non-shunt esophageal voice. However, others (Shames, Font and Matthews 1963; Gates et al 1982b) did find a positive correlation between how long speech therapy was continued

and the quality of non-shunt esophageal voice production. Pfau (1975) demonstrated that below-average intelligent laryngectomees required longer, and more speech therapy sessions to acquire a reasonable esophageal voice. Diedrich and Youngstrom (1966) stated that good, fluent and intelligible non-shunt esophageal speech may take six months or more to acquire. This gives an indication as to how long speech therapy should at least be continued. It is generally advised to continue speech therapy for non-shunt esophageal speech during half a year to one year, with more frequent sessions in the beginning than at the end.
Our experience is similar to that of Edels (1983) who states that:
'it is imperative that the patient is seen often for therapy and that he practises regularly on his own. In the early days the laryngectomee should receive a minimum of one daily therapy session lasting up to one hour, followed by two or three weekly sessions on discharge'.
It is, however, apparent that many laryngectomees do not have the opportunity to follow this advised regimen of speech therapy.
Varying methods of laryngectomee speech therapy, different moments at which therapy is started and variations in intensity and duration of therapy are probably the best explanation for the great varieties in reported success rate.
The statement of Shames and co-workers (1963) that:
'the laryngectomee needs a competent teacher who is proficient in the esophageal speech process, general learning process and who can provide proper motivation' seems to be correct, but not quite complete. This statement can be completed with the important addition: 'and who can start therapy shortly after the operation and has enough time available to guarantee an intensive and continuous voice rehabilitation program'.

3.3.2 **Failing esophageal voice production in shunt methods**

The number of laryngectomees who fail to acquire esophageal voice production with a shunt method is much smaller than the number who fail to acquire esophageal voice with the non-shunt methods. Initially reported success rates of shunt esophageal methods with valve prostheses, e.g. ranged from 56 per cent (Donegan, Gluckman and Singh 1981) to 93 per cent (Johns and Cantrell 1981) with an estimated average of 85 per cent. Later reports mention higher success rates, most likely as the result of functional P-E segment surgery (5.5).
If all who were not successful are regarded to be failures, then this places the estimated average percentage of failed shunt esophageal speakers with a valve prosthesis at 15 per cent in the early reports. Some factors which are considered for failing non-shunt esophageal voice acquisition, can also account for failing voice acquisition with shunt methods. However, the shunt methods seem to be less influenced by most of these factors. On the other hand there are specific factors associated with shunt methods which may interfere with shunt esophageal voice production.
Factors responsible for failing shunt esophageal voice production can be divided into the same groups as have been mentioned for non-shunt methods (3.3). However, since the group of shunt methods is not a homogenous group, a subdivision of factors must be made:
- General factors of failing voice production associated with shunt esophageal voice rehabilitation procedures in general, e.g. hypertonicity of the P-E segment.
- Specific factors of failing voice production associated with the specific shunt technique, e.g. obstruction of air flow in the shunt, as a result of excessive hair growth in skin lined shunts.

A detailed discussion on all specific factors is beyond the scope of this work. Therefore, only the general factors, and the specific factors associated with the shunt methods using valve prostheses, are discussed in the following section. The valve prostheses shunt methods are the only specific methods which are discussed, because they are presently the most important and widely used shunt methods (Chapter IV). Most other shunt methods have been discredited because of the associated complications, aspiration being the most important (2.5.2.2).

3.3.2.1 **Physiological and anatomical factors**

Factors related to air intake

The air charging mechanism with the shunt methods seldom presents a problem. The only general problem that can arise, is that the air cannot pass the shunt as a result of obstruction. In shunt methods with valve prostheses, such a situation may occur if the prosthesis is misfitted or improperly placed, which results in an inadequate connection between trachea and esophagus/pharynx. Furthermore, the valve part of the prosthesis can be obstructed either by a food bolus, or by deterioration (4.2). When the prosthesis is too long, or excessive digital pressure is applied for stoma occlusion, its esophageal end may be pressed against the dorsal esophageal wall, thus shutting the valve. Consequently, the air flow from the trachea into the esophageal air reservoir is obstructed. Proper replacement by a new, well fitting valve prosthesis or less vigorous stoma occlusion, will enable esophageal voice production in all of these cases. Furthermore, a stenosis or spontaneous closure of the shunt following inadvertent dislocation of the prosthesis may be the cause of failing voice production. Dilatation or repuncture of the shunt with subsequent valve prosthesis replacement is then required. The valve prosthesis can also be obstructed by an inflammatory reaction of the tissue around the shunt or by granulations or hypertrophic mucosa around the shunt opening, either at its tracheal or at its esophageal end. Sometimes excision of granulations or hypertrophic mucosa is required.

Occasionally, a laryngectomee does not build up enough air pressure in the trachea to overcome the opening resistance of the valve. Replacement by a valve prosthesis with a lower opening resistance, or training the patient to build up a higher intratracheal air pressure more effectively, will then result in shunt esophageal voice production.

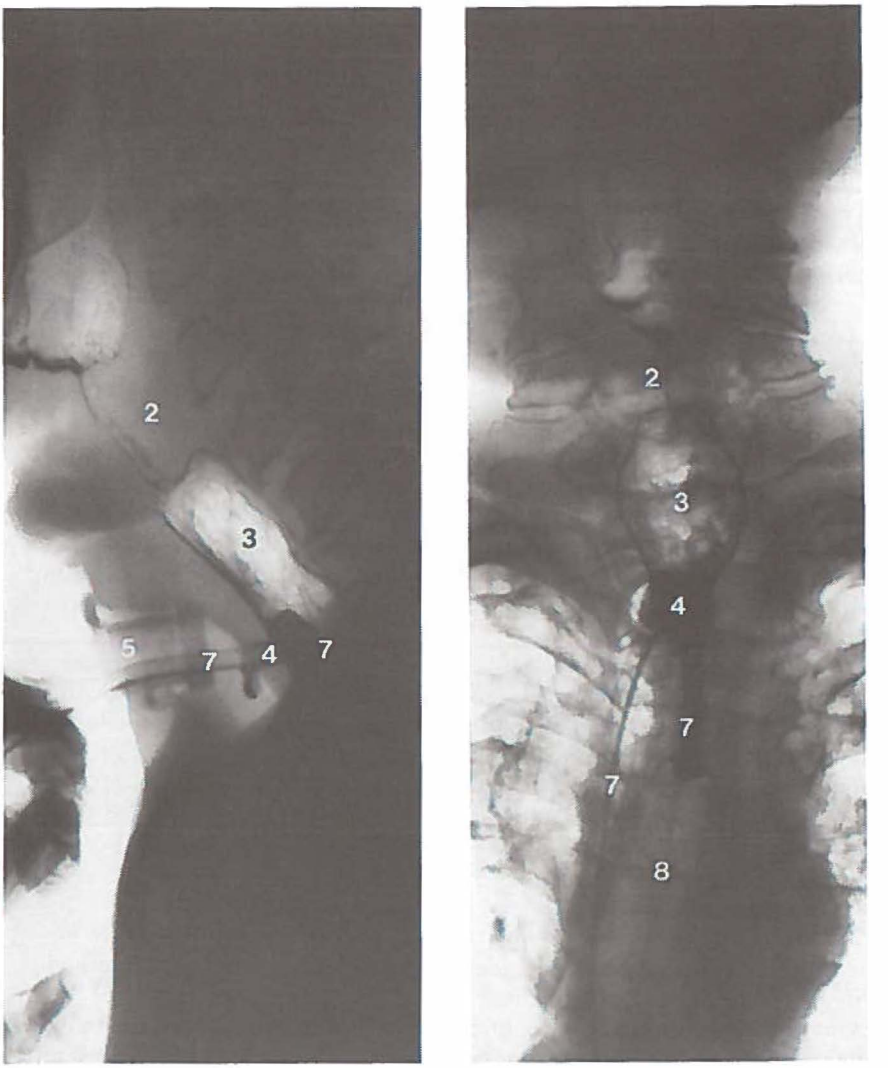
Light or moderate pulmonary dysfunction is not considered to have a negative effect on air intake or expulsion of shunt esophageal voice production (Blechschmidt et al 1982; Brendebach, Schmidt and Brugger 1986).

Factors related to air expulsion

Hypertonicity or stricture of the P-E segment can provide a general problem for air expulsion in the shunt methods, just as it does in the non-shunt esophageal methods. Hypertonicity of the P-E segment is the most important factor in failing shunt esophageal voice production. Myotomies of the P-E segment (5.5) to eliminate this problem have resulted in nearly 100 per cent voice acquisition success rate for the shunt methods with valve prostheses (Singer and Blom 1981; Henley and Souliere 1985; Blom, Singer and Hamaker 1986; Mahieu et al 1987). A simple test can distinguish between failing shunt esophageal voice production as a result of factors associated with the valve prosthesis, or as a result of factors associated with the shunt and with the P-E segment. If shunt esophageal voice production still cannot be achieved after removal of the valve prosthesis from the shunt, then the cause of failure is not the valve prosthesis, but either obstruction of the shunt or of the P-E segment. A further distinction can then

be made by introducing an air insufflation catheter through the shunt. If the shunt can be passed with the catheter, but insufflation of air does not result in esophageal sound production, then the P-E segment is obstructed, most likely as a result of hypertonicity. A distinction between obstruction of the P-E segment due to hypertonicity or due to other causes can be made by performing this air insufflation test under fluoroscopic control (fig 3.7).

Fig. 3.7



Fluoroscopic pictures in lateral *(left)* and antero-posterior *(right)* projection of an insufflation test in a laryngectomee who failed to develop shunt (and non-shunt) esophageal voice as a result of a hypertonic P-E segment. The air insufflation catheter has been introduced, through the tracheostoma and the valve prosthesis, into the upper part of the esophagus. Even with air thus insufflated no esophageal sound could be produced.
Note the massive appearance of the pseudoglottis (as compared to figures 3.1, 3.2 and 3.4) preventing the expulsion of air from the air reservoir superiorly.
2 = pseudoglottis, 3 = air reservoir, 4 = valve prosthesis in shunt, 5 = tracheostoma with tracheostoma vent, 7 = air insufflation cathether, 8 = air escaping downwards to the stomach.

Furthermore, a too low tonicity of the P-E segment can result in failing, or more likely poor, voice production with the shunt method, just as with the non-shunt esophageal methods. In such cases external pressure applied to the site of the pseudoglottis with either a finger or a collar can improve voice production. However, the tonicity of the P-E segment is less critical with respect to esophageal voice production in the shunt methods, than in the non-shunt esophageal methods.

Factors related to radiotherapy
The effect of radiotherapy on shunt esophageal voice acquisition with valve prostheses seems negligible. Most authors report no failures which can be attributed to radiotherapy. We have, however, observed a temporary decrease in esophageal voice quality during or shortly following radiotherapy.

Anatomical factors
Tracheostoma size and shape may be anatomical factors associated with failing shunt esophageal voice production. In order to produce esophageal voice with the shunt method, the laryngectomee must be able to accurately occlude the tracheostoma. Abnormal size or shape of the tracheostoma may interfere with stoma occlusion.

3.3.2.2. **Patient related factors**

Age and *sex* are not reported to have influence on voice acquisition with a shunt method.

Hearing acuity probably has less influence on shunt esophageal voice acquisition than on the non-shunt esophageal voicing methods.
First of all, because the shunt esophageal voice is generally louder than the voice produced with the non-shunt methods. This makes it slightly easier for the hearing impaired laryngectomee to monitor his own voice.
Secondly, because stoma noise does not occur if a shunt method is used with a properly occluded tracheostoma.
In contrast, stoma noise presents one of the major monitoring problems for hearing impaired laryngectomees in the non-shunt esophageal voicing methods.

Some laryngectomees have a *hypersensitive stoma* which may also interfere with proper stoma occlusion. Occasionally some are simply afraid or anxious to occlude their tracheostoma.

An additional factor influencing shunt esophageal voice acquisition is *manual dexterity,* which is needed to occlude the tracheostoma. Proper stoma occlusion is a very difficult task for patients with severe arthritis, hemiparalysis or other manual dysfunctions. Some types of valve prostheses have to be regularly removed from the shunts, cleansed and then replaced by the laryngectomees themselves. This requires an even better manual dexterity than is needed for shunt esophageal methods in general.

Psychological and sociological factors have less influence on shunt esophageal voice acquisition, than on voice acquisition with the non-shunt esophageal methods. Voice acquisition with a shunt method is normally achieved within a few days, requiring less endurance from the laryngectomee and the people surrounding him. Furthermore, shunt esophageal substitute voice is of a better quality and is better intelligible, than the non-shunt esophageal voice. Consequently the laryngectomee can better meet the

requirements of occupational and other social situations, when he uses a shunt method. Rapid and good shunt esophageal speech acquisition may be expected to have positive effects on most laryngectomees and may result in less depressed and anxious states. As mentioned earlier (3.3.1.2) a mental state associated with fear or depression may in its turn negatively influence esophageal voice acquisition or further esophageal voice development.
Pfrang and co-workers (1986) found that the better intelligibility of shunt esophageal speakers, compared to non-shunt esophageal speakers, did not greatly influence the laryngectomees psycho-social adjustment. However, they did find a higher score on the 'loneliness' scale for non-shunt esophageal speakers, which indicates a greater sense of social isolation in these laryngectomees, than in the shunt esophageal speakers.
In another study Pfrang (1986) concluded that voice restoration with a shunt method seems to be more desirable than voice restoration with the non-shunt esophageal methods, from a psychological point of view. His conclusion was based upon the facts that good motivation and learning capacity are less important for substitute voice acquisition and intelligibility and acceptance are higher, if a shunt method is used.
Occupational constraints can also interfere with shunt esophageal voice production, e.g. needing two hands for a job evidently interferes with stoma occlusion. In some of these cases tracheostoma valves, which automatically occlude the tracheostoma on forced expiration, may be helpful (Blom, Singer and Hamaker 1982; Singh 1985; Amatsu et al 1986a; Herrmann and Koss 1986). However, fixation of these valves to the tracheostoma can be difficult. The fixation problems and the problems associated with adjusting the valve to varying respiratory demands, greatly limit the use of such tracheostoma valves.

3.3.2.3 **Speech therapy related factors**

Speech therapy related factors in shunt esophageal voice acquisition are of minor importance compared to those involved in the acquisition of non-shunt esophageal voice. The instructions and training in the shunt esophageal method mostly concern the stoma occlusion and prosthesis maintenance, for those valve prostheses which require such. Furthermore, relaxation of neck musculature (and consequently P-E segment musculature) is an essential part of the shunt esophageal voice training program. This training program can be completed in a short period of time. Esophageal voice production with the shunt methods are based upon a normal physiological mechanism, i.e. phonation on expiration using expired air. Therefore, learning (and teaching) to use a shunt method of esophageal voice production is much easier than learning to phonate with the non-shunt esophageal methods.

3.4 COMMENT ON THE ESOPHAGEAL VOICE

Esophageal voice either produced with the shunt methods, or with the non-shunt methods, is generally considered to be the best form of substitute voice production. Acquisition of esophageal voice, using either method, largely depends upon physiological and anatomical factors, patient related factors (including psychosociological factors), speech therapy related factors, and interactions between these factors. It should be noted that non-shunt methods of esophageal voice production generally are difficult to learn, requiring much patience and endurance of both the laryngectomee and the speech therapist. In contrast, the shunt methods of esophageal voice production generally are easy to learn and can be mastered within a short training

period. Therefore, it is not surprising that many more laryngectomees are able to speak with a shunt method, than with the non-shunt method of esophageal voice production. Although the esophageal voice produced with the shunt methods is superior to the esophageal voice produced with the non-shunt methods, the use of shunts has been limited for a long time, as a result of the associated surgical and deglutitional complications. The development of valve prostheses which are inserted into these shunts, has drastically changed this situation. Valve prostheses prevent the leakage from esophageal contents into the airway, and at the same time allow an easy passage of intratracheal air into the air reservoir of the esophagus. With these valve prostheses, shunt esophageal voice production has become a method which is associated with few complications, low morbidity and high success rate of voice acquisition. In the next chapter a review of the various valve prostheses, and tracheo-esophageal puncture procedures for creation of a shunt, will be presented.

Chapter IV

VALVE PROSTHESES IN TRACHEO-ESOPHAGEAL SHUNTS

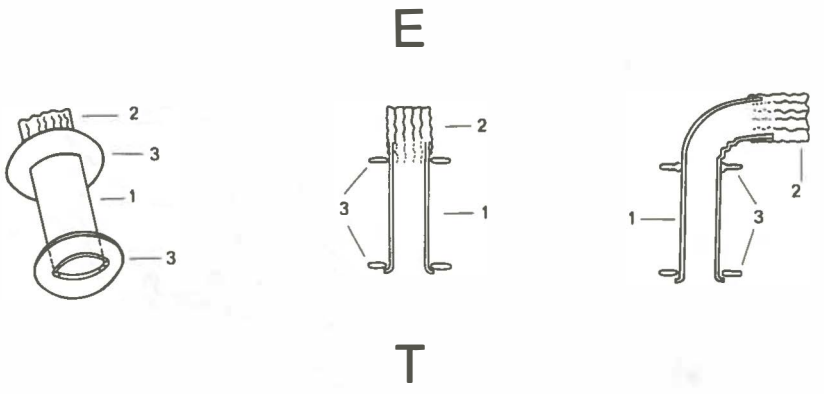
Voice restoration with shunt esophageal voice production methods results in a very good voice quality when compared to other methods of substitute voice production. Therefore, it has always been a topic of interest. However, many problems have been associated with these tracheo-esophageal shunt methods. Aspiration through the shunt and stenosis of the shunt have been the most important problems.
As already described, some investigators have sought to overcome these problems by using modifications of surgical techniques (2.5.2.2). Others have directed their efforts towards the development of a prosthetic valve mechanism, which is introduced into the tracheo-esophageal shunt. Such a prosthesis effectively prevents stenosis of the shunt, as well as aspiration due to leakage of food and saliva from the upper digestive tract through the shunt.
In 1966 Barton described a tracheo-esophageal prosthesis which consisted of an indwelling esophageal tube with a 'T' extension, which protruded through a surgically constructed tracheo-esophageal shunt at the upper rim of the tracheostoma. This extension was attached to a stand-pipe on top of a speaking tracheotomy tube. Leakage of esophageal contents was prevented by an upward tilt of the connecting T-tube. A tracheostomy valve was attached to the tracheotomy tube to allow 'fingerless' shunt esophageal voice production. Voice rehabilitation was successful, the device, however, had to be disconnected and cleaned twice weekly. Mozolewski (1972) is credited with the development of the first real valve prosthesis which is inserted into an internal tracheo-esophageal shunt. Griffiths and Frederickson (1978) developed a bio-carbon valve, which was experimentally placed in tracheo-esophageal shunts of dogs. To our knowledge no results of placement of this device in humans have been published.
It was, however, not until after the introduction of the silicone valve prosthesis by Blom and Singer (1979), that world-wide interest in this type of voice restoration was initiated. Shortly after the reports by Blom and Singer several other valve prostheses were developed.
Most of the prostheses mentioned in this chapter consist of a tube part and a one-way valve. These devices are placed in an internal tracheo-esophageal shunt. The shunts are mostly created by relatively simple puncture techniques. Such a puncture of the tracheo-esophageal wall can either be performed at the time of the laryngectomy (primary puncture procedure), or the puncture can be performed later (secondary puncture procedure). Secondary puncture procedures are performed in a period ranging from several weeks until many years after the laryngectomy. The physiology of shunt esophageal phonation with a valve prosthesis is identical to other shunt esophageal voicing methods (3.2.1.4). When the tracheostoma is occluded on expiration, the air pressure rise in the trachea will result in the opening of the valve, and consequently air can pass from the trachea into the upper part of the esophagus. Subsequently, this pressurized air in the esophagus is directly used as energy source and medium for esophageal voice production, which is generated by the pseudoglottis in the P-E segment.
It is important to realize that none of the valve devices described in this chapter contain a sound source. They only function as one-way valves, which allow the passage of air from the trachea into the esophagus. The most interesting and widely used prostheses and tracheo-esophageal puncture techniques will be discussed in this chapter.

4.1 TYPES OF PROSTHESES AND SURGICAL TECHNIQUES

4.1.1 The semi-permanent supratracheal valve prosthesis by Mozolewski

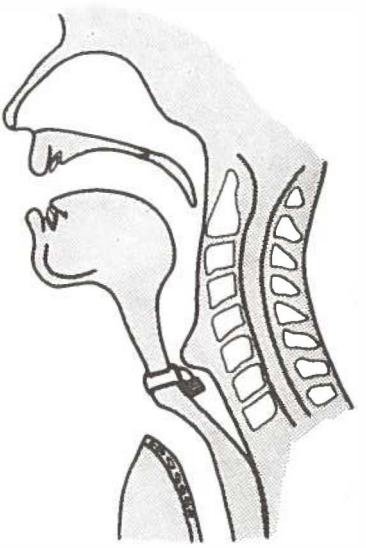
This prosthesis, developed in Szczecin (Poland) by Mozolewski and co-workers (1986), is hand-made for each individual patient, in the Szczecin Hospital Laboratory. The tube part is either made of polyethylene which is a stiff material, or of polyvinyl which is much more elastic. The device has two retention collars by which it is secured in the shunt (fig. 4.1). The outer retention collar is a separate part, which is attached to the tube part after placement of the prosthesis.
The tube is either straight, or curved downwards (occasionally upwards) at the esophageal end. The valve part is situated on the esophageal side and consists of several layers of very thin polyethylene foil. These layers are pressed together when the pressure in the esophagus exceeds the pressure in the trachea, e.g. during swallowing.
In contrast with most other tracheo-esophageal puncture techniques, Mozolewski prefers to make a shunt just above the tracheostoma (fig. 4.2). This is done to avoid obstruction of the prosthesis by tracheo-bronchial secretions.
The tracheo-esophageal shunt is created under endoscopic control. A rigid endoscope is introduced into the pharynx. Subsequently, a puncture is performed through the skin and the anterior P-E segment wall into the opening of the endoscope. After removal of the puncture needle, a catheter is inserted in the shunt from the tracheal side and advanced through the P-E segment until it comes out of the mouth, where the prosthesis is attached to it. The catheter is retracted until the tube part of the prosthesis is positioned in the shunt. The outer retention collar is then attached to the prosthesis from the skin side to secure the position.
The results achieved with this prosthesis are reported to be satisfactory (Mozolewski et al 1986; Mozolewski and Tarnowska 1986). The air flow resistance of the prosthesis is said to be low, which enables fluent and effortless esophageal voice production. To our knowledge, the use of this device has remained limited to Mozolewski's group.

Fig. 4.1



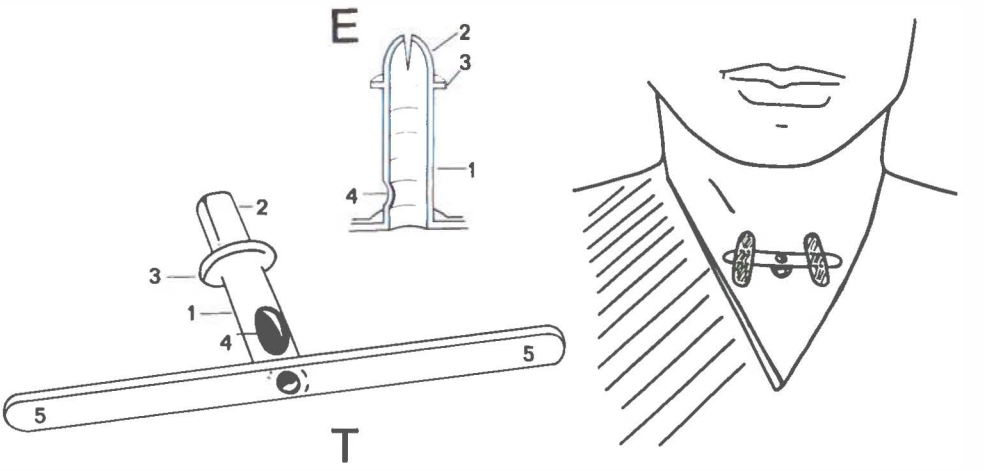
(after Mozolewski et al 1986)
Left: Mozolewski valve prosthesis, the straight version.
Middle: longitudinal-section of the straight version.
Right: longitudinal-section of the curved version.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part, 3 = retention collars.

Fig. 4.2



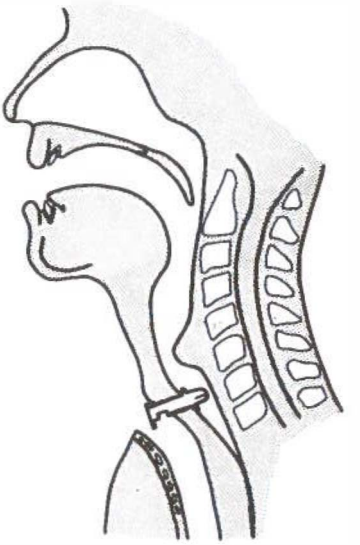
Mozolewski valve prosthesis (curved version) situated in the supratracheal shunt.

Fig. 4.3



Left: Blom-Singer duckbill valve prosthesis.
Middle: longitudinal-section duckbill type valve.
Right: Blom-Singer prosthesis taped to the peritracheostomal skin.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part, 3 = retention collars, 4 = air port, 5 = fixation flaps.

Fig. 4.4



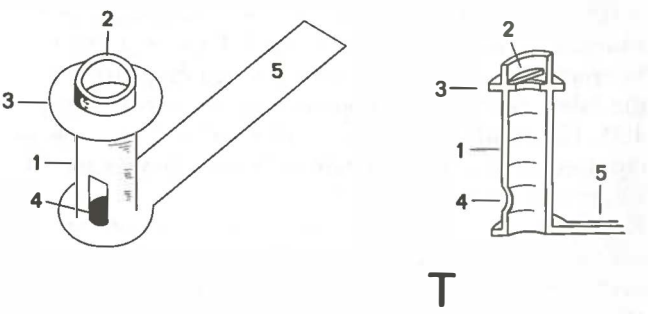
Blom-Singer duckbill valve prosthesis situated in tracheo-esophageal shunt.

4.1.2 **The Blom-Singer prosthesis**

The initial Blom-Singer prosthesis consists of a straight tube with a one-way valve (Blom and Singer 1979). It is introduced into a shunt in the tracheo-esophageal wall. The initial manufacturer of this, in the United States developed device, was Bivona (U.S.A.). Presently Blom and Singer collaborate with the American V. Mueller Company (U.S.A.). The prosthesis is made of silicone material. The valve is formed by a horizontal slit in the round esophageal end of the tube.
This type of valve has been descriptively termed a duckbill (figs. 4.3 and 4.4).
The diameter of the tube is 5.4 millimeters and the length varies from 2.2 to 4.3 centimeters. A port at the tracheal end enables the passage of air from the trachea into the prosthesis.
Just like all later modifications, the duckbill Blom-Singer prosthesis has to be fixed to the peritracheal skin with adhesives. For this purpose one or two flaps are attached to the tracheal part of the tube. The device was modified by the construction of a retention collar at the esophageal end. This collar was designed to prevent spontaneous dislodgement from the shunt, and to prevent leakage of fluids around the tube into the trachea. Later a second modification was introduced: the duckbill slit valve was replaced by a hinged trapdoor valve (fig. 4.5). This trapdoor mechanism lowers the pressure which is required to open the valve (Smith 1986). Therefore, this modified prosthesis is termed the Blom-Singer low pressure valve.

Fig. 4.5

Left: Blom-Singer low pressure valve prosthesis.
Right: longitudinal-section.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part (trapdoor valve), 3 = retention collar, 4 = air port, 5 = fixation flap.



Both the duckbill Blom-Singer prosthesis and the low pressure Blom-Singer prosthesis are commercially available.
Initial placement and reinsertion of the prosthesis is performed from the tracheal side, through the tracheostoma into the tracheo-esophageal shunt.
The method described by Blom and Singer (1979, 1985) and Singer and co-workers (1980, 1981, 1983, 1985b) to create a tracheo-esophageal shunt, is a secondary puncture procedure, performed after the laryngectomy. Under general anesthesia a rigid endoscope is introduced into the hypopharynx, until it reaches the tracheo-esophageal wall at the level of the tracheostoma. Subsequently, the tracheo-esophageal wall is pierced from the tracheal side towards the endoscope.
Others have described a primary puncture procedure (Maves and Lingeman 1982; Hamaker et al 1985). However, McConnel and Duck (1986) reported that all five punctures which they had performed as primary procedures, were failures as a result of

immediate infection. They suggested a correlation between this complication and the fact that the mucosa between posterior tracheal wall and esophagus may have been separated. Apparently pockets or false tracts occurred during their primary puncture procedures. Casiano and co-workers (1985) also observed more infectious complications following primary puncture procedures (41 per cent abscesses and inadvertent pharyngocutaneous fistuli) than following secondary puncture procedures (22 per cent abscesses and pharyngocutaneous fistuli). However, others found the primary puncture procedure to be successful in many patients, and not more prone to serious complications than the secondary puncture procedure (Trudeau, Hirsch and Schuller 1986). Singer prefers to use the secondary puncture procedure, because he feels that this enables him to perform a better preoperative patient selection (personal communication 1986). A secondary puncture is often only considered when non-shunt esophageal voice production efforts have failed. In these cases the patient selection largely depend upon the result of the insufflation test (Blom, Singer and Hamaker 1985, 1986; Baugh, Lewin and Baker 1987; 3.1.5).
After the puncture procedure a stent is inserted into the shunt to prevent spontaneous closure. The Blom-Singer prosthesis is inserted when epithelialization of the shunt has occurred, generally two weeks after the puncture.
Fitting of the prosthesis is very critical (Hausfeld and Henly Cohn 1986). A too short prosthesis may result in failing voice production due to spontaneous closure of the dorsal part of the shunt. A too long prosthesis may result in poor or failing voice production, because the valve part of the prosthesis is pressed against the dorsal esophageal wall, thus closing the valve (Herrmann and Zenner 1984). This closure of the valve or the also reported injuries of the posterior esophageal wall can easily occur, because the valve part of the Blom-Singer prothesis protrudes rather far into the esophagus lumen (Andrews et al 1987). Radiologic evaluation may be used to determine whether the prosthesis is well fitted (Pope et al 1982).
Leakage of esophageal contents through the prosthesis into the trachea may occur when the valve mechanism is impaired due to deterioration of the silicone material (4.2 and 4.3). The prosthesis then has to be replaced by a new one. The mean device life-time is reported to be approximately sixty days (Singer and Blom 1980), or even less (Blom, Singer and Hamaker 1986).
Regular maintenance of the prosthesis requires its removal from the shunt, cleansing of the valve and subsequent reinsertion of the device a few times weekly. This can be performed by the laryngectomee himself.
Speech rehabilitation results with the Blom-Singer prosthesis are reported to be excellent: successful speech acquisition ranges from 56 per cent (Donegan, Gluckman and Singh 1981) to 93 per cent (Johns and Cantrell 1981) or even almost 100 per cent after additional selective myotomy of the P-E segment (Singer and Blom 1981). A study by Schuller and co-workers (1983) indicated that stoma size (either too small or too large) and alcohol abuse were the most important prognostic factors affecting the success of voice rehabilitation with a Blom-Singer prosthesis.

Complications of the endoscopic puncture procedure initially were reported to be non-existent (Singer and Blom 1980), but in 1981 Wood and co-workers reported a case of cervical cellulitis following tracheo-esophageal puncture. Sisson and co-workers (1981) reported on a case of para-esophageal abscess after inadvertently manipulated dislocation of the prosthesis. A recent report by Silver and co-workers (1985) mentioned serious operative complications in 15 per cent of the cases, including mediastinitis, cervical cellulitis and cervical spine fracture. This last complication, however, may

more justifiably be credited to the endoscopic experience of the surgeon, rather than to the puncture procedure itself. The most recent report on complications folowing the Blom-Singer procedure has been presented by Andrews and co-workers (1987), who encountered no less than 25 per cent complications in a group of 104 laryngectomees. Early complications included esophageal perforation, severe allergic reactions to tape or to the prosthesis, cervical osteomyelitis, severe cellulitis, severe leakage and death secondary to aspiration of esophageal contents.

Apart from the early complications of the Blom-Singer puncture technique, this method also has late complications and drawbacks, most of which are associated with the prosthesis itself. The prosthesis has to be removed and reinserted regularly from the shunt for cleansing purposes. This maintenance job is mostly performed by the laryngectomee himself, a situation which can easily lead to complications. Improper reinsertion by the laryngectomee may result in the creation of a false tract, aspiration of the prosthesis or esophageal contents, spontaneous closure of the shunt, extrusion of the prosthesis, etc.

Aspiration of the prosthesis has been reported by several authors (Johns and Cantrell 1981; Wetmore, Krueger and Wesson 1981; Silver, Gluckman and Donegan 1985; Andrews et al 1987), the highest incidence involving seven patients in a group of 104 (Andrews et al).

The problem of spontaneous extrusion of the prosthesis from the tracheo-esophageal shunt has been observed in 15 to 20 per cent of the patients (Singer, Blom and Hamaker 1983; Trudeau, Hirsch and Schuller 1986). Hausfeld and Henley Cohn (1986) simply state that the extrusion rate of the Blom-Singer valve prosthesis is high. In addition to improper replacement, certain movements of head and neck, especially rotation and flexion, can also cause 'spontaneous' dislocation, as a result of the fixation method of the prosthesis to the skin with adhesives (Herrmann and Zenner 1984, Hausfeld and Henley Cohn 1986). Hall and co-workers (1985) observed problems associated with fixation of the prosthesis in eight of their thirty patients.

If improper placement or spontaneous dislocation is not noticed in time, inadvertant spontaneous closure of the shunt may occur, which requires a new surgical puncture procedure. Hall and co-workers (1985) observed inadvertant shunt closure or stenosis in nine of their thirty patients.

Leakage around the prosthesis, due to shunt dilatation has been observed in 10 to 13 per cent of the cases (Wetmore, Johns and Baker 1981; Hall, Dahl and Arnesen 1985; Silver, Gluckman and Donegan 1985; Fuller 1987). This is not caused by a malfunction of the prosthesis, but by an insufficiency of the tracheo-esophageal shunt which has become too wide for the prosthesis. Andrews and co-workers (1987) described that major surgical procedures were required to close the tract in such cases of progressively expanding tracheo-esophageal shunts.

Herrmann and Zenner (1984) have systematically listed various drawbacks of the Blom-Singer prosthesis. Among other things they described a wandering of the tracheo-esophageal shunt to the cranial edge of the tracheostoma, due to the caudally oriented force on the dorsal part of the prosthesis during swallowing and due to the cranially oriented force on the ventral part of the prosthesis during stoma occlusion for voice production. In a period ranging from several months to several years, the shunt and prosthesis may be displaced so much, that air can no longer pass into the esophagus. This migration of the fistula has also been observed by Andrews and co-workers (1987). Herrmann further observed hypertrophy of the tracheal mucosa, due to chronic irritation caused by the prosthesis. This hypertrophic mucosa has been observed to occlude the port in the prosthesis, thus obstructing the passage of air into the esophagus.

Hall and co-workers (1985) noticed such 'granulations' in seven of their thirty patients. Andrews and co-workers (1987) reported infection, and esophageal stenosis secondary to the prosthesis, as late complications.
Despite the above described drawbacks associated with the use of a Blom-Singer prosthesis the opinion is generally held, that the need for effective vocal communication clearly outweighs the inconveniences and risks involved. Even Andrews and co-workers, who reported the highest complication rate, are of this opinion. By introducing this prosthesis, Blom and Singer have given a world-wide impulse. This impulse has resulted in further developments and modifications of the valve prosthesis and tracheo-esophageal puncture technique (Herrmann and Zenner 1981b, 1981c; Maniglia 1982, 1985; Maran, Murray and Johnson 1982; Ossoff et al 1982, 1984; Perry, Cheesman and Eden 1982; Shapiro and Ramanathan 1982; Mohr, Paddock and Boekler 1983; Spofford 1984; Parker 1985; Stewart and Sherwen 1987). Furthermore, this impulse initiated the development of other valve prostheses and puncture techniques, many of which are described in the following sections.

4.1.3 **The Panje voice button**

Another valve prosthesis developed in the United States is the Panje 'voice button', described by Panje in 1981. It is manufactured by Xomed (U.S.A.). Despite the name which suggests that the prosthesis itself is capable of sound production, this is not the case. It is only a valve prosthesis like all prostheses in this category are. The prosthesis is made of silicone. It consists of a tube with two retention collars or flanges, a tracheal and an esophageal flange (figs. 4.6 and 4.7). The tracheal flange is larger and thicker, and consequently less flexible than the esophageal flange. The valve is situated at the esophageal end of the tube and consists of cross slits in a round tip.
The prosthesis is available in three lengths, based on interflange distance ('short', 7 millimeters; 'medium', 9 millimeters; 'long', 12 millimeters). A safety shield is attached with a thread to the tracheal end of the tube in order to prevent serious complications when the prosthesis is aspirated. Dislocation towards the trachea may occur, because the esophageal retention flange is more flexible than the tracheal flange. The shield is too large to pass through the tracheostoma. In the case of aspiration of the prosthesis, it can be retrieved by pulling the shield away from the tracheostoma. Some patients find this shield irritating and conspicuous.
Panje employs a method to create the tracheo-esophageal shunt, which is slightly different from the endoscopic method which is generally used. First of all he performs the secondary puncture procedure under local anaesthesia. Instead of introducing an endoscope into the upper alimentary tract, Panje introduces an esophageal dilator. Subsequently, an incision of the tracheo-esophageal wall is performed through the tracheostoma. The posterior esophageal wall is protected by the dilator. After this incision, a 14 French Foley catheter is inserted into the tracheo-esophageal shunt. This catheter remains in place as a stent for approximately two weeks after which time the prosthesis can be introduced into the shunt. Later (1985) Shagets and Panje also described the creation of a tracheo-esophageal shunt as a primary procedure during laryngectomy. For this procedure they developed an instrument, the Panje-Shagets tracheo-esophageal fistula clamp. This instrument is provided with a cup which is introduced in the upper esophagus and on which the incision of the tracheo-esophageal wall can be performed, without damage to the posterior esophageal wall.
According to another recent publication (Panje and Vandemark 1985) they presently prefer primary tracheo-esophageal puncture procedures. Like most valve prostheses the Panje voice button is inserted into the tracheo-esophageal shunt from the tracheal side, through the tracheostoma. Similar to the Blom-Singer prosthesis, regular maintenance of the Panje voice button is required. Sometimes this maintenance job can be performed with the prosthesis in place. The process of removal, cleansing, and reinsertion as performed by the patient may lead to the same complications as are described for the Blom-Singer prosthesis. This maintenance job of the Panje voice button, proved to be even more difficult for the patient than that of the Blom-Singer prosthesis (Stuart, Kotsanis and Borkenhagen 1983; Andrews et al 1987).
Initially Panje advocated almost daily removal, cleansing and reinsertion of his prosthesis, but because of irritation of the shunt and consequently local thickening of the tracheal and esophageal tissue, he presently advises a less frequently performed regime (Panje 1987). The device life-time varies from several weeks to eight months (Panje, Vandemark and McGabe 1981).
Speech rehabilitation results with a Panje voice button have been reported to be initially favourable. Eighty-five per cent of the patients are able to produce shunt esophageal sound and 78 per cent are able to produce intelligible speech. However, the long term

results are somewhat disappointing, since only slightly more than half of the patients still produce intelligible speech after six months (Panje and Vandemark 1985; Panje 1987). The causes of failure described by Panje include: inability to retain the prosthesis, poor phonatory qualities, inability to attain good stomal occlusion, and the patient's decision not to use the voice button.

Fig. 4.6

Panje voice button.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part, 3 = tracheal retention flange, 4 = esophageal retention flange, 6 = safety shield, 7 = open end.

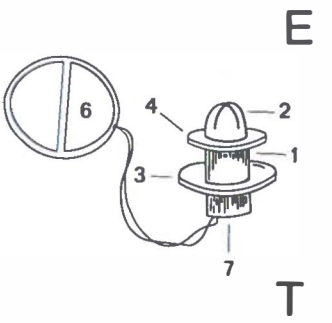
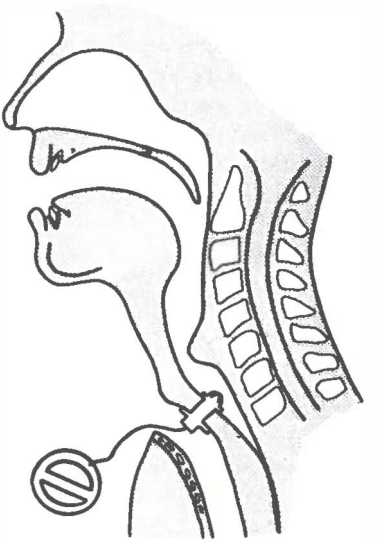


Fig. 4.7

Panje voice button situated in tracheo-esophageal shunt.



The advantage of the Panje voice button is its self-retaining capacity, which requires no adhesives. The relatively small part of the prosthesis which protrudes into the esophagus lumen and the small part protruding into the tracheostoma are also considered to be advantages. Furthermore, the fitting of the prosthesis with respect to the correct length is less critical for the Panje voice button than it is for the Blom-Singer prosthesis. The possibility to perform the secondary puncture procedure under local anaesthesia, and the little endoscopic experience required for this procedure, may be considered advantages of the puncture technique described by Panje.
Disadvantages of the Panje voice button are, the already mentioned requirement of maintenance by the patient, and the extremely high air flow resistance (Weinberg 1982; Moon and Weinberg 1984; Weinberg and Moon 1984; Hausfeld and Henley Cohn 1986; Karschay 1986; Karschay et al 1986). This high air flow resistance has a negative influence on voice production. Recently a Panje low-pressure prosthesis has been developed, in an effort to reduce the air flow resistance. However, reports by Weinberg and Moon (1986a, 1986b), showed no essential difference in air flow resistance between the normal voice button and the low-pressure device. A disadvantage of both the primary and the secondary puncture procedures described here is the variability in the length of the incision and consequently in the diameter of the shunt. A shunt with a too large diameter will cause leakage around the prosthesis and will facilitate dislocation of the prosthesis. Panje solves this problem by introducing a thicker Foley catheter into the shunt, to stop the leakage. Subsequently, every few days a slightly smaller catheter is introduced until a 14 French catheter fits snugly into the tracheo-esophageal shunt.
Some serious complications have been reported as a consequence of Panje's technique. Senders and Bumsted (1985) attributed the occurrence of pneumomediastinum eight weeks following puncture and voice button placement, to the puncture procedure. Ruth and co-workers (1985) reported a deep neck abscess and subsequent cervical osteomyelitis, one month following puncture and prosthesis placement. Furthermore, frequent prosthesis dislodgement has been observed during coughing (Andrews et al 1987).
Twenty-two per cent of 196 head and neck surgeons in the United States who answered a questionnaire, reported to use the Panje prosthesis, 66 per cent of them reported to use the Blom-Singer prosthesis (Lopez et al 1987).

4.1.4 **The Groningen button**

The Groningen button is a silicone valve prosthesis, consisting of a tube with two flanges and a valve which is incorporated in the esophageal flange (figs. 4.8 and 4.9).
It is manufactured by BMS/Medin (the Netherlands) and marketed by Entermed (the Netherlands). It was developed in 1980 in the ENT department of the Groningen University Hospital by Nijdam and co-workers, who were inspired by the excellent results reported by Singer and Blom. This led to the creation of a silicone valve prosthesis which is self-retaining, requires no maintenance, can stay in place for a considerable time, is easily fitted, and of which only a small part protrudes into the esophagus lumen. Thus the greatest disadvantages of the Blom-Singer prosthesis, i.e. the frequent maintenance by the patient and fixation to the skin, have been eliminated. At the same time, the favourable conditions for voice production as presented with the Blom-Singer prosthesis have been maintained with the Groningen button.
The primary and secondary tracheo-esophageal puncture procedures used for the button are described in detail in Chapter V.
The Groningen button probably is the first prosthesis which has been placed either with a primary procedure, or with a secondary endoscopic procedure (Nijdam et al 1982; Annyas et al 1984; Mahieu and Leemhuis 1984; Nijdam et al 1986a, 1986b). No stent has to be used following the tracheo-esophageal puncture, which is an advantage over the Blom-Singer and Panje tracheo-esophageal puncture procedures. Thus, the valve prosthesis is immediately available for voice production.
The study presented in this book deals specifically with the voice rehabilitation of laryngectomees with a Groningen button. Therefore, more detailed information concerning this valve prosthesis and the puncture and placement procedures, is presented in Chapter V. The results achieved with this prosthesis are presented in Chapter VI. The Groningen button has been in use for several years, in most head and neck surgical centers in the Netherlands, and many centers elsewhere in Europe. It has recently been marketed in the United States.

Fig. 4.8

Groningen button valve prosthesis.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part, 3 = tracheal retention flange, 4 = esophageal retention flange, 7 = open end, 8 = string used for insertion.

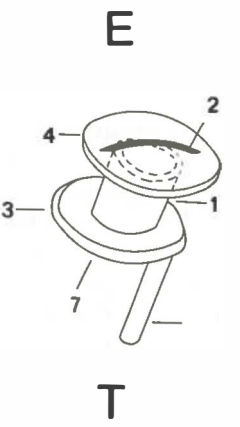
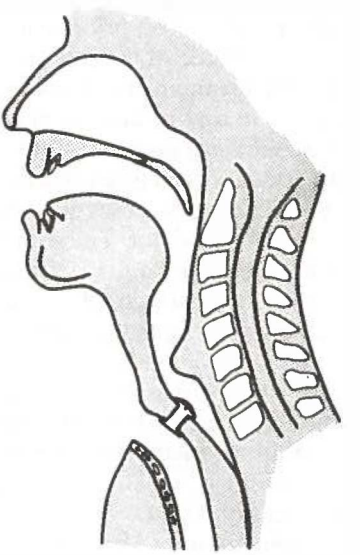


Fig. 4.9

Groningen button situated in tracheo-esophageal shunt.



4.1.5 **The Herrmann prosthesis**

The Herrmann prosthesis has been developed by Herrmann in Würzburg, West-Germany (Herrmann and Kley 1981a, 1981b; Herrmann and Zenner 1981a; Herrmann, Buchwald and Zenner 1984; Zenner et al 1984, 1985, 1986a, 1986b; Herrmann and Koss 1985; Herrmann 1986a) and is manufactured by Eska (W-Germany).
It is a silicone valve prosthesis consisting of a tube part, two retention flanges and a duckbill type of valve (figs. 4.10 and 4.11). The duckbill valve is formed by a vertically positioned slit. This is in contrast to the Blom-Singer duckbill valve, which is formed by a horizontal slit. According to Karschay and co-workers (1986) this vertically positioned slit has a positive effect on the air flow resistance of the valve when it is situated in the patient, and the valve is in direct contact with the esophageal wall. This device seems to be a combination of the Blom-Singer duckbill prosthesis and the Panje voice button. The tube is curved, so that the valve in the esophagus is directed upwards in the direction of the P-E segment. This is said to facilitate the air flow through the P-E segment. To keep the tube part curved, it is strengthened by a metal tube, which is incorporated in the silicone material.
There are three sizes of Herrmann prostheses: 'short', 'medium', and 'long', based on the length of the tube. Since the distance between the retention flanges is the same in all three sizes, the increase in length is only noticeable in the intraesophageal part of the prosthesis. Because of the curve in the tube, elongation of the prosthesis is associated with a higher in the P-E segment situated duckbill valve.
Although the prothesis is self retaining by the two retention flanges, two flaps are attached to the tracheal flange which can be taped to the skin with adhesives. However, these flaps are rarely used and are mostly cut off prior to insertion of the prosthesis. Insertion is performed from the tracheal side of the shunt, through the tracheostoma. Similar to the Panje voice button, the Herrmann prosthesis has a safety shield attached to it, in order to avoid complications in case of aspiration of the device.
Herrmann performs the tracheo-esophageal puncture both as a primary and as a secondary procedure. During the primary puncture procedure a platysma fascia flap is interposed between trachea and esophagus, to strengthen the tracheo-esophageal wall at the site of the future tracheo-esophageal shunt. The shunt is made by introducing a curved puncture needle into the open pharynx and piercing the strengthened tracheo-esophageal wall from the esophageal side. The needle is taken out through the tracheostoma. At the end of the needle a silicone stent is attached, which can be pulled in the freshly created tracheo-esophageal shunt. The stent will stay in place until the prosthesis can be inserted. The prosthesis insertion takes place 10 to 12 days postoperatively. The secondary puncture procedure is almost identical to that described by Blom and Singer, and our secondary puncture procedure (Chapter V): a rigid endoscope is introduced into the hypopharynx and with a curved puncture needle the tracheo-esophageal wall is punctured from the tracheal side through the tracheostoma. The needle is directed into the esophagoscope. After removal of the needle a silicone stent is inserted into the tracheo-esophageal shunt with a metal inserter. After two weeks the stent is removed and the prosthesis can be inserted. The prosthesis requires no maintenance by the patient and can stay in place for several months. Voice rehabilitation results which have been reported with a Herrmann prosthesis are good. Good intelligible speech has been reported in 60 per cent of the patients following a secondary puncture procedure, and in 82 per cent following a primary procedure with a myotomy of the constrictor pharyngeal muscles (Löbe 1986, 1987; Zenner and Herrmann 1986b).

Fig. 4.10

Herrmann valve prosthesis.
E = esophageal side, T = tracheal side, 1 = tube part (silicone and metal), 2 = valve part (duckbill valve), 3 = tracheal retention flange, 4 = esophageal retention flange, 5 = fixation flaps, 6 = safety shield, 7 = open end

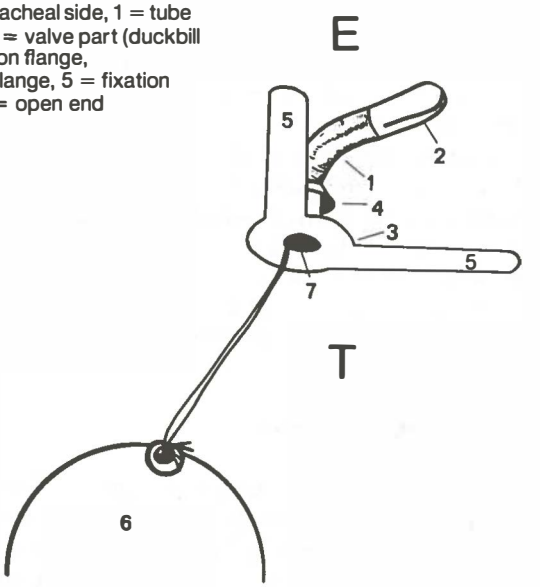
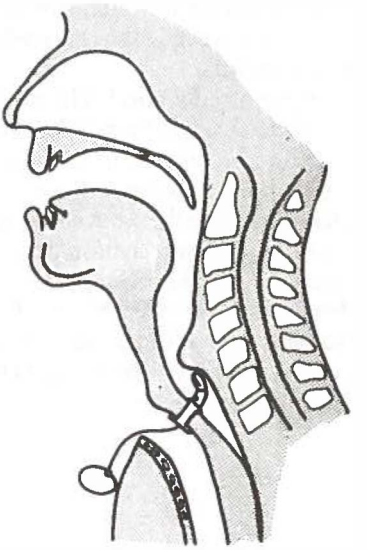


Fig. 4.11

Herrmann valve prosthesis situated in tracheo-esophageal shunt.



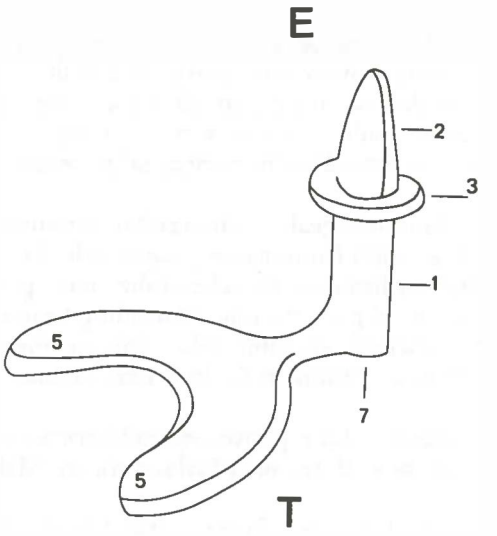
Complications described include:
- insufficiency of the tracheo-esophageal shunt, resulting in leakage of esophageal contents around the prosthesis
- turning of the prosthesis over 180 degrees, so that the valve is not directed upward towards the P-E segment, but downwards. This results in a poor voice production because the air is directed into the lower esophagus and stomach
- granulations around the shunt
- disconnection between the metallic and silicone part of the prosthesis.

The large part of the prosthesis protruding into the esophagus lumen is another drawback of the Herrmann prosthesis. Especially the long type of prosthesis can cause deglutitional problems (Löbe 1986; own observations).
The Herrmann prosthesis is used in several centers in Europe. In our department this prosthesis is used only in selected cases, e.g. in patients with recurrent hypopharyngeal stenosis, which can interfere with the replacement procedure of the Groningen button prosthesis (Chapter V).

4.1.6 **The Henley Cohn voice prosthesis**

The Henley Cohn prosthesis has been developed by Henley Cohn in the United States (Henley Cohn 1981; Henley Cohn, Hausfeld and Jakubczak 1984; Hausfeld and Henley Cohn 1986) and is manufactured by Dow Corning (U.S.A.). This silicone valve prosthesis consists of a tube part, one retention collar and a slightly modified duck-bill type of valve with horizontal slit (figs. 4.12 and 4.13). The tube part is not round, but it is ovally shaped. The fixation flaps which are attached to the tracheal end of the prosthesis, point upwards, which enables fixation with adhesives cranially to the tracheostoma and medially to the sternocleidomastoid muscles. Thus the extrusive force associated with neck rotation or flexion is said to be prevented. The fixation flaps are larger than the tracheostoma in order to prevent aspiration of the prosthesis. A one size device will fit all of the patients. The prosthesis has been reported to possess favourable aerodynamic properties when compared to the Blom-Singer duckbill type of prosthesis and to the Panje voice button. It does not require frequent removal, cleansing is done by the patient with the device in place. However, it has been advocated to insert a new prosthesis at three to four months intervals.
The voice rehabilitation results are reportedly good. The need of fixation to the skin, maintenance by the patient and a relatively large part of the prosthesis protruding into the esophagus lumen are considered to be the major drawbacks of this prosthesis.
Creation of the tracheo-esophageal shunt is exclusively performed as a secondary procedure and is carried out under local anaesthesia. A suction device with a curvature and blunt tip (modified long velvet eye Jackson suction device) is introduced into the mouth and the pharynx, until it can be seen stretching the tracheo-esophageal wall at the site of the tracheostoma. Subsequently, an incision is made in the tracheo-esophageal wall onto the blunt end of the suction device and a catheter introduced into the tracheo-esophageal shunt. Later this catheter will be replaced by the prosthesis. To our knowledge the use of the Henley Cohn prosthesis has remained limited.

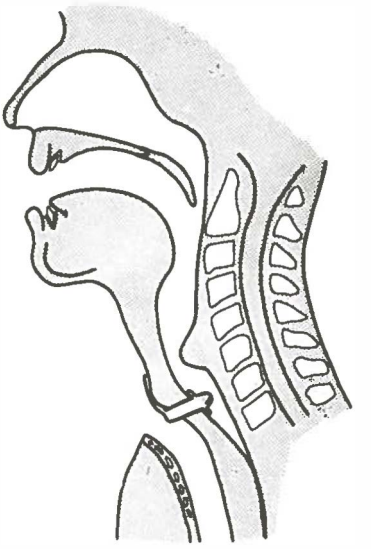
Fig. 4.12



Henley Cohn voice prosthesis.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part (duckbill valve), 3 = retention collar, 5 = fixation flaps, 7 = open end.

Fig. 4.13

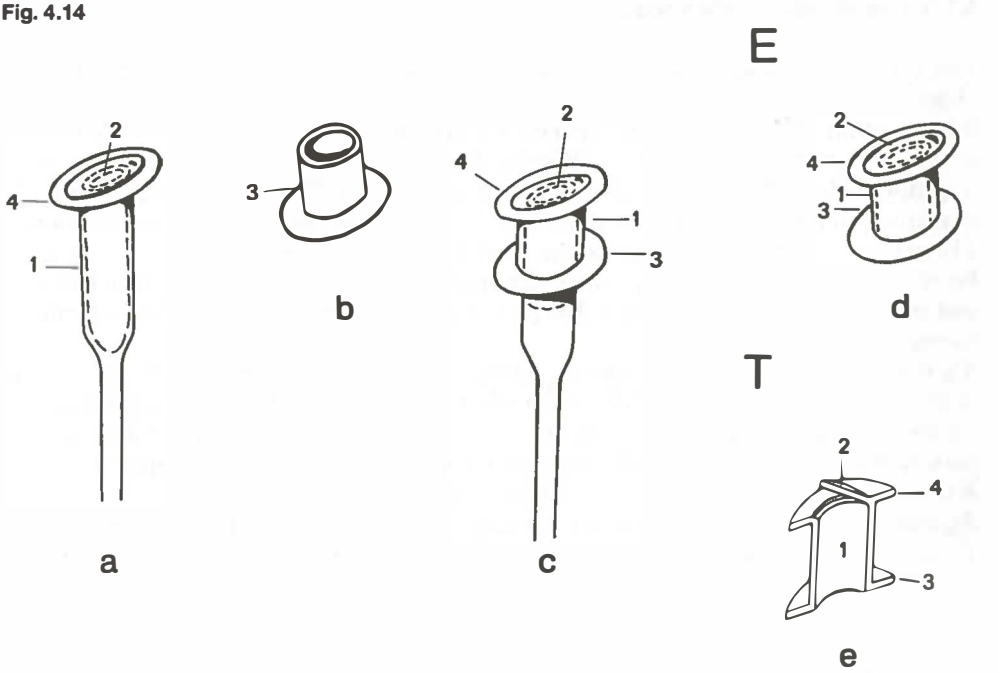
Henley Cohn voice prosthesis situated in tracheo-esophageal shunt.



4.1.7 **The Traissac voice prosthesis**

This prosthesis which was developed by Traissac in Bordeaux, France, is manufactured by the Vygon Company (France) using polyurethane plastic materials.
The prosthesis consists of two parts, the one ('male' part) sliding into the other ('female' part). The combination of both parts results in a tube with two retention collars and a trapdoor type of valve which is incorporated in the esophageal retention collar (figs. 4.14 and 4.15)
The 'male' part, with the tube and the esophageal retention collar containing the valve, is inserted in the tracheo-esophageal shunt from the esophageal side. The 'female' part with the tracheal retention collar is pushed over the tube of the 'male' part. After fixation of the 'female' part to the 'male' part, the tube protruding from the tracheostoma is cut flush with the tracheal retention collar. This has the obvious advantage that the prosthesis is fitted according to the individual tracheo-esophageal shunt length.
The creation of the tracheo-esophageal shunt is performed endoscopically as a secondary procedure, similarly to the procedures described previously. Maintenance by the patient is not required.
The initially reported success rate of 51 per cent (Traissac et al 1986a, 1986b) seemed to be somewhat disappointing, but the later reported success rate (1987) of 85 per cent is comparable to that of other valve prostheses.
Most of the failures seem to be caused by shunt insufficiency, due to the expansion of the tracheo-esophageal shunt. Furthermore, infections and problems concerning fixation of one part of the prosthesis to the other, are reported to be causes of failure.
Primary puncture and prosthesis placement procedures were abandoned by Traissac because of postoperative complications, e.g. the development of scar tissue in 50 per cent of the cases.
To our knowledge the use of the Traissac prosthesis has remained limited to the ENT-department in Bordeaux.

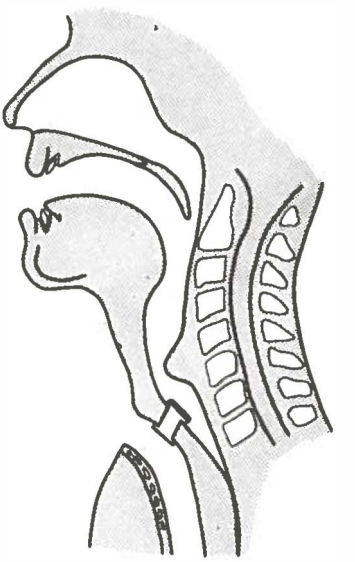
Fig. 4.14



Traissac voice prosthesis (after Traissac et al 1986).
a = 'male', b = 'female' part, c = coupling of 'female' part to 'male' part, d = prosthesis after excess of 'male' part has been cut off, e = longitudinal-section.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part (trapdoor valve), 3 = tracheal retention collar, 4 = esophageal retention collar.

Fig. 4.15

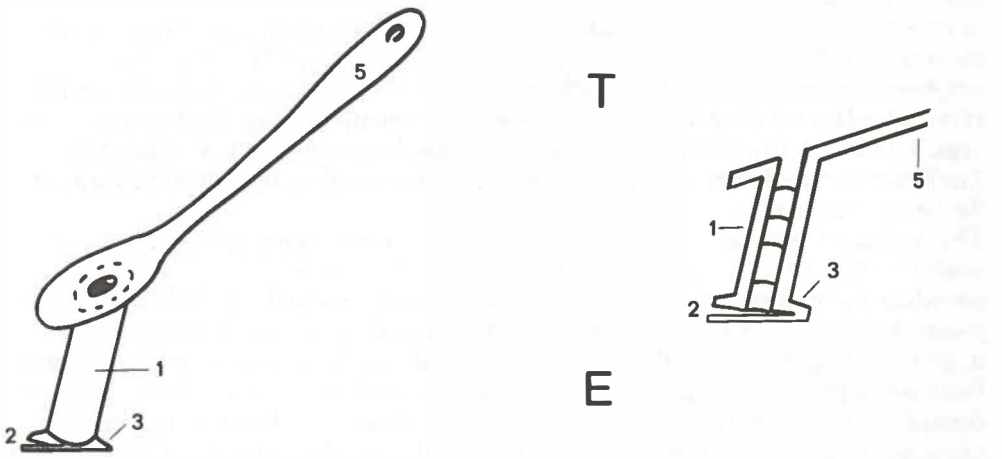
Traissac voice prosthesis situated in tracheo-esophageal shunt.



4.1.8 **The Algaba voice prosthesis**

This prosthesis was developed by Algaba and co-workers in San Sebastian, Spain (Algaba et al 1986, 1987).
It is a custom made silicone biflanged device (figs. 4.16 and 4.17), which is obtainable in three different lengths and two different diameters. The valve mechanism used is a trap-door valve, which is situated in the esophageal flange. The tracheal flange is placed in an angle of about 60 degrees with the tube part of the prosthesis. This is said to allow a better adjustment of the flange to the anatomical proportions of the tracheostoma. Fixation of the device is achieved with a strap which is connected to the tracheal flange and which can be taped to the skin. The prosthesis can be removed and replaced by the laryngectomee himself.
Algaba performs the tracheo-esophageal puncture as a secondary procedure under local or general anaesthesia. A flexible endotracheal tube is inserted into the esophagus. Under fiber optical control through this tube, the tracheo-esophageal puncture is performed from the tracheal side, through the tracheo-esophageal wall, into the tube. A stent is placed into the tracheo-esophageal shunt during the first weeks.
Algaba reported a success rate of 83 per cent in a group of thirty-five laryngectomees . To our knowledge the use of Algaba's prosthesis has remained limited to his own group.

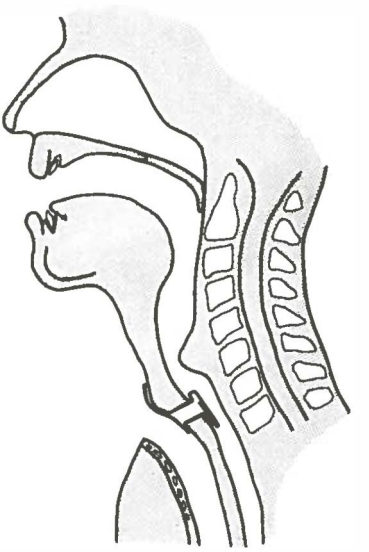
Fig. 4.16



Left: Algaba voice prosthesis.
Right: longitudinal-section.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part (trapdoor valve), 3 = retention collar, 5 = fixation flap.

Fig. 4.17

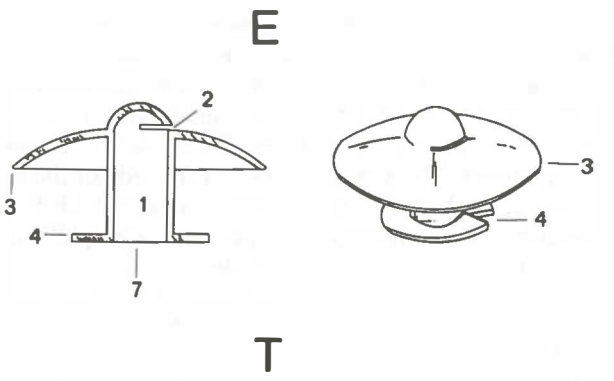
Algaba voice prosthesis situated in tracheo-esophageal shunt.



4.1.9 **The Staffieri prosthesis**

Recently, a silicone valve prosthesis has been introduced by Staffieri (Staffieri 1985, 1987) from Italy.
The custom made prosthesis consists of a tube part and two retention collars, of which the esophageal collar is relatively large. The tube extends slightly beyond this esophageal retention collar. The esophageal end of the tube is closed, but a slit situated at the side of the tube just dorsally to the esophageal retention flange functions as a valve (figs. 4.18 and 4.19). Three sizes based on the tube length are used: 5 millimeters, 7 millimeters, 9 millimeters. The shape of the prosthesis slightly resembles the shape of the Groningen button.
The method of insertion of the prosthesis into the tracheo-esophageal shunt is very similar to the insertion technique of the Groningen button. A thread or wire is introduced into the tracheo-esophageal shunt from the tracheal side. Subsequently, it passes through the P-E segment and the mouth, where the prosthesis can be attached to it. By retracting the thread, the prosthesis is pulled into the tracheo-esophageal shunt from the esophageal side. The Staffieri prosthesis is developed for insertion in surgically created 'Staffieri shunts'. They are only applied in shunts which are insufficient and cause aspiration. Other authors have mentioned the use of various of the above described prostheses for the same purpose (Nijdam et al 1982; Manni et al 1984; Löbe 1986; Traissac et al 1986a).
The use of the Staffieri prosthesis has remained limited and results have not yet been reported.

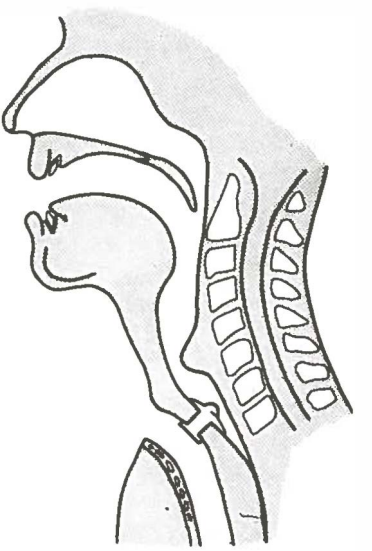
Fig. 4.18



(after Staffieri 1987).
Left: longitudinal-section.
Right: Staffieri prosthesis.
E = esophageal side, T = tracheal side, 1 = tube part, 2 = valve part, 3 = esophageal flange, 4 = tracheal flange.

Fig. 4.19

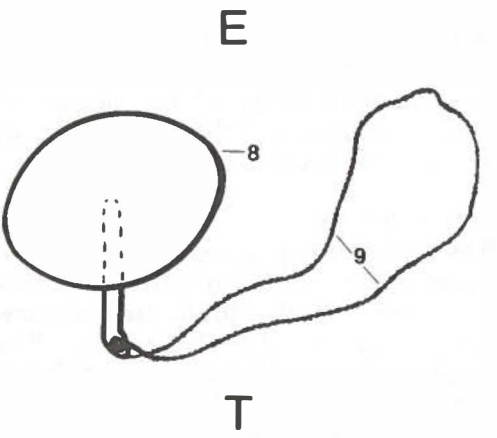
Staffieri prosthesis situated in tracheo-esophageal shunt.



4.1.10 **The Bonelli valve**

A totally different type of valve used in a tracheo-esophageal shunt is the custom made device developed by Bonelli and co-workers (1982a, 1982b) in Italy. It is the only device discussed here that has no tube part (figs. 4.20 and 4.21). The mechanism of Bonelli's valve is very simple. It consists of a shield with two strings attached to it. The shield is situated in the P-E segment and the strings pass through the tracheo-esophageal shunt and come out of the tracheostoma. The strings pass on either side of the neck to the back, where they are knotted together, thus securing the valve in the P-E segment. The air required for phonation passes through the tracheo-esophageal shunt from trachea to esophagus, when the tracheostoma is occluded.
The shield will shut off the shunt during swallowing, because it is pressed onto the shunt opening as a result of the pressure rise in the P-E segment. If the shield does not shut off the shunt completely, a slight pulling on the strings will seal off the shunt, thus preventing aspiration of food. The functional results are reported to be good (Bonelli 1987). Out of 250 cases only 9 per cent did not acquire serviceable speech and most of these failures were successfully treated with a modified pharyngeal decompressive type of surgery, which more or less resembles pharyngo-esophageal myotomy (Aversa 1987). To our knowledge the use of Bonelli's valve has remained limited to the San Luigi Hospital in Turin.

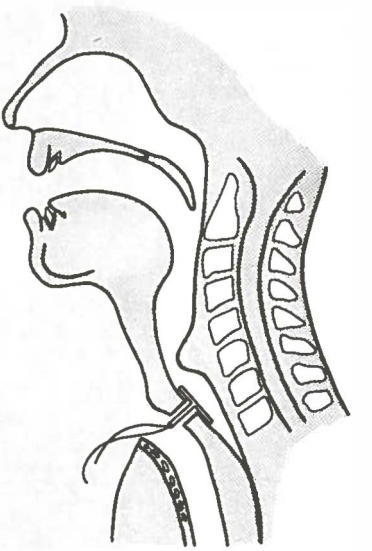
Fig. 4.20



Bonelli valve.
E = esophageal side, T = tracheal side, 8 = shield, 9 = strings.

Fig. 4.21

Bonelli valve situated in tracheo-esophageal shunt.

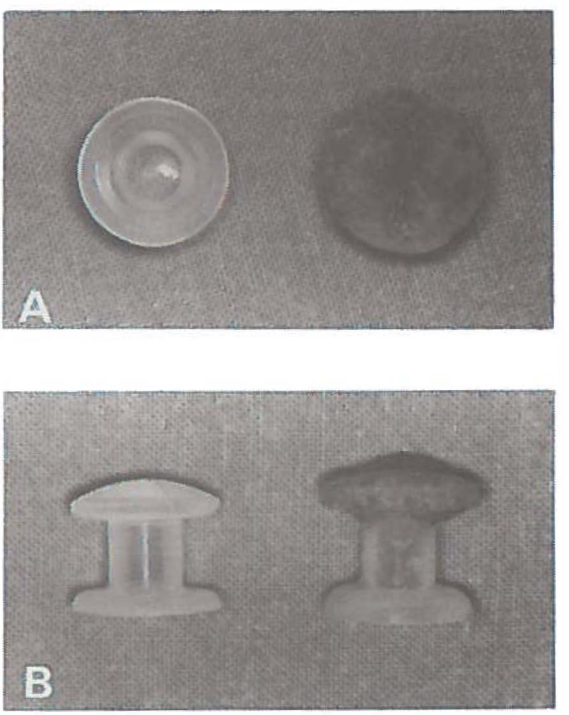


4.2 **DETERIORATION OF VALVE PROSTHESES**

Most types of valve prostheses described in this chapter are made of silicone. Silicone seems to be a very suitable material for this purpose, because of its inert, flexible, elastic and biocompatible properties. One of the disadvantages of these silicone valve prostheses, however, is their tendency to deteriorate. Although there is a large interindividual variability, most silicone valve prostheses function properly only for a few months.
Impaired valve function, manifesting itself by leakage of esophageal contents through the prosthesis or by increased air flow resistance of the valve, marks the end of the device life. In case of valve malfunction, the prosthesis will have to be replaced. This is a simple procedure which only occasionally presents a problem for the laryngectomee. Often yellow-brownish deposits are observed (Mahieu et al 1985; Herrmann, Poschet and Zöhren 1986), especially on the esophageal surface of prostheses which have been situated in a tracheo-esophageal shunt for some time (fig. 4.22). These deposits are held responsible for the malfunction of the valve mechanism.

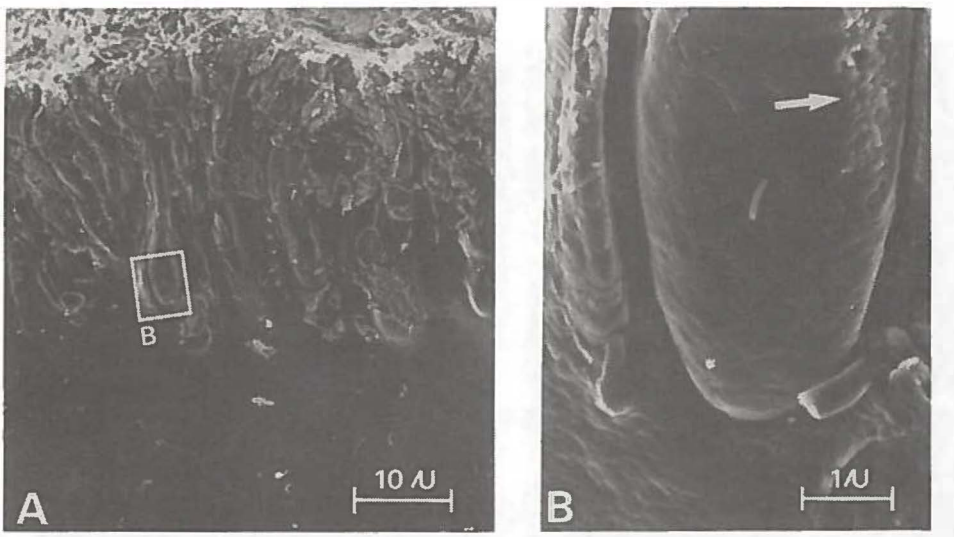
Fig. 4.22

Left: top and bottom: new Groningen button voice prosthesis.
Right: top and bottom: Groningen button voice prosthesis showing deposits on the esophageal flange after having been situated in a tracheo-esophageal shunt for three weeks.
A: view of esophageal flange.
B: side view.



In a scanning electron microscopical and microbiological study Mahieu and co-workers (1986a) found that these deposists largely consisted of colonies of *Candida* species. The growth of these *Candida* species proved to be not only confined to the surface of the valve prosthesis, but an invasive growth into the silicone material was observed as well (fig. 4.23).

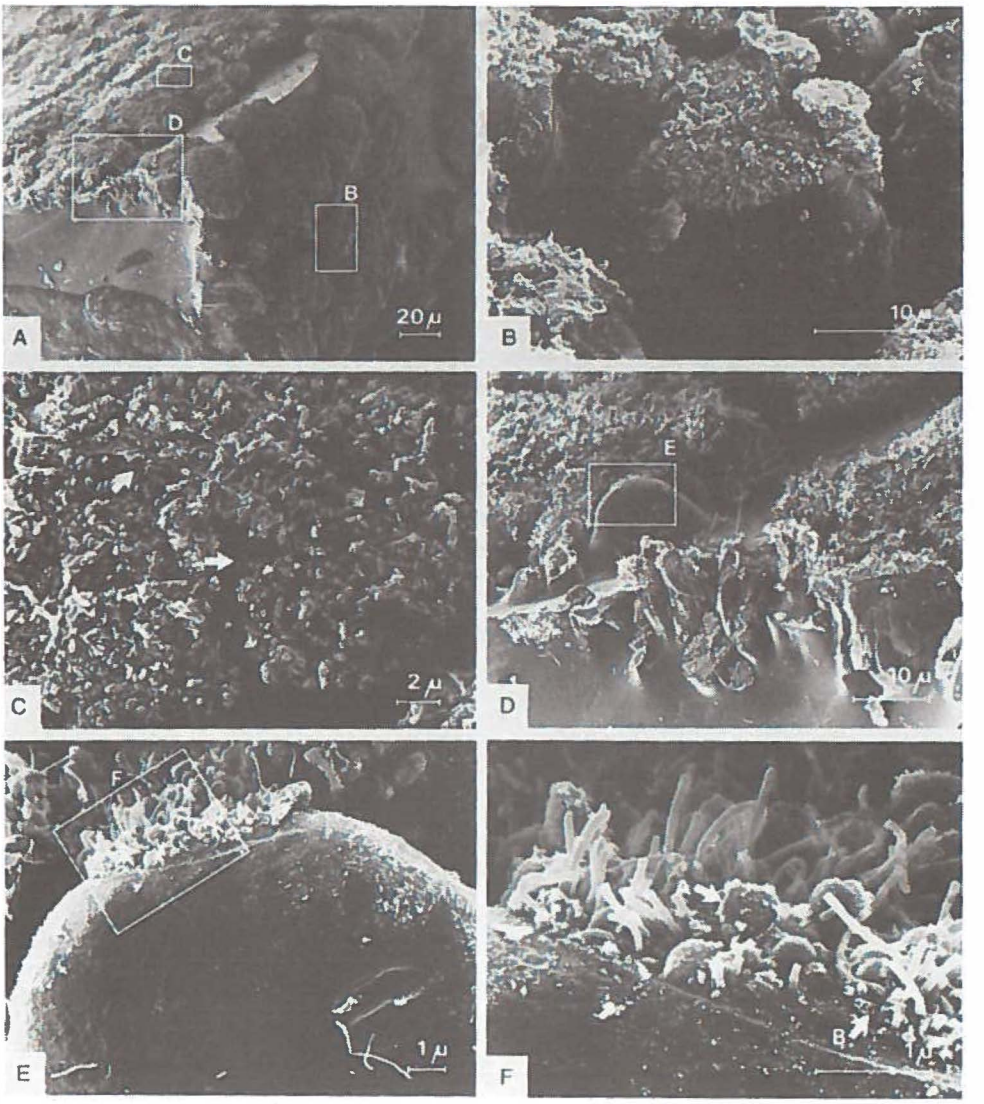
Fig. 4.23



Scanning electron micrograph from the cut edge of the esophageal surface of a Groningen button valve prosthesis which had been situated in a tracheo-esophageal shunt for three months.
A: showing invasive wedge-like growth of *Candida* vegetations into the silicone material.
B: detail from A showing *Candida* mycelia where the silicone is damaged (arrow).

This invasive growth explains why it proves almost impossible to remove the deposits from the prostheses. Furthermore, signs of expanding forces of the invasive growth were found to result in rupture of the silicone material and in deterioration of the valve prothesis (fig. 4.24).

Fig. 4.24



Scanning electron micrograph of another Groningen button valve prosthesis which had been situated in a tracheo-esophageal shunt for almost four months.

A: survey of the esophageal flange at the site of the valve slit, showing dense vegetations on the valve slit surface (B), and on the esophageal surface (C), and furthermore invasive growth can be seen at the cut edge (D).

B: detail of valve slit surface showing silicone bulges filled with yeast vegetations.

C: detail of esophageal surface, where only a few shreds of silicone material (arrows) remain between expanding vegetations.

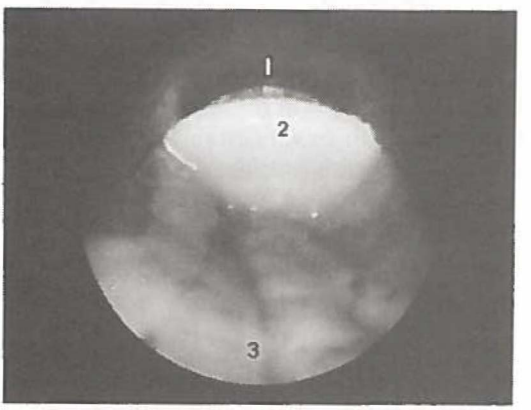
D: detail demonstrating silicone bulge on esophageal surface.

E: detail showing vegetations on top of bulge.

F: detail where yeast buds (arrow A) and mycelia (arrow B) typical for *Candida* organisms can be seen growing out of silicone bulge.

In the same study most of the laryngectomees were found to be oropharyngeal carriers of *Candida* species. Extremely high concentrations of *Candida* species were found in the tracheo-esophageal shunts of these laryngectomees, without clinical signs of infection. Apparently, the *Candida* species affect only the silicone prosthesis and not the host. This observation is in concordance with various reports in the literature, which do mention local infections of tracheo-esophageal shunts, but *Candida* species have never been referred to as the pathogenic microorganism. Mahieu and co-workers hypothesized that the continuous supply of oropharyngeal yeasts contaminates the intraesophageal part of the silicone valve prosthesis. Subsequently, the *Candida* species adhere to the prosthesis' surface, and lodgement and invasion follow shortly afterwards.
Other studies confirmed that vegetations of *Candida* species can be held responsible for valve prothesis dysfunction (Herrmann, Poschet and Zöhren 1986; Blom and Singer 1986; Izdebski, Ross and Lee 1987). In one of these studies (Herrmann, Poschet and Zöhren) colonization of the valve prosthesis with *Candida* was observed as soon as one day following insertion of the prosthesis into the shunt.
In a study, with a follow-up period of one month, Mahieu and co-workers (1986c) succeeded in reducing the *Candida* colonization of valve prostheses and tracheo-esophageal shunts by eliminating the oropharyngeal yeast source with amphotericin B lozenges (10 milligrams four times daily). A case report from this study (fig. 4.25), and preliminary results from another study (Mahieu and van Saene 1987), support the notion that selective oropharyngeal decontamination can prevent deterioration of the valve prosthesis. In order to verify this notion, a study has been performed, which is described in the following section.

Fig. 4.25



Endoscopic view of esophageal flange of Groningen button valve prosthesis, which has been situated for four months in the tracheo-esophageal shunt of a laryngectomee who has been using amphotericin B lozenges during this period. The old valve prosthesis with dense vegetations shown in figure 4.22 after only three weeks, came from the same laryngectomee, before oral decontamination. In the period before oral decontamination this laryngectomee had to change his valve prosthesis every three weeks because of valve malfunction.
1 = tip of endoscope, 2 = esophageal flange of Groningen button, 3 = posterior esophageal wall.

4.3 PREVENTION OF VALVE PROSTHESIS DYSFUNCTION; A STUDY

Following the identification of *Candida* species as a cause of silicone valve prosthesis deterioration and the successful short term reduction of colonization of valve prostheses achieved by selective decontamination of the oropharynx, the hypothesis was postulated, that early valve prosthesis dysfunction can be prevented by selective oropharyngeal yeast decontamination.
To prove this hypothesis a placebo controlled randomized double blind study has been designed, which was concentrated on two aspects:

1. Does the valve prosthesis function better in the absence of *Candida* colonization?
2. Can prevention of *Candida* colonization of the valve prosthesis be achieved by a long term administration of amphotericin B lozenges?

The end of the valve prosthesis life-time is marked by signs of valve dysfunction: leakage of esophageal contents through the prosthesis or increased air flow resistance of the valve, interfering with shunt esophageal voice production. However, long before the end of the device life-time and even before the air flow resistance of the valve has become so high that it actually interferes with the voice production, a gradual increase of valve air flow resistance has already occured. Consequently, a gradually increasing intratracheal air pressure is required for shunt esophageal phonation. This increase may have been so gradual that it has remained unnoticed by the laryngectomee, who nevertheless has to exert more effort in order to phonate. For shunt esophageal phonation a much higher subpseudoglottic air pressure is required (Jach, Mozolewski and Zietek 1979; Weinberget al 1982; Mahieu 1987; Mahieu et al 1987; Nieboer and Schutte 1987; Vuyk et al 1987; Nieboer, Schutte and De Graaf 1988), than the subglottic air pressure which is required for laryngeal phonation (Schutte 1980). In terms of efficiency of voice production (Schutte 1980) this means that shunt esophageal phonation is less efficient than laryngeal phonation and, consequently, voice production with the shunt esophageal method requires more effort than laryngeal voice production does. Therefore it is important to prevent a further decrease in the efficiency of shunt esophageal voice production, caused by the increased air flow resistance of a deteriorating valve prosthesis. Consequently, we consider the intratracheal air pressure required for shunt esophageal phonation to be an important parameter, which can monitor the functioning of the valve prosthesis.

4.3.1 Patients and methods

Patients
Thirty laryngectomees (26 males, 4 females; mean age 62 years) participated in this study. All have been laryngectomized at least half a year prior to the start of the study. All have received radiotherapy preoperatively (varying from 30 to 70 Gy), and all have undergone a tracheo-esophageal puncture as a primary procedure. When the laryngectomees visited our outpatients department, requesting replacement of their Groningen button valve prosthesis because of problems associated with valve prosthesis dysfunction, they were asked to participate in this study. Other inclusion criteria were an active use of the valve prosthesis and an informed consent to use lozenges four times daily for half a year.

Design of trial
This study was conducted as a prospective randomized double blind placebo controlled

study.
An inventory culture sample was taken from the oropharynx, the tracheo-esophageal shunt, and the old valve prosthesis, just before a new Groningen button was to be inserted. Also prior to insertion of the prosthesis, the tracheo-esophageal shunt was cleansed with a taurolin 1 per cent solution. Following the valve prosthesis replacement, the phonatory intratracheal pressure was determined, as described below. The laryngectomees received either lozenges containing 10 milligrams of amphotericin B (active substance) or lozenges containing only flavor additives (placebo). The patients were instructed to start using the lozenges immediately following the valve prosthesis replacement. Neither patients nor investigators knew whether the active substance or the placebo was administered. Only the manufacturer of the lozenges, who was not involved in the further treatment or measuring procedures, was familiar with the contents of the lozenges. Fifteen laryngectomees received treatment with the amphotericin B lozenges and fifteen used the placebo lozenges.
All laryngectomees again visited the outpatients department one month, three to four months and six months after insertion of the new prosthesis, and additionally each time that they experienced problems with the prosthesis. During each of these visits the phonatory intratracheal pressure was determined and culture samples were taken from the oropharynx, the valve part of the prosthesis and the tracheo-esophageal shunt, without removing the prosthesis. Very thin cotton tipped swabs were used for this culturing purpose.
If the prosthesis had to be replaced again during the half year period, the follow-up period concerning the monitoring of intratracheal phonatory pressure was considered to be terminated at that moment. The laryngectomee was, however, requested to continue using the lozenges for the mycological assessment.
If no prosthesis changement took place, the follow-up period was terminated after six months.

Mycological assessment
All samples were cultured on a selective yeast medium in a qualitative and semiquantitative way as described by Van Saene and co-workers (1983). A yeast isolation agar plate was inoculated using the four quadrant method. The tips of culture swabs from the oropharynx, the tracheo-esophageal shunt, and the valve prosthesis, were put into brain heart infusion broth. Broth and agar plates were incubated at 37 degrees Celsius for two nights. If the broth was turbid, inoculation on the yeast isolation agar was performed. Standard mycological techniques were used for identification of the microorganisms (Ajello et al 1966). Semi-quantitative estimation of the yeast concentration was made on a scale of +1 to +5 according to their presence in broth (+1) and the growth density of the four quadrants of the yeast isolation agar plate (+2 to +5). The lowest concentration of +1 corresponds with 10 or fewer microorganisms per millimeter; +2 with 10^3 to 10^5 microorganisms per millimeter; +3 with 10^5 to 10^7; +4 with 10^7 to 10^9; and +5 with 10^9 or more microorganisms per millimeter.
The results are represented by means of colonization indices. A colonization index is the ratio of the sum of growth-densities of the isolates divided by the number of samples obtained. The index allows representation of the findings in a qualitative as well as quantitative way (Wade et al 1982).

Estimation of intratracheal pressure required for phonation
Immediately after the insertion of a new prosthesis and at each following visit to the

outpatients department, the intratracheal air pressures required for sustained soft, normal, and loud shunt esophageal phonation were registered. These pressures were measured with a custom-built electronic measuring device (Lab. for Medical Physics, Groningen) in the trachea, during sustained phonation of the vowel /a/ with occluded tracheostoma. Simultaneously, voice intensity was recorded using a sound level meter (Bruël & Kjaer, type 2607) with a condensor type microphone (Bruël & Kjaer, type 4144) at a standard distance of 50 centimeters. From the obtained intratracheal pressure measurements and the corresponding voice intensity values, the intratracheal pressure required for a phonation of 67 dB was interpolated. The intensity level of 67 dB was chosen because this value was the mean intensity value for normal phonation in more than hundred similar measurement procedures performed in one of our unpublished studies and it was considered to be a comfortable phonation level.
It is possible to interpolate the required intratracheal pressure for a corresponding intensity, because a correlation is known to exist between intratracheal pressure and shunt esophageal vocal intensity (Vuyk 1987; Nieboer, Schutte and de Graaf 1988). The intratracheal phonatory pressure change (at the 67 dB intensity level) after one month, three to four months, and six months, as compared to the initially interpolated intratracheal pressure for a phonation of 67 dB, was considered to be a parameter with which the condition of the valve could be monitored. We assumed that no other factors in the shunt esophageal phonation of a laryngectomee other than changes in the valve air flow resistance, could be held reponsible for a change in the intratracheal air pressure required for phonation.

Definitions
At the outset of the study, a laryngectomee was considered to be colonized with *Candida* species, when at least one of the inventory cultures yielded these yeasts in the concentration of +1, or more. During the course of the study a laryngectomee was considered to be colonized, when after one month at least one culture was found to be +1 or more.

Analysis of data
For the evaluation of results four groups were distinguished, subjects who:
1. were free of *Candida* colonization after the first month of the study (non-colonized group)
2. were colonized with *Candida* species after the first month of the study (colonized group)
3. used amphotericin B lozenges (active substance group)
4. used placebo lozenges (placebo group).

In the last two groups only those subjects were included, who were colonized with *Candida* species at the outset of the study.
The data analysis was performed from two different points of view. Firstly, the intratracheal phonatory pressure changes were related to the first two groups, irrespective of whether placebo or active substance lozenges had been used. This was done to determine the actual influence of *Candida* colonization on valve prosthesis dysfunction.
Secondly, the intratracheal phonatory pressure changes and the colonization indices were related to the last two groups, which enabled an estimation of the effect of prescribing amphotericin B lozenges on these parameters.
For statistical analysis the Student's *t*-test was used for evaluation of the intratracheal phonatory pressure changes, as well as the colonization indices.

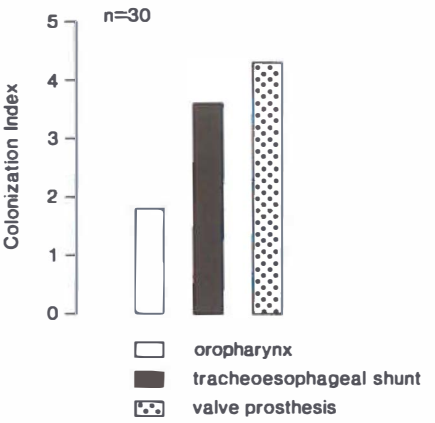
Furthermore, correlation coefficients were calculated (Pearson's correlation coefficient) in search of a correlation between the degree of mycological contamination and the intratracheal phonatory pressure change.

4.3.2 **Results**

Patients
One subject has been excluded from evaluation, because shortly after entering the study he started having problems with shunt insuffiency, which required temporary valve prosthesis removal (6.3.6). He had received active substance lozenges.
Three subjects were not colonized with *Candida* species at the outset of the study (negative inventory cultures). Two of them received active substance lozenges and the other one placebo lozenges. They have been excluded from, respectively, the active substance subject group and the placebo subject group.
Four subjects reported that they stopped using the lozenges during the study, or used them infrequently. One subject claimed to have used the lozenges as prescribed, but at the end of the study he had approximately one hundred lozenges left, whereas all lozenges should have been consumed. These latter five laryngectomees all received active substance lozenges. They have been excluded from the active substance subject group. Two subjects from the placebo group also reported to have stopped using the lozenges, but this occurred only after the valve prosthesis had already been replaced again. Therefore, these two subjects have been excluded from evaluation of the placebo subject group with respect to the mycological findings following, respectively, the ninth and fifteenth week. However, their phonatory pressure change data have been included, since at the time that they stopped using the lozenges, these data had already been obtained.
The non-colonized subject group consisted of twelve subjects. Three of these subjects yielded positive yeast cultures later on in the study, respectively after ten, twelve, and sixteen weeks. For evaluation purposes these subjects, however, remain in the non-colonized subject group. All other subjects in the non-colonized subject group remained uncolonized for the duration of the study.
The colonized subject group consisted of seventeen subjects. One of these subjects yielded only one positive yeast culture (valve prosthesis culture after one month + 3), all of the other cultures from this subject remained negative. For evaluation purposes this subject remained in the colonized subject group. All other subjects yielded positive yeast cultures each time.

Mycological findings
The colonization index of the inventory yeast cultures of all thirty subjects is presented in figure 4.26.

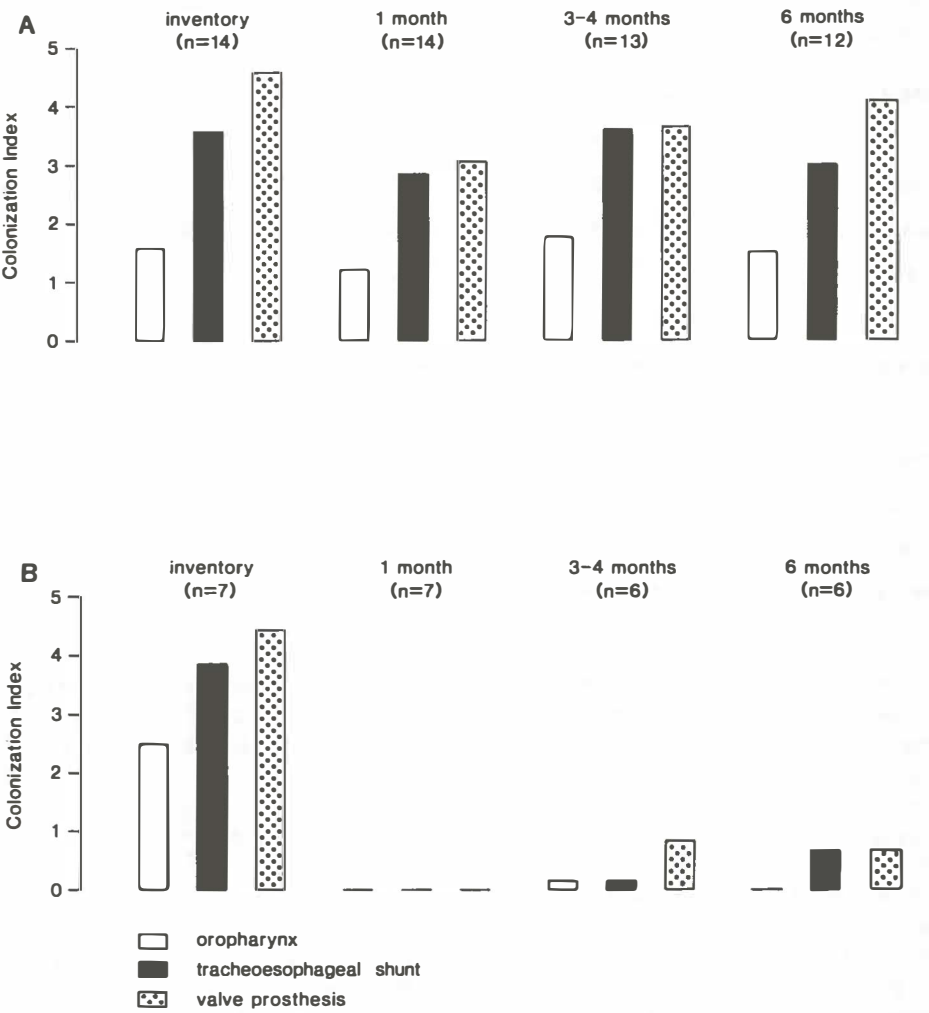
Fig. 4.26



Inventory *Candida* colonization index showing high concentrations of *Candida* species especially on the valve prosthesis and in the trachea-esophageal shunt.

There is no significant difference in colonization index between the fifteen subjects receiving active substance lozenges and the fifteen subjects receiving placebo lozenges. Three subjects (two receiving active substance lozenges and one receiving placebo lozenges) were not colonized with *Candida* in either the oropharyngeal, the tracheo-esophageal shunt or the valve prosthesis inventory culture. All three remained free of colonization during the 26 weeks of the study. The yeast colonization indices for the active substance subject group and the placebo subject group at the onset of the study (inventory culture), after one month, after three to four months and after six months are presented in figure 4.27. This figure demonstrates that a marked reduction in oropharyngeal, tracheo-esophageal shunt, and valve prosthesis yeast colonization is achieved by the administration of amphotericin B lozenges, whereas administration of placebo lozenges does not result in a reduction of yeast colonization.
All colonization indices (excepting the inventory colonization indices) of the actives substance subject group are significantly lower than the corresponding colonization indices of the placebo subject group (concerning the oropharyngeal colonization index after three to four months Student's *t*-test $p<0.02$; concerning all other colonization indices Student's *t*-test $p<0.01$).
Of the six subjects from the active substance subject group, who were mycologically assessed during the total duration of the study, one demonstrated *Candida* colonization, on the valve prosthesis (+4) after sixteen weeks, and in the tracheo-esophageal shunt (+4) after twenty-six weeks. The oropharyngeal cultures of this subject remained negative for *Candida* species for the duration of the study.
This subject is considered to be the only active substance failure in the group of subjects who used the lozenges as prescribed. All other subjects in this group remained free of *Candida* colonization during the study.

Fig. 4.27



A: *Candida* colonization indices of the placebo subject group showing high concentrations of *Candida* species at all times. No significant reduction of oropharyngeal colonization has occurred following the administration of placebo lozenges. After one month already a high concentration of *Candida* species was found on the new prosthesis and in the shunt.

B: *Candida* colonization indices of the active substance subject group showing high concentrations of *Candida* species on the inventory cultures. A marked reduction of oropharyngeal colonization has occurred following the administration of active substance lozenges. Also the *Candida* concentrations of the new prosthesis and the shunt remain extremely low during the whole follow-up period.

Phonatory intratracheal pressure change

The mean intratracheal phonatory pressure changes after one month, three to four months and six months, are presented in table 4.1. (in table 4.1a the results of the active substance subject group and the placebo subject group; in table 4.1b the results of the non-colonized subject group and the colonized subject group). These pressure changes are given in mean values for each subject group.

Table 4.1a Intratracheal phonatory pressure change (in kilopascal*)

	1 month	3-4 months	6 months
active substance subject group	-1.06 kPa (n=7)	-0.82 kPa (n=4)	-0.45 kPa (n=3)
placebo subject group	1.56 kPa (n=14)	2.83 kPa (n=7)	0.87 kPa (n=3)
Student's *t*-test	P<0.01	p<0.01	not significant

Table 4.1b Intratracheal phonatory pressure change (in kilopascal*)

	1 month	3-4 months	6 months
non-colonized subject group	-1.01 kPa (n=12)	-0.78 kPa (n=7)	-0.94 kPa (n=6)
colonized subject group	1.84 kPa (n=17)	2.11 kPa (n=10)	-0.31 kPa (n=5)
Student's *t*-test	p<0.01	p<0.01	not significant

* one kilopascal is approximately 10 cm H_2O pressure

The mean intratracheal phonatory pressures of the active substance subject group and the non-colonized subject group demonstrate a decrease, when compared to the initially interpolated phonatory pressure. In other words: the air flow resistance of the valve prostheses has diminished in these two subject groups.

The mean intratracheal phonatory pressures of the placebo subject group and the colonized subject group demonstrate an increase (with the exception of the colonized subject group after six months), when compared to the initially interpolated phonatory pressure. In other words: the air flow resistance of the valve prostheses has increased in these subject groups. With the exception of the phonatory pressure changes after six months, the differences between, respectively, the active substance subject group versus the placebo subject group, and the non-colonized subject group versus the colonized subject group, are all significant (Students *t*-test $p<0.01$). The phonatory pressure changes after six months for the colonized subject group and the placebo subject group are not considered representative, because in these groups a selection has apparently occurred during this period: in a large number of subjects from these latter two subject groups, the phonatory pressure change could not be determined after six months, because in the mean time they had already undergone new valve prosthesis replacements.

The correlations between phonatory pressure changes after one, three to four, and six months, and the corresponding mycological concentrations (colonization indices) are presented in table 4.2.

Table 4.2 Correlation between intratracheal phonatory pressure change and Candida colonization indices (Pearson's correlation coefficient).

Colonization index of:	Intratracheal phonatory pressure change after		
	1 month (N=29)	3-4 months (N=17)	6 months (N=11)
oropharynx	not significant	not significant	not significant
tracheo-esophageal shunt	r = 0.55 (p<0.01)	r = 0.61 (p<0.01)	not significant
valve prosthesis	r = 0.64 (p<0.01)	r = 0.53 (p<0.03)	not significant

A positive correlation is found between the mycological concentration of both the tracheo-esophageal shunt and the valve prosthesis samples, and the phonatory pressure changes, after one month and three to four months. Higher mycological concentrations of the shunt and the prosthesis, thus correspond with an increased air flow resistance of the valve prosthesis.

4.3.3 **Discussion**

The presented results confirm both aspects of the hypothesis postulated at the onset of the study.

1. The valve prosthesis functions better in the absence of *Candida* colonization.
2. A *Candida* colonized situation can be prevented effectively by long term administration of amphotericin B lozenges.

In addition to the observed positive effect of *Candida* decontamination on valve prosthesis air flow resistance, it also seems that the device life-time of the prosthesis is longer in the absence of local *Candida* growth. A study to verify this notion is in progress.

Our previous conclusion that valve prosthesis deterioration is caused by *Candida* species (Mahieu et al 1985, 1986a, 1986c, 1986d, 1986e; Mahieu and van Saene 1987) is substantiated by the results from the present study. A high percentage of the laryngectomized subjects involved in each of our three studies on this topic, proved to be colonized with *Candida* species in the oropharynx. Since selective decontamination of the oropharyngeal *Candida* source is found to influence the functioning of the valve prosthesis positively, all of these yeast colonized laryngectomees are likely to profit from the use of amphotericin B lozenges. However, as is also demonstrated in this study, not all subjects will regularly use the medication as prescribed. This factor of poor patient motivation is a well recognized problem in all clinical trials involving long term medication. To achieve good results with long term medication, patients will have to be highly motivated to use the prescribed medication regularly. Therefore, we do not routinely advocate the use of amphotericin B lozenges for all laryngectomees with silicone valve prostheses, but only for those who experience problems with increasing valve air flow resistance.

It is evident that the regular administration of antimycotic medication is not the ideal solution for preventing silicone voice prosthesis dysfunction. Therefore, we have suggested coating of the prosthesis with materials to which *Candida* species show less affinity. Furthermore, we have tried to impregnate the esophageal surface of the prosthesis with antimycotic agents or disinfectants. So far these attempts have failed,

because they negatively influenced the flexibility of the silicone material and consequently increased the air flow resistance of the valve. Research in this direction still continues.
Frequent prosthesis removal and cleansing with antimycotic solutions or soap and water has been recommended to prevent valve prosthesis deterioration (Blom and Singer 1986; Izdebski, Ross and Lee 1987; Modica 1987). However, we do not believe that this is the correct remedy, because frequent removal of voice prostheses is known to be associated with a higher complication rate and irritation of the tracheo-esophageal shunt (4.1.2 and 4.1.3). Furthermore, it is our experience as well as that of others (Herrmann, Poschet and Zöhren 1986), that once lodgement and invasion of *Candida* species into the silicone material has taken place, it is impossible to remove these yeasts without damaging the prosthesis.

The importance of a low air flow resistance of valve prostheses to facilitate shunt esophageal phonation has been stressed in many discussions. This has led to the development of low pressure types of valve prostheses. However, the intratracheal pressure required for phonation ('phonatory' pressure) depends upon a combination of factors, including the tonicity of the P-E segment, the design and condition of the prosthesis, especially the valve part, and the patient's acuity of shunt esophageal phonation. The increase, over time, of intratracheal phonatory pressure, in one subject, is almost exclusively attributable to valve prosthesis deterioration. We observed that in the non-colonized subject group, the interpolated intratracheal phonatory pressure after one month was lower than the initially interpolated intratracheal phonatory pressure. This decrease of intratracheal phonatory pressure can be attributed to the fact that the valve flaps of the Groningen button prosthesis tend to be rather adherent in the beginning, which results in an initially high air flow resistance of the valve. On the second or third day after insertion of a new Groningen button valve prosthesis this adherence of the valve flaps has diminished. Generally, patients then notice that they require less intratracheal pressure for phonation, than immediately after the insertion. We may assume that after the first day, the prosthesis is fully adjusted to the body temperature and humidity. Both of these factors are known to influence the flexibility of silicone and thus the air flow resistance of the valve prosthesis (Nieboer and Schutte 1986).
Recently, several types of 'low pressure' or 'low resistance' valve prostheses have been designed, in order to facilitate the shunt esophageal voice production. The air flow resistance of these low pressure prostheses is lower than that of the normal valve prostheses and therefore lower intratracheal air pressures are required for phonation. As is shown in this study, a considerable rise in valve prosthesis air flow resistance usually occurs within a month following the insertion of the prosthesis, if no action is taken to prevent *Candida* growth on the prosthesis. The rise in air flow resistance will very soon have neutralized the gain, which has been obtained by using a low pressure type of valve prosthesis. Therefore, the advantage of a low pressure device only exists for a short time, if deterioration of the prosthesis is not prevented simultaneously. In order to improve the efficiency of shunt esophageal phonation with a valve prosthesis for a longer period, all aspects which influence the air flow resistance should be taken into account. This implicates that simultaneous application of P-E segment myotomy, low pressure prosthesis, and prevention of valve deterioration, can create an optimal situation for efficient shunt esophageal phonation.

4.4 COMMENT ON VALVE PROSTHESES IN TRACHEO-ESOPHAGEAL SHUNTS

Many different valve prostheses have been presented in this chapter, each with their advantages and disadvantages. Naturally, the question arises: which is the best prosthesis? To answer that question a comparison of the results, patient acceptance and complications is required. Such a comparison is, however, impossible because of differences in patient population, patient selection, criteria used to establish the success rate, patient follow-up, etc.

Even with the interpretation of seemingly objective data, such as air flow resistance values, we must be very careful. As Nieboer and Schutte (1986) pointed out, no standard measurement procedures have been used in the different air flow resistance studies. They demonstrated the different results when compressed air was used for in vitro measurements, instead of moistened and warm expiratory air.

Therefore, the question of which prosthesis is the best, cannot be answered easily. The best prosthesis to use, however, will be one with which the clinician has a lot of experience, so that he can effectively respond to specific problems. Consequently, it is advisable not to use too many different prostheses. Furthermore, it is important to realize that the voice rehabilitation results do not only depend upon the type of prosthesis used, but also upon the type of initial surgery which is performed, whether or not a P-E segment myotomy is performed, whether or not good speech therapy assistance is available, whether or not deterioration of prostheses is effectively prevented, and some other less specific factors.

In general we can state that the silicone valve prostheses present a major breakthrough in laryngectomee voice rehabilitation, because a low complication rate is combined with the excellent alaryngeal voice production of the surgically created tracheo-esophageal shunts.

The puncture techniques for the creation of a tracheo-esophageal shunt are simple and applicable to patients who are undergoing a laryngectomy and to patients who have already been laryngectomized. Generally, good voice production can be achieved shortly after the procedure. Another important advantage is that radical cancer surgery is not compromised, as may be the case in reconstruction techniques, in which tissue is preserved for voice restoration purposes.

The necessity of digital occlusion of the tracheostoma is considered to be the major drawback. However, this is mandatory for almost every shunt method of esophageal voice production. Although various tracheostoma valves have been developed (Blom, Singer and Hamaker 1982; Herrmann and Koss 1985, 1986d; Herrmann 1987; Singh 1985; own unpublished experiences) to overcome this drawback, only a minority of the laryngectomees seems to be able to manage these devices.

Another drawback of valve prostheses, is the deterioration observed in most of them, which can, however, be effectively prevented by selective oropharyngeal yeast decontamination. Although valve prostheses, inserted into a tracheo-esophageal shunt, are undoubtedly not the final solution for the substitute voice problems of the laryngectomee, it seems to be the best voice rehabilitation method available at this moment. Therefore it is not surprising that laryngectomee voice rehabilitation with a valve prosthesis has quickly become the most frequently applied method of surgical voice rehabilitation. In the United States the Blom-Singer prosthesis seems to be most frequently applied. In Europe, with the exception of Great-Britain, where the Blom-Singer prothesis is often used, the Groningen button and the Herrmann device seem to be the most frequently applied valve prostheses. In the following chapters the Groningen button and our experience with this device, are presented in detail.

Chapter V

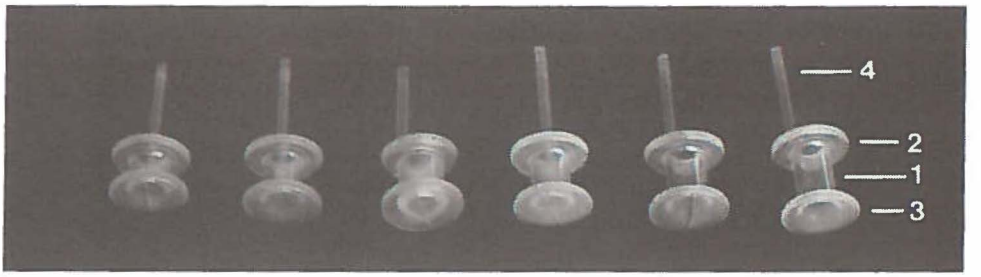
THE GRONINGEN BUTTON: DEVICE AND TECHNIQUES

In this chapter a discription is given of: the Groningen button valve prosthesis, the tracheo-esophageal puncture techniques (both primary and secondary), the technique used to place and replace the prosthesis, and the laryngectomee voice rehabilitation program of the Groningen University ENT-department. Furthermore, a study concerning pharyngo-esophageal myotomy is presented.

5.1 THE GRONINGEN BUTTON VALVE PROSTHESIS

The Groningen button (figs. 4.8, 4.9 and 5.1) is a self-retaining silicone one-way valve prosthesis, which can be placed in the tracheo-esophageal shunt (fig. 5.2). The silicone material of which it is made has a stiffness of 55 Shore*[1], which is rather flexible.

Fig. 5.1



Groningen button valve prosthesis. Different sizes depending upon the interflange distance respectively from left to right: 5 mm, 7 mm, 7 mm special (thicker tube part), 8 mm, 9 mm, and 11 mm.
1 = tube part, 2 = tracheal flange, 3 = esophageal flange with valve mechanism, 4 = string used for insertion of the prosthesis.

The function of the prosthesis is to enable a free passage of air from the trachea to the esophagus and to prevent the passage of esophageal contents to the trachea. The device consists of a biflanged tube part and a valve part, which is situated in the esophageal flange. The flanges which retain the prosthesis, and the tube part have been designed in such a way, that protrusion into the lumen of esophagus and trachea is minimal. Thus, interference with deglutition and respiration is avoided (fig. 5.3). The valve is formed by a slit in the 'hat' of the mushroom like device (fig. 5.4). The form of the 'hat' is essential for proper functioning of the valve. There is a small silicone string attached to the tracheal flange of the prosthesis, which is only used during insertion of the prosthesis into the shunt (5.2 and 5.3).

*[1] Shore: manufactorers specification of elasticity of silicone material.

Fig. 5.2

Groningen button valve prosthesis situated in tracheo-esophageal shunt, the tracheal flange is visible through the tracheostoma.

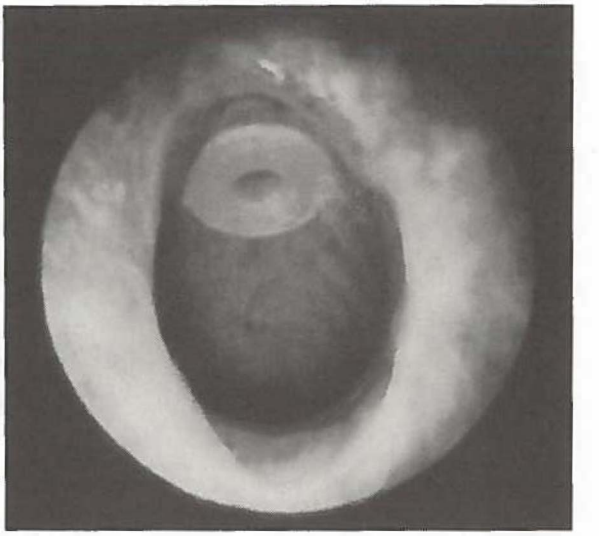
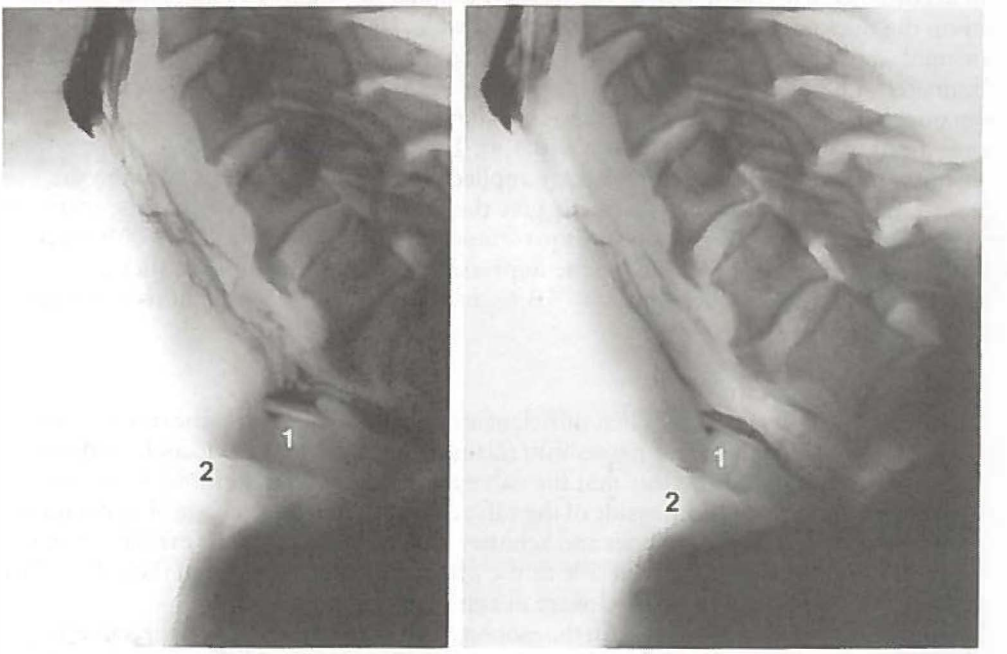


Fig. 5.3



Fluoroscopic imaging of the P-E segment of a laryngectomee with a Groningen button valve prosthesis situated in a tracheo-esophageal shunt.
Left: situation in rest just after swallowing.
Right: during non-shunt esophageal phonation. (In this myotomized laryngectomee, who is an excellent speaker both with the non-shunt and the shunt esophageal method, no pseudoglottis could be visualized.)
Note that the lumen of both trachea and esophagus is not reduced by the prosthesis.
1 = Groningen button in shunt, 2 = tracheostoma.

Fig. 5.4

Groningen button cut in half shows the slit (arrow) in the esophageal flange functioning as a one-way valve.
2 = tracheal flange, 3 = esophageal flange.

The prosthesis is available in five normal sizes and one special size. The flanges are the same in all these different sized prostheses and have a diameter of 12 millimeters. The prostheses have an interflange distance of 5, 7, 8, 9 or 11 millimeters. This enables fitting in accordance with the length of the tracheo-esophageal shunt, which mainly depends upon the thickness of the tracheo-esophageal wall. The outer tube diameter of all the normal sized prostheses is 7 millimeters. The special sized prosthesis has an outer tube diameter of 8 millimeters and is only available in the 7 millimeter interflange distance version. This slightly thicker prosthesis was developed to prevent leakage around the prosthesis in mild shunt insufficiency (6.3.6). The 7 and 8 millimeters interflange distance prostheses are most frequently applied. The small differences between the interflange distances might incorrectly give the impression that fitting of the prosthesis is very critical. Too long or too short prostheses will only rarely interfere with voice production. However, we do have the impression that minor problems, such as hypertrophy of the tracheal mucosa (6.3.6), may be avoided if a prosthesis of proper size is fitted.

Aerodynamic properties
In rest the valve slit is closed. When sufficient air pressure is built up in the trachea, the slit is forced open and the air passes into the esophagus. The valve closes by natural recoil of the material. It is clear that the valve must be completely closed at rest when no pressure is exerted on either side of the valve, in order to avoid leakage of esophageal contents into the trachea. Nieboer and Schutte (1986) found that an air pressure of 0.5 kPa[*2] is required on the tracheal side of the prosthesis in order to open the valve. This opening pressure ensures a firm closure in rest.
During deglutition a pressure rise in the esophagus will press the edges of the valve flaps closer together due to the form of the valve. In vitro studies by Nieboer and Schutte (1984, 1987) demonstrate that pressures of more than 20 kPa on the esophageal side still result in a firm closure of the valve. They found that a mean air pressure of 3.3 kPa on the tracheal side of the prosthesis results in a mean air flow of 0.14 liters per second

[*2] 1 kPa (kilopascal) is approximately 10 cmH_2O pressure.

through the valve*[3]. Nieboer and Schutte suggest that it may be better to speak of 'pressure loss over a prosthesis' then of 'air flow resistance of a prosthesis'. Especially in clinical research and in vivo studies the pressure loss over a prosthesis seems to be more important than the air flow resistance, because the air flow required for phonation shows a large interindividual variation. Nieboer, Schutte and de Graaf (1988) mention an air flow range of 0.02 to 0.80 liters per second, measured in eighteen shunt esophageal speakers.
Recently, a low pressure type of the Groningen button valve prosthesis has been developed, which results in a markedly reduced pressure loss. Preliminary results of in vivo measurements using a prototype of this low pressure device are very encouraging and suggest a reduction of the pressure loss by more than 50 per cent. The same favourable characteristics of the normal valve prosthesis concerning device life-time and prevention of leakage of esophageal contents are maintained in the low pressure type.

Prosthesis dysfunction
The prosthesis deteriorates after having been used for some time (4.2). The mean device life-time is approximately four months, but varies greatly. Valve dysfunction is signified by minor leakage or progressive air flow resistance. Leakage of esophageal contents through the valve is usually first noticed while drinking hot liquids such as tea or coffee. The high temperature of these beverages results in a higher flexibility of the valve and, consequently, valve insufficiency can more easily occur. Dysfunction of the valve requires replacement of the prosthesis, which is described in 5.3.

5.2 TRACHEO-ESOPHAGEAL PUNCTURE AND PROSTHESIS PLACEMENT PROCEDURES

The shunt is created by means of a simple puncture through the tracheo-esophageal wall, either at the time of the laryngectomy (primary tracheo-esophageal puncture procedure), or after the laryngectomy (secondary tracheo-esophageal puncture procedure). The valve prosthesis is placed immediately following the puncture. We prefer to use the primary puncture procedure, because rapid voice rehabilitation starting shortly after laryngectomy facilitates the return of the laryngectomee to his normal social environment and activities. Furthermore, the secondary puncture procedure is an additional surgical procedure, which again requires general anaesthesia.
These matters are discussed with the patients before laryngectomy. Most of them decide upon a primary tracheo-esophageal puncture.

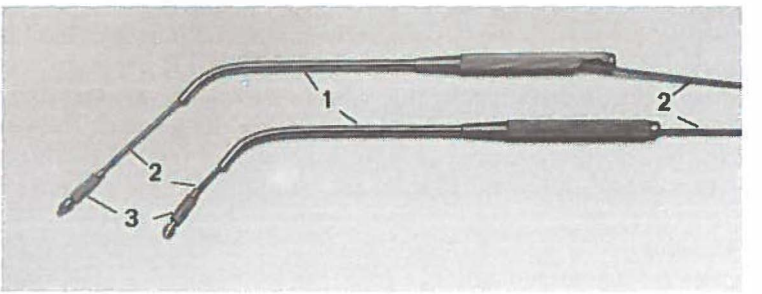
5.2.1 Primary puncture and placement procedure

During the laryngectomy, after the construction of the tracheostoma and before the

*[3] It must be noted that these in vitro measurements were performed with new prostheses. Our unpublished in vivo experiences show that the firmness of the silicone material and the adhesion of the valve flaps in new prostheses result in a significantly higher pressure loss, than in prostheses which have been situated for a few days. This finding is supported by another study (4.3), in which we found that one month after insertion of a new prosthesis, the required intratracheal air pressure for a standard phonation was more than one kPa lower than the initially registered air pressure, if the prosthesis had not deteriorated. Furthermore, Nieboer (1986) pointed out the importance of using watersaturated air of body temperature for these in vitro measurements. This is constantly overlooked in several publications concerning other silicone valve prostheses (Moon et al 1983, 1984; Weinberg et al 1982a, 1982b, 1982c, 1984, 1986a, 1986b). The results mentioned in these publications can therefore not be compared with those acquired by Nieboer.

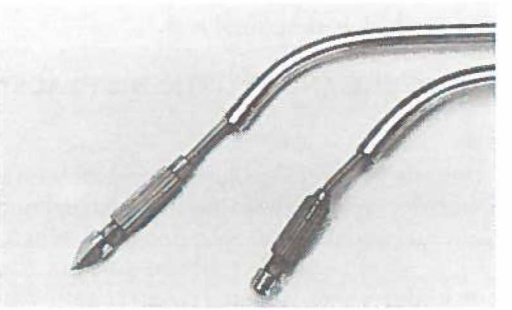
pharyngeal repair, the tracheo-esophageal shunt is created, with a sharp pointed metal wire in a rigid holder (figs. 5.5 and 5.6).
A myotomy of the P-E segment is performed prior to the puncture, when the tonicity in the P-E segment is judged to be too high for succesful (shunt) esophageal voice acquisition (5.5).

Fig. 5.5



Puncture (top) and replacement (bottom) instruments. The puncture instrument has a sharp tip, the replacement instrument has a blunt tip. 1 = rigid holder, 2 = wire, 3 = tip.

Fig. 5.6

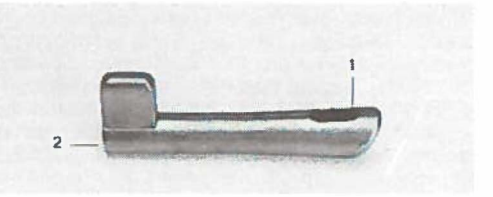


Detail of tips of puncture (top) and replacement (bottom) instruments.

During the puncture procedure the tracheostoma ventilation tube will have to be intermittently removed for small periods of time. The surgeon inserts the index finger of one hand through the pharyngeal defect into the upper part of the esophagus. With his other index finger situated in the tracheostoma, he can estimate the thickness of the tracheo-esophageal wall between his fingers. Thus, he is able to decide upon the size of the prosthesis.
A small metal tube is used, the so called 'receiver' (fig. 5.7), which is open at one end and has another opening at the side.

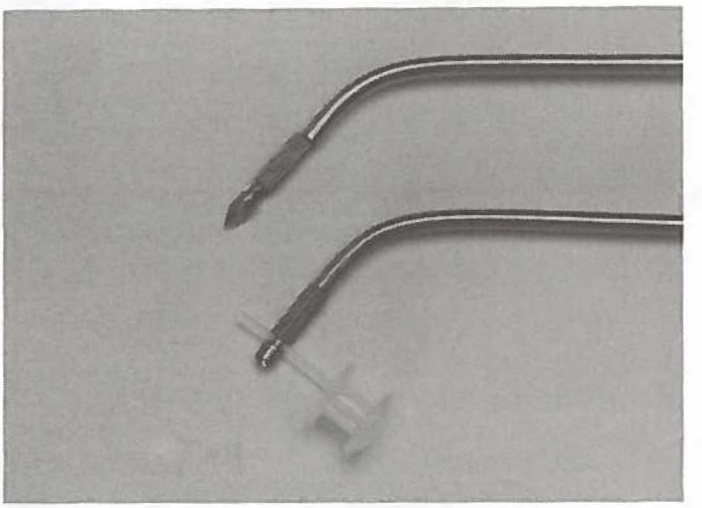
Fig. 5.7

'Receiver' tube. The tracheo-esophageal puncture is made into the side opening. 1 = side opening, 2 = open end.



This instrument is inserted with the closed end into the opened pharynx, until the opening at the side of the tube has reached the site where the tracheo-esophageal shunt is planned. The side opening of the tube can be palpated through the tracheo-esophageal wall. This wall is punctured with the sharp pointed metal wire from the tracheal side, into the side opening of the receiver, at a point 1 to 1.5 centimeters below the upper margin of the tracheostoma. In the original procedure, the tracheo-esophageal wall was punctured, without use of the receiver tube, towards the palpating finger in the upper part of the esophagus. The obvious advantage which the use of the 'receiver' tube has brought, is a better protection of the dorsal esophageal wall and the surgeons finger during the puncture.
After the puncture, the wire can be advanced through the rigid holder, the newly created tracheo-esophageal shunt, and the receiver, towards the pharyngeal defect. Here the sharp tip can be taken out of the receiver. Subsequently the receiver is removed from the pharynx, over the metal wire.
In the tip of the wire a hole is present, in which the small string of the prosthesis can be placed. Using a connecting device with a screw attached to the tip, the prosthesis can be fixed (fig. 5.8).

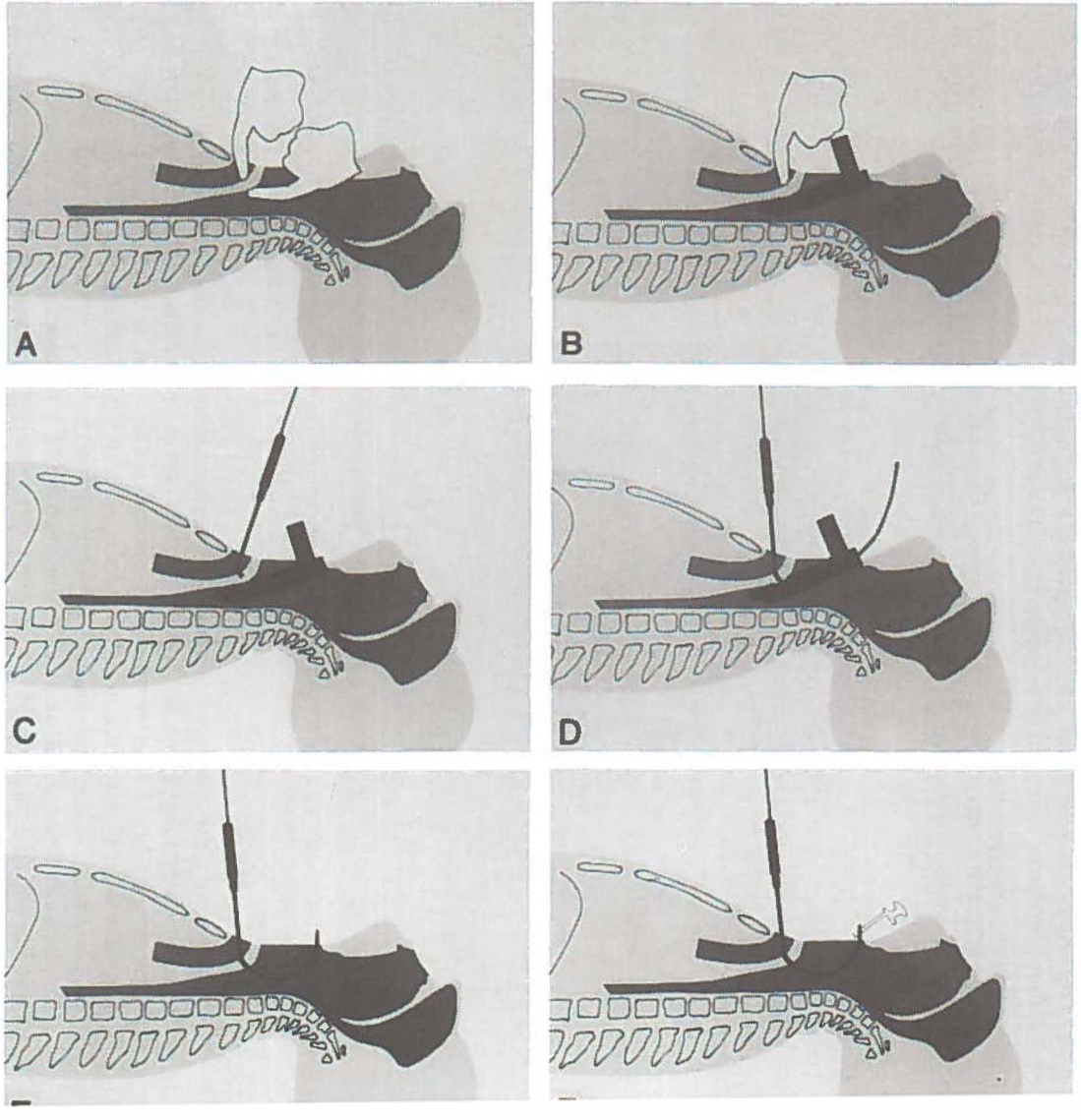
Fig. 5.8

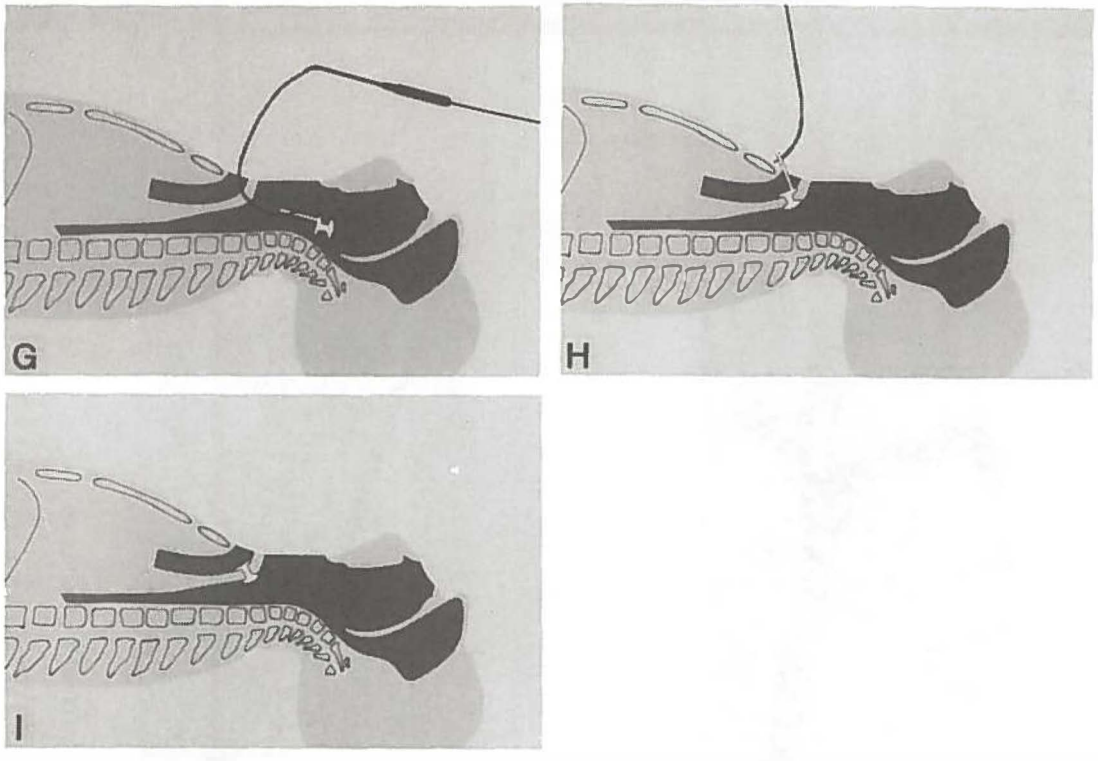


String of Groningen button fixed to tip of replacement instrument by a connecting device with screw. Same connecting device is present in the tip of the puncture instrument (top).

Subsequently, the metal wire, and the prosthesis attached to it, can be retracted into the tracheo-esophageal shunt. Because the shunt is narrow, some traction may be necessary to pull the tracheal flange through. Care should be taken that the whole tracheal flange has passed the shunt, since otherwise dislocation of the prosthesis towards the esophagus can occur. The small attachment string is cut from the tracheal flange, when the device is situated. Subsequently, the laryngectomy procedure can be continued, starting with the pharyngeal repair. The valve prosthesis is not used until the removal of the nasogastric feeding tube, twelve days postoperatively.
The primary tracheo-esophageal puncture procedure and prosthesis placement are schematically presented in figure 5.9.

Fig. 5.9.



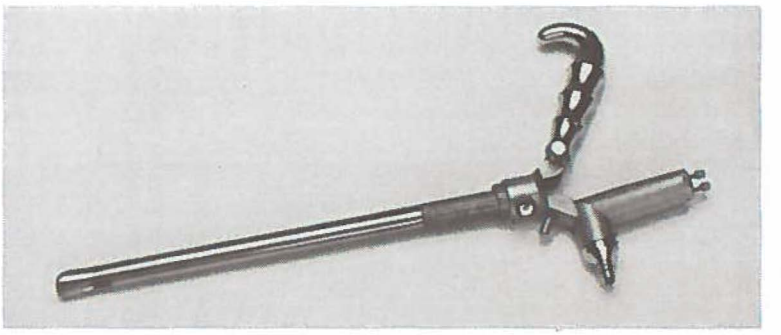


Primary tracheo-esophageal puncture procedure and Groningen button valve prosthesis placement.
A: Estimation of thickness tracheo-esophageal wall.
B: Insertion of 'receiver' tube through open pharynx, palpation of side opening of 'receiver' through tracheo-esophageal wall.
C: Creation of tracheo-esophageal shunt by puncture of tracheo-esophageal wall into side opening of 'receiver'.
D: Advancing of wire through 'receiver'.
E: Tip of wire coming out of open pharynx. 'Receiver' removed.
F: Fixation of Groningen button to wire.
G: Retraction of wire through tracheo-esophageal shunt.
H: Prosthesis pulled into tracheo-esophageal shunt.
I: Prosthesis situated. String cut off of tracheal flange. Primary puncture procedure and prosthesis placement accomplished.

5.2.2 **Secondary puncture and placement procedure**

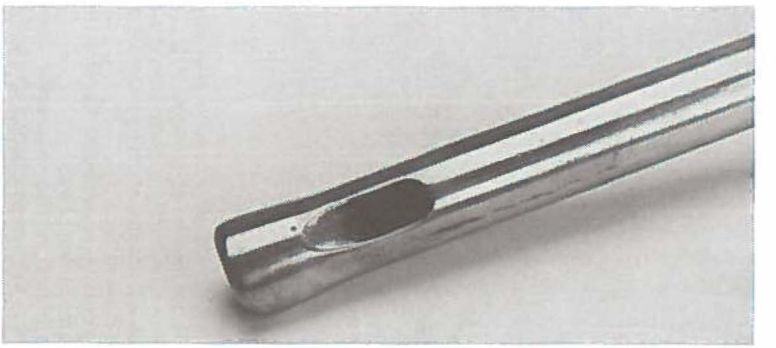
The technique used for the secondary tracheo-esophageal puncture procedure is a modification of the endoscopic technique described by Singer and Blom (1980). A prerequisite for tracheo-esophageal puncture after laryngectomy is a completed healing of the pharyngeal repair. Before this time no secondary puncture can be safely performed.
Preferably in general anaesthesia, a special rigid endoscope with a side opening (figs. 5.10 and 5.11) is introduced through the mouth and the P-E segment into the upper part of the esophagus*[4].

Fig. 5.10



Endoscope with side opening.

Fig. 5.11

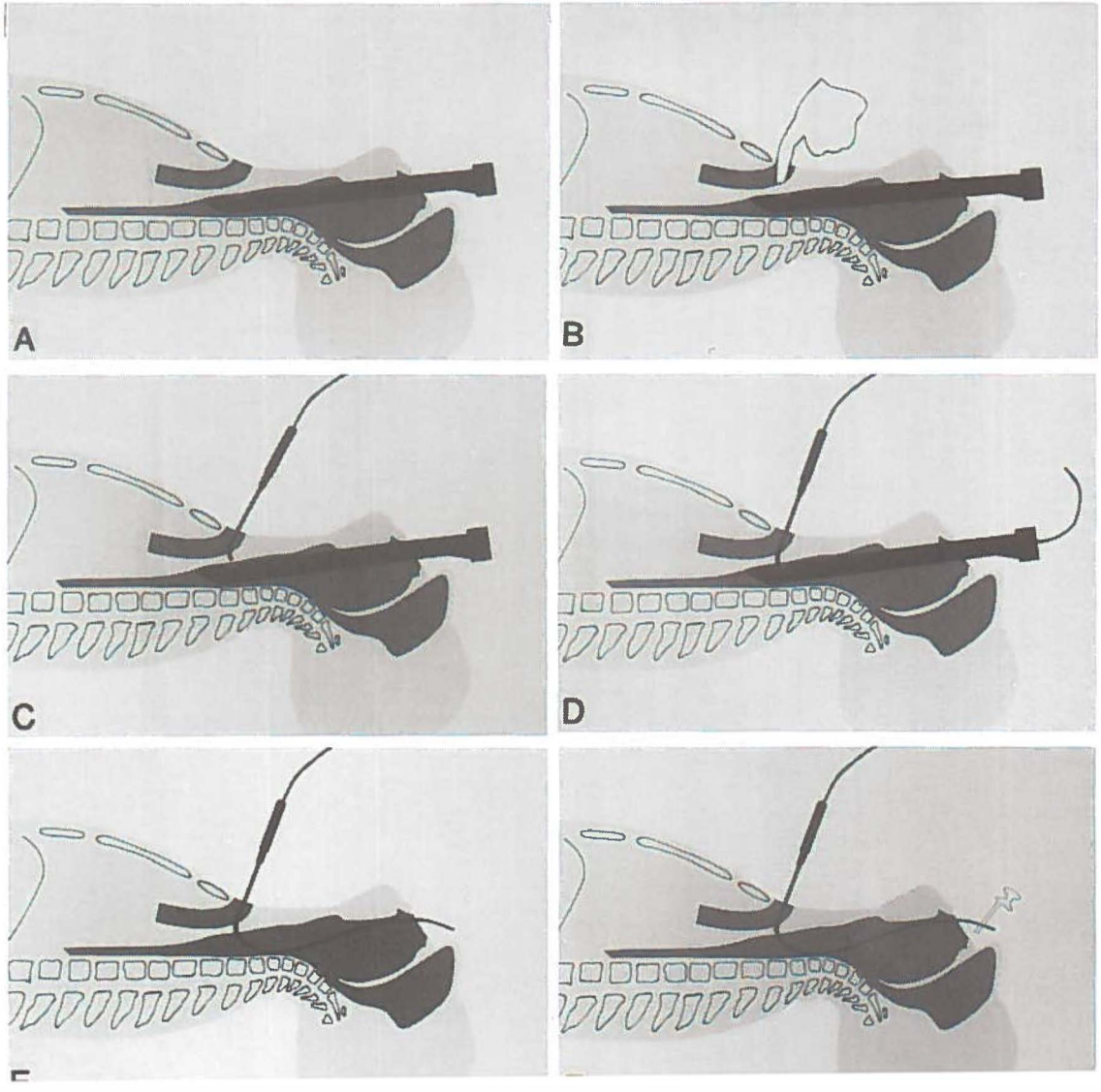


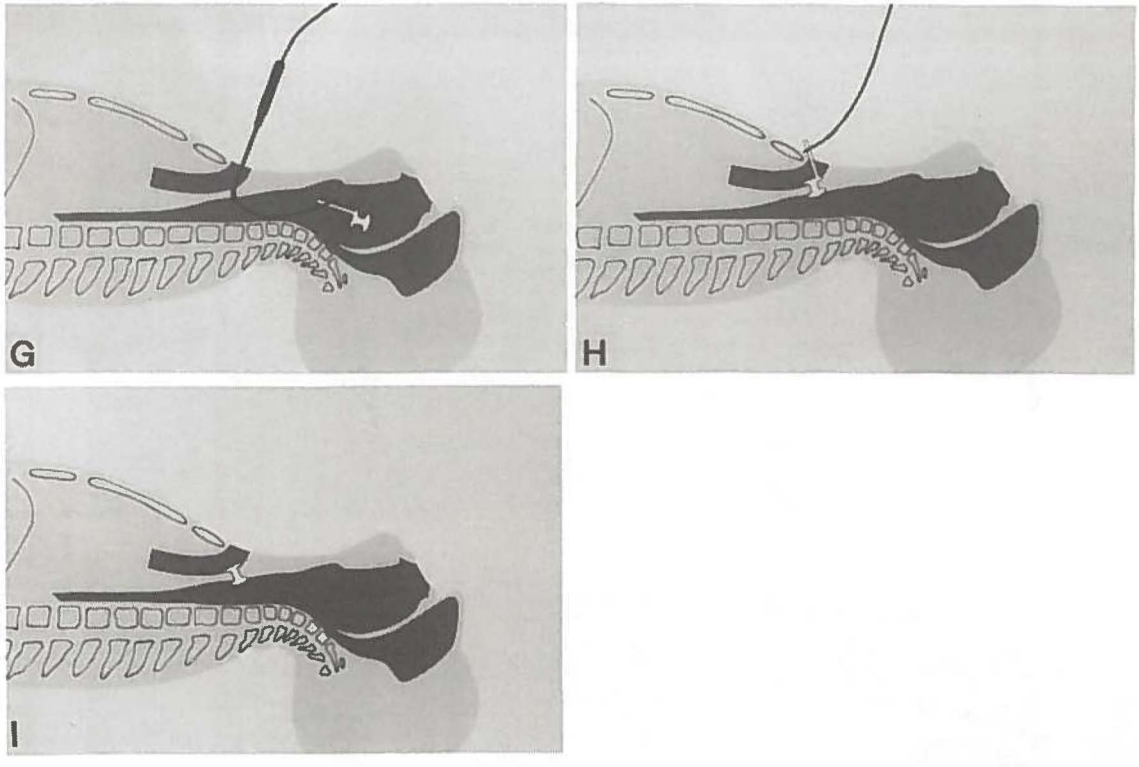
Detail of side opening into which puncture is performed.

*[4] A normal rigid endoscope can also be used. After introduction of the endoscope it must then be turned 180 degrees, so that the distal opening is directed towards the tracheal-esophageal wall at the site of the planned puncture. Thus, the puncture can be performed into the distal opening.

The side opening of the endoscope is directed towards the tracheo-esophageal wall at the site where the tracheo-esophageal shunt will be made. With a palpating finger in the tracheostoma, the surgeon can establish if the opening of the endoscope is indeed directed towards the point where the puncture will be made in the posterior tracheal wall, 1 to 1.5 centimeters below the upper margin of the tracheostoma. Furthermore, he can estimate the thickness of the tracheo-esophageal wall, to determine the appropriate size of the prosthesis. The tracheo-esophageal wall is punctured from the tracheal side, with the same sharp pointed wire as is used in the primary procedure (fig. 5.6). An assistent looking through the endoscope can ascertain that the sharp pointed wire is indeed directed into the opening of the endoscope. The wire is advanced through the endoscope, until the tip can be taken out by the assistent. Subsequently, the endoscope is removed, while the metal wire stays in place. The prosthesis is attached to the tip of the wire in the same fashion as is used in the primary procedure (fig. 5.8). The metal wire with the prosthesis is then pulled back into the tracheo-esophageal shunt. Just as with the primary procedure, care should be taken that the whole tracheal flange has passed the shunt, to prevent dislocation of the prosthesis towards the esophagus. Obviously, also during this puncture procedure, the ventilation tube will have to be removed intermittently from the tracheostoma for short periods of time. Following secondary placement the valve prosthesis can be used immediately from the first postoperative day. The secondary tracheo-esophageal puncture procedure and prosthesis placement is schematically presented in figure 5.12.

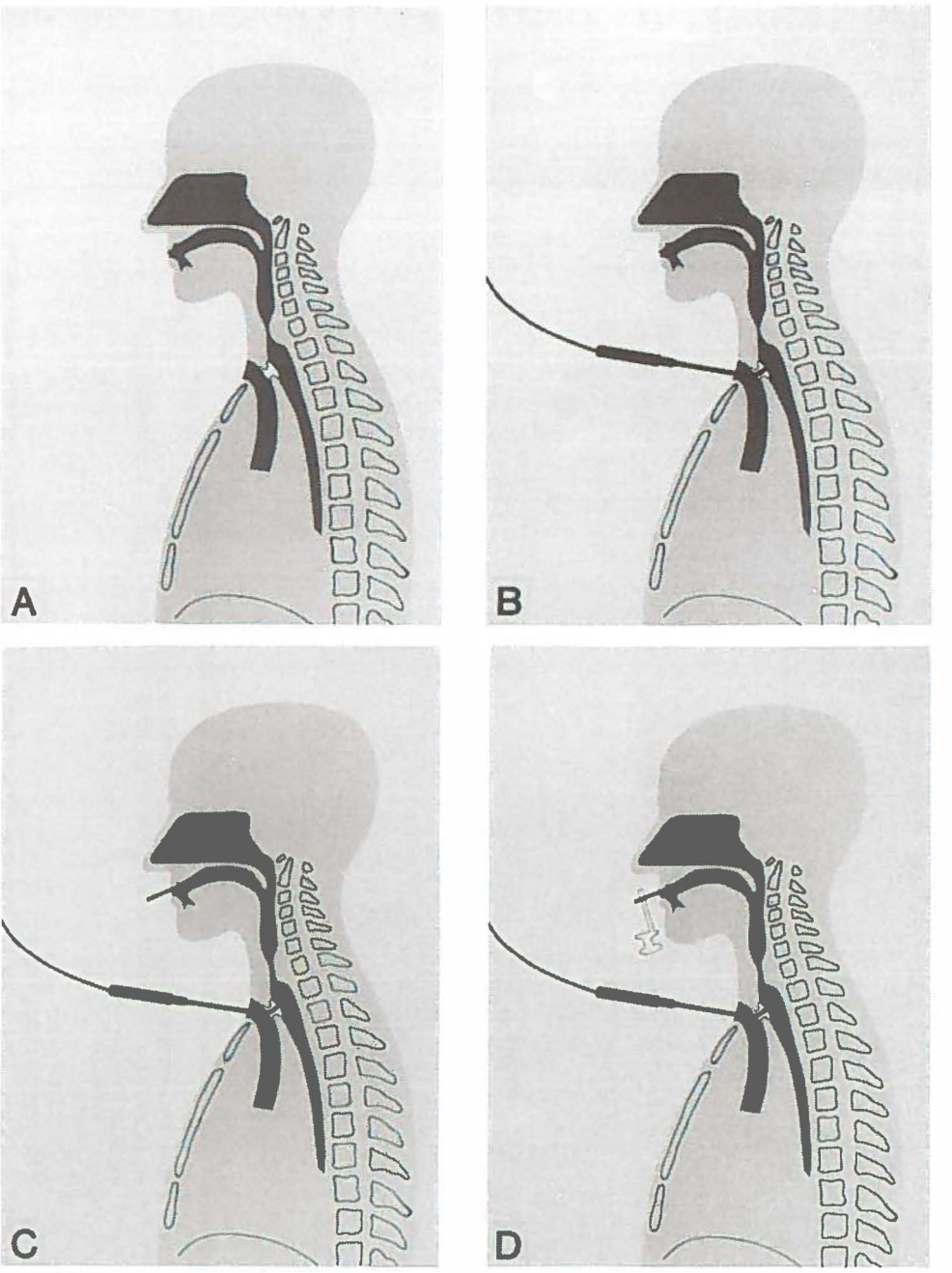
Fig. 5.12



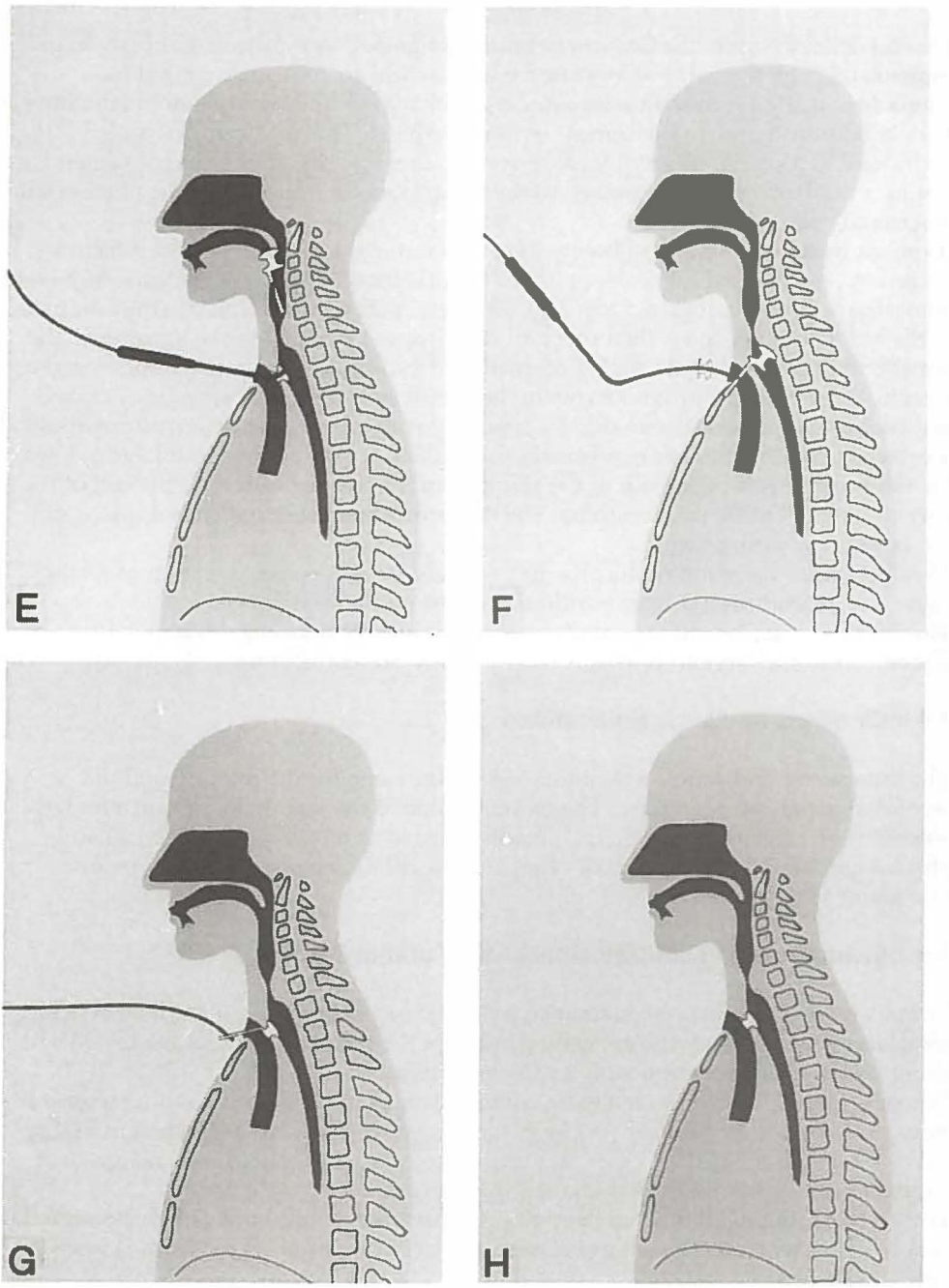


Secondary tracheo-esophageal puncture procedure and Groningen button valve prosthesis placement.
A: Introduction of endoscope.
B: Palpation of side opening through tracheo-esophageal wall and estimation of thickness of this wall.
C: Creation of tracheo-esophageal shunt by puncture of tracheo-esophageal wall into side opening of endoscope.
D: Advancing of wire through endoscope.
E: Tip of wire coming out of mouth.
F: Fixation of Groningen button to wire.
G: Retraction of wire through tracheo-esophageal shunt.
H: Prosthesis pulled into tracheo-esophageal shunt.
I: Prosthesis situated. String cut off of tracheal flange. Secondary puncture procedure and prosthesis placement accomplished.

Fig. 5.13



Replacement procedure of Groningen button valve prosthesis.
A: Old malfunctioning prosthesis situated in tracheo-esophageal shunt.
B: Introduction of blunt tipped replacement instrument through old prosthesis.
C: Advancing of wire through old prosthesis, tip of wire coming out of mouth.
D: Fixation of new Groningen button to wire.



E: Retraction of wire through old prosthesis.
F: Old prosthesis pulled out of tracheo-esophageal shunt over the wire.
G: New prosthesis pulled into tracheo-esophageal shunt.
H: New prosthesis situated, string cut off of tracheal flange. Prosthesis replacement procedure accomplished.

5.3 Prosthesis replacement procedure

The end of device-life of the Groningen button is signified by mild leakage of esophageal contents through the valve or increased intra tracheal air pressure required for phonation. The latter condition is caused by an increased air flow resistance of the valve. Both conditions require replacement of the prosthesis. This replacement can be performed as a simple office procedure and requires less than five minutes. Generally, a mild topical anaesthetic is applied to the upper tracheal mucosa and the pharyngeal mucosa to prevent coughing.
A similar metal wire in a rigid holder as is used in the tracheo-esophageal puncture procedure, is also used for replacement of the prosthesis. The tip of the wire, however, is not sharp, but blunt (figs. 5.5 and 5.6). The metal wire is introduced into the tube part of the old prosthesis and is then successively advanced through the old prothesis, the upper part of the esophagus, the P-E segment and the oropharynx until it appears in the mouth. The tip of the wire is taken out of the mouth and the new prosthesis is attached to it with the connecting device (fig. 5.8). Subsequently, the wire and the new prosthesis are retracted. Just before the new prosthesis is pulled into the tracheo-esophageal shunt, the old prosthesis is pulled out of the shunt from the tracheal side over the end of the wire coming out of the tracheostoma. The new prosthesis is then pulled in its place and the attachment string is cut.
This retrograde insertion of the prosthesis avoids the inadvertent creation of a false route and guarantees a proper positioning of the esophageal flange.
This prosthesis replacement procedure, which is usually performed without any discomfort to the laryngectomee, is schematically presented in figure 5.13.

5.4 Indications and contraindications

The indications and contraindications are not the same for the primary and the secondary puncture procedure. This is mainly due to the fact that a person who has already been laryngectomized, has already adjusted to the altered anatomical and physiological conditions, and has, often unsuccessfully, attempted to acquire a non-shunt substitute voice.

5.4.1 Indications and contraindications for primary puncture

Primary tracheo-esophageal puncture is indicated for almost all patients, who undergo total laryngectomy, and who are willing to accept the minor drawbacks associated with shunt esophageal phonation with a valve prosthesis.
Primary puncture is considered to be contraindicated in subglottic tumor extension, postcricoid tumor location, or very large tumors, which require the resection of a large part of the pharynx. In these cases the puncture may cause spread of malignancy, or at a later stage the prosthesis may conceal local recurrence of malignancy.
Furthermore, impaired manual dexterity is considered a contraindication, because this may interfere with proper stoma occlusion, which is a prerequisite for shunt esophageal voice production.
Relative contraindications are profession and hobby related, e.g. a mechanic, a farmer or a gardener. These people either need both hands for their jobs, or their soiled hands may present a problem for stoma occlusion. In such cases a tracheostoma valve, which automatically occludes the tracheostoma on forced exhalation, may be a solution. These tracheostoma valves can not be expected to be of use for laryngectomees with impaired

manual dexterity, because management of tracheostoma valves and their fixation to the tracheostoma also requires adequate manual dexterity.
Light or moderate pulmonary disfunction is not considered to be a contraindication, because patients who are able to undergo a laryngectomy are certainly able to produce shunt esophageal voice, from a pulmonary point of view.
Preoperative radiation is not considered to be a contraindication, unless the radiation has been excessive and has led to formation of abundant scar tissue. Radiation doses up to 75 Gy (7500 rad) present no problems.

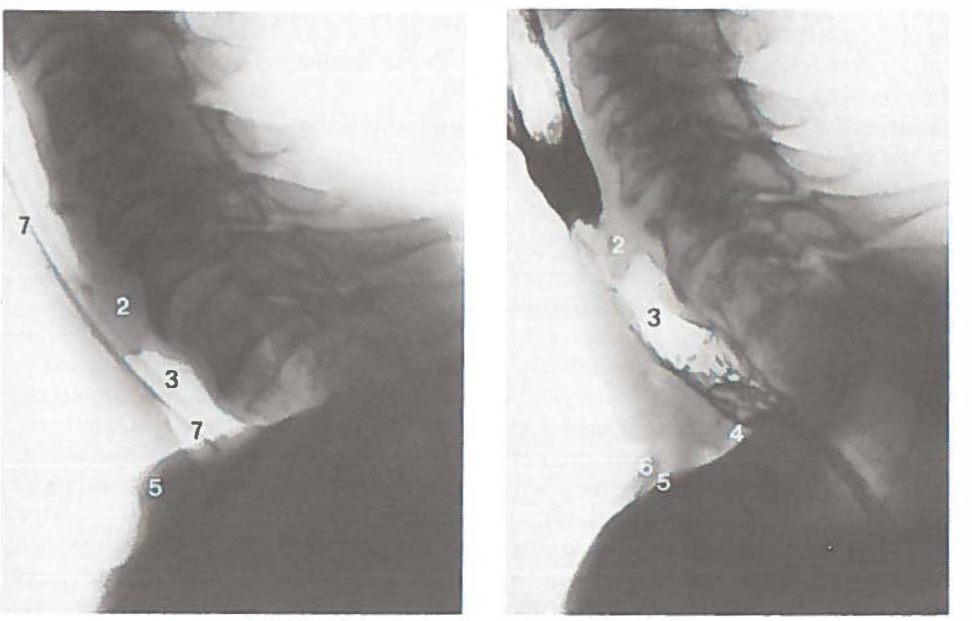
In one patient who had received up to 100 Gy! (10.000 rad) radiation for thyroid carcinoma, total laryngectomy was performed because of tumor extension into the larynx. She also underwent a primary puncture procedure, which alas resulted in a severe shunt insufficiency (6.3.6). Wound healing was almost absent, one year after surgery the tracheostoma wound still showed a dehiscence without signs of healing. In this patient the prosthesis had to be removed and the shunt closed because of shunt insufficiency. Therefore, we consider excessive preoperative radiotherapy of more than 75 Gy (7500 rad) a contraindication. This condition is, however, extremely rare.

5.4.2 **Indications and contraindications for secondary puncture**

Secondary tracheo-esophageal puncture is indicated when non-shunt esophageal voice production is poor, or when despite good non-shunt esophageal voice production higher vocal demands are made.
Furthermore, a secondary puncture can be indicated in some cases in which primary puncture could not be performed for surgical technical reasons, e.g. laryngo-pharyngectomies with gastric or myocutaneous reconstruction techniques. In such cases good non-shunt esophageal voice is rarely obtained (3.1.6), and therefore its development should not be expected. In anticipation of non-shunt esophageal voice failure, the secondary puncture can be performed as soon as the pharyngeal repair and the anastomoses have healed, and an esophagoscopy can safely be performed, which is generally a few weeks after the initial surgery. Because the person who is considered for secondary tracheo esophageal puncture has already been laryngectomized, tests can be performed to determine whether or not his condition is suitable for shunt esophageal voice production. If a laryngectomee with an impaired manual dexterity, or an abnormally formed tracheostoma, can nevertheless properly occlude his tracheostoma, a secondary puncture procedure may be considered. Sometimes a prosthetic aid or a surgical tracheostoma reconstruction may facilitate stoma occlusion. The pulmonary condition of some patients may have deteriorated since the time that the laryngectomy was performed. Therefore, contrary to the primary puncture procedure, it is advisable to take the pulmonary condition of the laryngectomee into consideration before contemplating a secondary puncture procedure. A simple preoperative test is performed to establish whether a laryngectomee's pulmonary condition can be considered suitable for shunt esophageal voice production with a valve prosthesis. The laryngectomee is requested to exhale forcefully while the tracheostoma is occluded. The resulting intratracheal air pressure rise is registered. Laryngectomees achieving sustained maximal intratracheal air pressures of 10 kPa or more are considered very suitable for a secondary puncture. Such intratracheal air pressures may be required for loud shunt esophageal phonation (Mahieu 1987). Sustained maximal intratracheal air pressures of less than 5 kPa are considered insufficient for shunt esophageal voice production. Between 5 and 10 kPa sustained maximal intratracheal pressure, the situation is critical

concerning shunt esophageal voice acquisition with a voice prosthesis. Laryngectomees in this last category are only considered suitable for secondary puncture when the tonicity in the P-E segment is estimated to be relatively low during the insufflation test (3.1.5). If this is not the case, a P-E segment myotomy (5.5) performed simultaneously with the secondary puncture may be taken into consideration. Furthermore, the laryngectomees in the last category are also candidates for prevention of prosthesis deterioration (4.3) and for low pressure type prostheses.
Because most laryngectomees who request a secondary puncture, are failed non-shunt esophageal speakers, a large number of them will have problems associated with coordination and relaxation of the P-E segment (3.1.5).
This condition interferes with the acquisition of non-shunt as well as shunt esophageal voice production. To detect this specific condition or an anatomical obstruction in or near the P-E segment, e.g. pharyngeal or high esophageal stenosis, a fluoroscopic examination is performed during 1) rest, 2) swallowing, 3) non-shunt esophageal phonatory effort and 4) an insufflation test. An insufflation test (fig. 5.14) gives a good impression of the shunt esophageal voice production that may be expected following secondary puncture (3.1.5).

Fig. 5.14



Fluoroscopic pictures of a laryngectomee who failed to acquire non-shunt esophageal phonation and was considered for a secondary tracheo-esophageal puncture and prosthesis placement procedure.
Left: situation pre-puncture. Air insufflated through a catheter passed through the nose and the P-E segment enables an effortless esophageal phonation of good quality and long duration, which is considered a positive indication for the secondary puncture procedure.
Right: situation post-puncture, during shunt esophageal phonation. The laryngectomee has become a good shunt esophageal speaker.
2 = pseudoglottis, 3 = air reservoir, 4 = valve prosthesis in tracheo-esophageal shunt, 5 = tracheostoma, 6 = finger occluding tracheostoma, 7 = air insufflation catheter.

If the fluoroscopic examination, especially during the insufflation test, reveals signs of

hypertonicity or coordination and relaxation problems in the P-E segment, then a myotomy of this P-E segment (5.5) should be performed simultaneously with the secondary puncture procedure. Blom and co-workers (1986) employ a criterion of at least eight seconds uninterrupted phonation during the insufflation test, as a positive indication for secondary puncture. If esophageal phonation during the insufflation test lasts less then eight seconds, they recommend P-E segment myotomy. Using this criteria, they report a 100 per cent success rate of secondary puncture procedures.
If constrictions of the upper digestive tract are diagnosed, then they should be treated before a secondary puncture procedure can be taken into consideration.
Contraindications for a secondary puncture procedure are present, when stomal occlusion causes excessive coughing because of a hypersensitive tracheostoma, or when occlusion of the tracheostoma leads to excessive anxiety.
Furthermore a relative contraindication is present, when the secondary puncture procedure is to be performed a long time after the laryngectomy. It is our experience (6.3.7) that if a period of two years or more has elapsed since the laryngectomy, the number of laryngectomees who acquire a satisfactory esophageal voice with the shunt method is small. This can be attributed to the adjustment of the laryngectomee to his altered physiological and anatomical condition, and to the often long and fruitless efforts to learn non-shunt esophageal voice production. After so many years the laryngectomee may have lost the ability to phonate on expiration with the use of expired air. Even more so, when he was trying to learn the non-shunt esophageal voice, he was taught to prevent forceful expiration during phonation, in order to avoid stomal noise. For shunt esophageal voice production the laryngectomee now has to learn again to exhale just before and during phonation. Considering this situation, it is quite understandable that a discoordination between respiration and phonation occurs. An additional interfering factor may be, that non-shunt esophageal phonation patterns come so automically to the long-time laryngectomee, that the shunt method and non-shunt methods are mixed up, which results in a poor substitute voice production.
The profession and hobby related relative contraindications are the same for the primary and secondary puncture procedures.

5.5 PHARYNGO-ESOPHAGEAL MYOTOMY; A STUDY

Hypertonicity of the P-E segment (3.1.4 and 3.1.5) is presently considered to be the major cause of failing shunt esophageal voice production, and is held responsible for speech rehabilitation failure in 10 to 20 per cent of the laryngectomees who are rehabilitated with a valve prosthesis in a tracheo-esophageal shunt.
In order to achieve voice production in these speech rehabilitation failures, a myotomy of the P-E segment has been propagated by several authors (Winans, Reichbach and Waldrop 1974; Singer and Blom 1981; Chodosh 1982; Herrmann and Koss 1985; Henley and Souliere 1985; Mohr et al 1985; Henley 1986; Mahieu 1987; Mahieu et al 1987). Such a myotomy is based upon the hypothesis, that failure to develop a substitute voice is caused by a hypertonicity in the P-E segment during the phonation onset. After distention of the esophagus, caused by the inflow of air into the esophageal air reservoir, a reflex rise in the upper-esophageal sphincter pressure may occur (Creamer and Schlegel 1957; Schutte 1980). The pressure necessary to sustain phonation probably depends upon the extent of this reflex mechanism and upon the ability of the patient to relax the P-E segment before and during air expulsion. A tight P-E segment will prevent the passage of air, while relaxation will facilitate air expulsion and subsequent phonation (Pruszewicz, Obrebowski and Woznica 1982; Vuyk,

Klinkenberg-Knol and Tiwari 1986).
Early reports of pharyngo-esophageal myotomies to improve laryngectomee voice rehabilitation concern myotomies performed as a secondary procedure, when the voice production failed to develop, but in more recent papers the performance of a myotomy is advised at the time of laryngectomy. There are several reasons for preferring a primary myotomy. First of all, a myotomy as a second stage procedure, in a patient who has undergone extensive neck surgery and radiation, can be a very difficult operation. In contrast, a myotomy at the time of laryngectomy is easily performed and takes no longer than 20 minutes. Secondly, we have the impression that in addition to a reduction of the number of speech rehabilitation failures, the esophageal voice is also produced with less effort, when a myotomy has been performed (Mahieu 1987). Furthermore, it is our experience that patients are often unwilling to undergo a second operation. Inspired by the reported advantages of primary P-E segment myotomies, we started to perform this procedure in December 1984. It stands to reason that a myotomy should be performed as a secondary procedure, when the indication for a myotomy establishes itself in those subjects who have already been laryngectomized.
Initially we employed the following myotomy technique:
The muscle layer of the middle and lower constrictor pharyngeal muscles, the cricopharyngeal muscle, and a small section of the upper esophageal musculature were incised medio-dorsally until the mucosa was free of muscle fibers. A narrow strip of muscle (0.5 centimeters) was excised over a length of 4 to 6 centimeters from cranially downwards to the level of the tracheo-esophageal shunt, leaving the mucosa intact.
Results of a study including the quality of the shunt esophageal voice, the intratracheal air pressure required for shunt esophageal phonation, and fluoroscopic examinations following this initially used myotomy technique have been previously published (Mahieu et al 1987). Not one shunt esophageal voice failure was observed following this myotomy technique, but the quality of the resulting shunt esophageal voice was less than the quality which was observed in non-myotomized laryngectomees. A tendency towards a breathy quality of the shunt esophageal voice was observed in more than half of the myotomized group of laryngectomees. They clearly demonstrated signs of a hypotonic P-E segment and were able to produce better voices when external digital pressure was exerted on the P-E segment. On the other hand, significantly lower intratracheal air pressures were required for sustained shunt esophageal phonation in the myotomized group of laryngectomees. This indicated that phonation was more efficient and required less effort in laryngectomees with a myotomy than in laryngectomees without a myotomy.

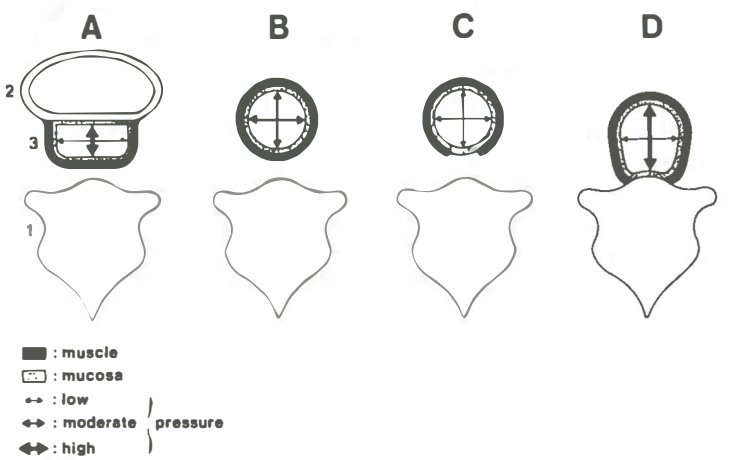
After evaluating these positive as well as negative results on esophageal voice production following the initially used *'total'* myotomy technique, we concluded that too much musculature may have been dissected, resulting in a hypotonic state of the P-E segment.
Therefore, we now perform a less rigorous P-E segment myotomy and our experience with this *'modified'* myotomy technique has been very promising so far. To evaluate the results which are achieved with this modified myotomy, a study has been performed, in which the intratracheal air pressure required for shunt esophageal phonation and the quality of the resulting speech have been used as parameters. This study is presented in the following section.

5.5.1 'Modified' pharyngo-esophageal myotomy

Technique

If, during laryngectomy, the surgeon inserts his index finger through the opened pharynx into the esophageal entrance, he can feel the tightness and tension of the P-E segment. This estimation of P-E segment tightness and tension is of course only reliable if the patient is at that moment not under the influence of neuromuscular blocking agents. A myotomy of the middle and lower constrictor pharyngeus muscle is then performed until the surgeon feels that the tension in the upper esophageal sphincter is diminished, but not totally lost. This estimation of the tension requires some experience, but the three surgeons who perform laryngectomees in our department repeatedly demonstrated a unanimity of judgement. The severed muscles are sutured paramedially to the prevertebral fascia, so that contraction of these muscles results in a tonicity rise in the P-E segment. Thus, a better regulation of this tonicity is achieved. Suturing the severed muscles to the prevertebral fascia was already advocated by Herrmann and Koss (1985) to prevent a reunion of these muscles. Studies of non-laryngectomized subjects by Welch and co-workers (1979a, 1979b) and Gates (1980) showed that pressure build-up in the upper esophageal sphincter is normally in an antero-posterior direction, due to the fixation of the musculature to the cricoid cartilage. After laryngectomy the sphincter has become completely annular, with a radially oriented intraluminal pressure build-up. Our hypothesis is that by suturing the severed muscle paramedially to the prevertebral fascia after myotomy, a horseshoe shaped sphincter is created again, resulting in an anteroposterior accentuation of peak pressures (fig. 5.15). If the muscle edges are not sutured to the prevertebral fascia, as is the case with the initially employed myotomy technique, contraction of the musculature will predominantly result in a thickening of the P-E segment wall, rather than in an intraluminary pressure rise. Studies to verify this hypothesis are in progress.

Fig. 5.15



Intraluminal pressure build-up in the P-E segment.
A: before laryngectomy, B: after laryngectomy, C: after laryngectomy, with 'total' myotomy, without fixation to the prevertebral fascia, D: after laryngectomy, with 'modified' myotomy and fixation to the prevertebral fascia.
The arrows indicate the direction and the force of the intraluminal pressure build-up.
1 = cervical vertebra, 2 = cricoid cartilage, 3 = P-E segment.

Sometimes when, during the laryngectomy the surgeon inserts his index finger through the openend pharynx into the esophagus entrance, he will feel a rather lax P-E segment. In these cases no myotomy is performed,which occurs in approximately 20 per cent of all our laryngectomy procedures.

5.5.2 **Patients and methods of assessment**

Patients
Ten patients (9 male, 1 female; mean age 63 years) participated in this study.
All patients had undergone a total laryngectomy and primary modified myotomy after preoperative irradiation with doses varying from 30 to 70 Gy (modifiedly myotomized subject group). No selection on speech quality grounds was performed. The only inclusion criterion was that these laryngectomees had been using the shunt esophageal voice with a valve prosthesis for at least three months.
With regard to the estimation of the for shunt esophageal phonation required intratracheal air pressure, as described below, a reference group was randomly selected. This reference group was composed of thirteen male laryngectomees (mean age 65 years) who actively used the shunt esophageal voice with a valve prosthesis and who had been laryngectomized in the period before pharyngo-esophageal myotomies were performed (non-myotomized subject group).

Estimation of for phonation required intratracheal pressure
Of both the modifiedly myotomized subject group and the non-myotomized subject group, the intratracheal air pressure ('intratracheal phonatory pressure') required for a shunt esophageal phonation of 67 dB was estimated as described in 4.3.1, immediately after a new Groningen button valve prosthesis had been inserted into the shunt.

Method of assessing speech quality
The speech quality of the modifiedly myotomized subject group, concerning both shunt esophageal voice production as well as non-shunt esophageal voice production, was evaluated by trained speech pathologists according to the criteria as described in 6.2. The evaluation was performed three months after the start of the speech rehabilitation program and the results are expressed in terms of good, moderate, and poor. Special notice was taken of breathiness of shunt esophageal phonation, occuring either during the speech rehabilitation program or at the moment of evaluation, three months after the start of this program.
The results of a non-myotomized group of laryngectomees as presented in table 6.6 and our previously reported (Mahieu et al 1987)results of a group of laryngectomees who underwent a P-E segment myotomy as it was performed initially (*total* myotomy), are used as reference values.

5.5.3 **Results**

Patients
No serious complications attributable to the modified myotomy procedure were observed. Once a small perforation of the pharyngeal mucosa occured, which was carefully closed using Ticron^{R} 5-0 sutures. Postoperatively, no pharyngocutaneous fistulas were observed in the modifiedly myotomized subject group.

Intratracheal phonatory pressure
The mean intratracheal phonatory pressure for a phonation of 67 dB was 7.5 kPa (standard deviation 1.3) for the non-myotomized group of laryngectomees.
The modifiedly myotomized group of laryngectomees required a mean intratracheal phonatory pressure of 5.3 kPa (standard deviation 1.4) for such a phonation.
The difference in mean intratracheal phonatory pressure is significant ($p<0.01$; Student's *t*-test).

Speech quality
The speech quality results as judged by trained speech pathologists are presented in table 5.1 for:
1) the non-myotomized group of laryngectomees (data from table 6.6)
2) the *totally* myotomized group of laryngectomees (data from Mahieu et al 1987)
3) the *modifiedly* myotomized group of laryngectomees.
The results of both shunt and non-shunt esophageal voice production are presented for each group.

Table 5.1 Esophageal speech quality.

		SHUNT METHOD			in percentages	NON-SHUNT METHOD		
subject group	N	good	moderate	poor		good	moderate	poor
non-myotomized	70	83	10	7		41	23	36
totally myotomized	16	63	37	0		19	37	44
modifiedly myotomized	10	90	10	0		40	20	40

Just as reported earlier for the totally myotomized group of laryngectomees, no poor or failing voice rehabilitation result was observed in the modifiedly myotomized group of laryngectomees. The percentage of good shunt esophageal speakers is higher in the group of modifiedly myotomized subjects than in the group of totally myotomized subjects. In contrast to the breathiness of phonation which was often observed in the totally myotomized group, this was only found in one subject of the group of modifiedly myotomized laryngectomees. This subject showed a very mild degree of breathiness, which was only present during the first four weeks of the speech rehabilitation program. After this period he developed a very good shunt esophageal voice, and at the moment of evaluation, three months after the start of the rehabilitation program, no sign of breathiness was found.

5.5.4 **Discussion**

Although the group of modifiedly myotomized laryngectomees in this study is rather small, the preliminary results seem to indicate that a modified myotomy can be performed as a primary procedure without serious additional complications to the laryngectomy procedure. Furthermore, this procedure apparently facilitates shunt esophageal voice production, as can be derived from the markedly lower intratracheal air pressure required for phonation. This finding is in agreement with the result of an earlier study (Mahieu 1987).
Unlike the experiences with total myotomies, no signs of a hypotonic P-E segment were observed in the group of modified myotomized subjects.

Our additional experience with more than thirty laryngectomees who all have undergone a primary modified myotomy, support the positive observation described here. No poor or failing shunt esophageal speech was observed in this larger group either. Furthermore, we have the impression that both shunt and non-shunt esophageal voice production of these modifiedly myotomized laryngectomees are of a better quality than those of the group of totally myotomized subjects. The follow-up period has, however, been to short to allow definitive judgements of speech quality of this larger group of modifiedly myotomized laryngectomees.
The patients who did not undergo a modified myotomy, because it was not deemed necessary, judging the tension of the P-E segment at the time of surgery, have all developed a good shunt esophageal voice. Their number is, however, too small and their follow-up too short to draw any definite conclusions.
Our experiences with the modified myotomy as a primary procedure justify the performance of this procedure during every laryngectomy, when the tonicity and tightness of the P-E segment is judged to be too high or outspoken.
The preliminary results obtained with this type of functional P-E segment surgery, justify a new research project concerning this topic, which presently may be considered to be one of the most important aspects of laryngectomee voice rehabilitation: improving the efficiency of esophageal voice production. This new research project has recently started with an effort to obtain a more objective criterion of the tension in the P-E segment, by performing manometrical measurements peroperatively.

5.6 LARYNGECTOMEE VOICE REHABILITATION PROGRAM

The voice rehabilitation program actually starts before the puncture procedures, with preoperative counseling. The importance of adequate preoperative counseling has been extensively pointed out (Duguay 1966; Kommers, Sullivan and Yonkers 1977; Keith, Linebaugh and Cox 1978; Johnson, Casper and Lesswing 1979; Minear and Lucente 1979; Salmon 1979c, 1979d; Square 1979; Blanchard 1982; Murrills 1983; Natvig 1983b; Schultz-Coulon 1984; Berkowitz and Lucente 1985). In our department the surgeon and the speech therapist explain and discuss in detail the possible voice rehabilitation methods with the patient and his family, before the operation. In most cases the patient is also visited by a laryngectomee who has developed a good substitute voice and who will discuss the matters associated with the operation and the laryngectomized state. The different voice rehabilitation programs after respectively primary and secondary puncture procedure are described below.

5.6.1 Voice rehabilitation program following primary puncture

During a twelve day period following laryngectomy, primary puncture and placement of the valve prosthesis, no action concerning voice rehabilitation is undertaken. If after twelve days no sign of breakdown of the pharyngeal repair has occurred, the nasogastric feeding tube is removed and the actual voice rehabilitation program can start.
First of all, slightly pressurized air is blown through the prosthesis using a small pipe which is introduced into the tube part of the prosthesis, from the tracheal side. Thus the first esophageal sound is produced with air artificially brought in the esophageal air reservoir under the P-E segment. Subsequently, an effort is made to produce esophageal sound with air expired by the laryngectomee. The stoma is occluded by the surgeon or the speech therapist and the laryngectomee is instructed to open his mouth, and exhale in spite of the occluded stoma. With instructions to try to blow away the finger

occluding the tracheostoma, most patients are able to produce a loud and clear esophageal sound. At this stage some patients are already able to occlude the tracheostoma properly by themselves and produce a fluent shunt esophageal voice. Most of them are, however, too tense and are not yet able to properly occlude the tracheostoma and at the same time relax the P-E segment.
The fact that esophageal sound production can thus be achieved, immediately after the removal of the nasogastric feeding tube, often is a reasurance for the laryngectomee. It provides him with self-confidence, which is important in the further rehabilitation process. The laryngectomee generally stays another five days in the hospital, receiving intensive speech therapy two times half an hour to one hour daily. During this period he will be taught both the shunt method of esophageal voice production and the non-shunt method of esophageal voice production.
Several methods of teaching the non-shunt method of esophageal voice production are described in manuals on this subject and will not be further discussed here.

During the teaching of the shunt method of esophageal voice production with a valve prosthesis emphasis is placed upon:
1. proper stoma occlusion
2. voluntary relaxation of the head and neck musculature, and consequently relaxation of the P-E segment during phonation
3. coordination of respiration and phonation
4. control of the force of expiration and the amount of expired air, required for phonation.

After five days of the clinical voice rehabilitation program most laryngectomees are able to produce more or less fluent speech with the shunt esophageal voice and the majority is able to produce the basic esophageal sound with the non-shunt methods (Bors, de Boer and Schutte 1986). Fluent non-shunt esophageal voice production is only rarely obtained during this period and usually requires several months of training. If the clinical voice rehabilitation program has not been sufficiently successful within five days, it is continued for another five days.
Following dismissal from the hospital, the laryngectomee can practice with a local speech therapist several times a week, with most emphasis on the non-shunt method of esophageal voice production. Depending upon the progress of vocal rehabilitation, this speech therapy will continue for three months to one year. During the first year following laryngectomy, the patient will visit our outpatients department every month for oncological and vocal rehabilitational follow-up. If the progress of vocal rehabilitation during this period is unsatisfactory, a new clinical voice rehabilitation program as outlined above may be considered.

5.6.2 **Voice rehabilitation program after secondary puncture**

After secondary puncture and placement of the valve prosthesis the clinical voice rehabilitation program can start on the following day. This program is similar to the program outlined for the voice rehabilitation after primary puncture, with the exception that following secondary puncture only the shunt method of esophageal voice production is emphasized. Laryngectomees undergoing a secondary puncture procedure are either already familiar with the non-shunt method of esophageal voice production, a minority, or were not able to learn it, the majority.
It is, however, not an exception that after a secondary puncture laryngectomees also

develop a non-shunt esophageal voice, even though they were not able to use this method of esophageal voice production before the puncture procedure. To prevent the patient from confusing the shunt method with the non-shunt method, the production of the non-shunt esophageal voice is discouraged after secondary puncture, until the laryngectomee has fully mastered the shunt esophageal voice.
The reason why some laryngectomees were not able to use the non-shunt method of esophageal voice production before the secondary puncture, but after this procedure have developed non-shunt esophageal voice production, is probably twofold. First of all, less strain and pressure is put on learning the non-shunt method of esophageal voice production once the shunt method can be successfully used. Secondly, the laryngectomee is trained to relaxe the P-E segment during the shunt esophageal voice production. This relaxation might be just what the laryngectomee lacked in order to learn the non-shunt esophageal voice.
The clinical and local voice rehabilitation programs applied for laryngectomees after a secondary puncture are less strict and generally shorter than for laryngectomees after a primary puncture. This is because after a secondary puncture most emphasis is placed on the shunt method of esophageal voice production, which is easier to learn than the non-shunt method.

Chapter VI

RESULTS WITH THE GRONINGEN BUTTON

On the eighth of December 1980, a Groningen button valve prosthesis was placed for the first time. It was inserted into a Staffieri type of tracheo-pharyngeal shunt because the patient suffered from severe leakage through the shunt and subsequent aspiration. With the insertion of the prosthesis, the leakage and aspiration problems were solved, and a good shunt esophageal voice could be produced.
Two days later a Groningen button was placed in another patient. This time simultaneously with a primary puncture technique during laryngectomy.
Since that time every patient who underwent a laryngectomy was also considered for a primary puncture procedure.
In the period from December 1980 until December 1984 only minor changes in tracheo-esophageal puncture technique and in the valve prosthesis itself (Chapter V) occurred. Therefore, the patients who underwent a primary or secondary puncture procedure with prosthesis placement during this period are very suitable for evaluation of the results of this valve prosthesis. The aim of this part of the study was to determine whether or not the puncture procedures and the shunt esophageal voice production with the Groningen button valve prosthesis can be considered a safe and effective method of substitute voice production.
In a prospectively designed follow-up study the laryngectomees were observed during the period from December 1980 until the first of January 1986. The period until the first of January 1983 is considered the starting period. During this period the necessary experience has been gathered and minor modifications in puncture technique, prosthesis design, and patient selection, have been brought about in order to overcome the inevitable starting problems. Where appropriate this differentiation between the starting period and the later period will be taken into account.

6.1 PATIENTS

Ninety-seven patients underwent total laryngectomy in our department in the period from December 1st, 1980 until December 1st, 1984 (table 6.1).
Of these ninety-seven patients, seventy four (76 per cent) underwent a primary puncture procedure with placement of a Groningen button as described in 5.2.1.

Table 6.1 Total laryngectomies dec. 1980 – dec. 1984

primary puncture	74	76%
no puncture	17	18%
secondary puncture	6	6%
N = 97		

Primary puncture was not performed in twenty-three patients, because of:
- A large tumor with either subglottic extension or location in the hypopharynx, which required resection of a large part of the pharyngeal mucosa (fourteen patients, three of whom underwent a secondary puncture procedure in a later stage).

- Refusal of puncture procedure and prosthesis placement (two patients).
- Severe chronic obstructive pulmonary disease (two patients). This was considered a contraindication for shunt esophageal voice rehabilitation with a valve prosthesis only during the starting period.
- Anticipated problems with tracheostoma occlusion (three patients), due to dementia, hemiparalysis, and psychological problems, respectively (the patient with the hemiparalysis and the patient with the psychological problems both later underwent a secondary puncture procedure with good voice rehabilitation results).
- Complication of the laryngectomy in one patient, which consisted of a tear in the tracheo-esophageal wall of several centimeters of length (a secondary placement procedure was successfully performed six months later).
- No reason was given for not performing a primary puncture (one patient).

Four out of the seventy-four primary puncture patients could not be evaluated: two patients because of postoperative complications of the laryngectomy, which interfered with the use of valve prosthesis. One patient as a result of early local tumor recurrency (or more probably: at the time of surgery overlooked residual tumor) in the hypopharynx, within two weeks after the laryngectomy, which prevented all voice rehabilitation efforts. Finally one patient was lost to follow-up because he refused participation in the voice rehabilitation program and did not attend the regular oncological check-ups.
The remaining seventy patients were evaluated, together with nineteen patients, who underwent a secondary puncture procedure in the same period (table 6.2). This results in a group of eighty-nine patients (82 male, 7 female).

Table 6.2 Laryngectomees evaluated.

primary puncture	70	79%
secondary puncture	19	21%

N = 89

Nine of the nineteen secondary puncture procedures were performed within a year after the laryngectomy and ten after a longer period, varying from thirteen months to ten years. Fifteen of the secondary puncture procedures were performed during the starting period, before the first of January 1983. The preoperative tests as described earlier (5.4.2) were not yet used as indication criteria during this starting period.

The *initial surgery* was a standard total laryngectomy for seventy-five of the eighty-nine patients. Thirteen patients underwent a total laryngectomy and unilateral neck dissection. One patient had total laryngectomy and bilateral neck dissection.
Two patients developed orocutaneous fistulas, which required myocutaneous flap reconstruction of the pharynx shortly after the initial surgery.
Myotomy of the P-E segment (5.5), either as a primary or as a secondary procedure was not performed in our department until December 1984. None of the laryngectomees in this study have undergone such a myotomy.

The mean *age* of the eighty-nine patients at the time of the puncture procedure was 60.5 years (range 36 - 80 years).

All but three patients received *radiotherapy*, preoperatively and/or postoperatively.
- Twenty-six patients were laryngectomized because of recurrency of tumor, after radiation therapy. Radiation doses varied from 60 – 70 Gy*[1].
- Fourty-six patients were irradiated immediately prior to the laryngectomy. One patient with a dose of 20 Gy, fourty-two patients with a dose of 30 Gy and three patients with a dose of 50 Gy.
- Seven patients were irradiated only postoperatively with doses varying from 50 to 60 Gy.
- Seven patients underwent a combination of preoperative and postoperative radiation, with overall doses varying from 50 to 70 Gy.

The mean *follow-up* period is twenty-three months (range 1 – 61 months).

6.2 **METHODS**

All laryngectomees were studied prospectively from the moment of the laryngectomy, through the hospitalized period, the period of speech training and during every visit to our oncological outpatients department. The outpatients department was at least visited monthly during the first year following the laryngectomy, and every three or four months during the following years. Furthermore, the laryngectomees visited our outpatients department whenever problems with the valve prosthesis or the substitute voice occurred.
During this period all complications attributable to the puncture technique, the tracheo-esophageal shunt, and the valve prosthesis were registered.
Furthermore, as criteria for effectivity of shunt esophageal voice production with the Groningen button and as reference values we registered:
- early esophageal voice acquisition immediately at the start of the voice rehabilitation program, twelve days following primary puncture, and one day following secondary puncture,
- the primary mode of substitute voice production which was used at the end of the follow-up period,
- the frequency and reasons for valve prosthesis replacement or removal,
- the satisfaction percentage of the laryngectomees concerning the valve prosthesis at the end of the first or during the second year,
- the quality of both the shunt and the non-shunt esophageal speech as judged by trained speech pathologists or the author, according to a slight modification of the criteria described by Bors and Schutte (Bors et al 1984, 1986; Schutte et al 1986).

The criteria used for the shunt esophageal method were based on the speech performance data of the first seventeen laryngectomees who received a Groningen button valve prosthesis. The criteria used for the non-shunt esophageal method were based on data obtained from the literature. Judgement was performed three months after the start of voice therapy because earlier studies (Bors et al 1984, 1986; Schutte et al 1986) showed that after this period a fairly accurate estimation of the speech quality can be obtained.
The criteria are different for the shunt method and the non-shunt method of esophageal voice production.

*[1]: 1 Gy = 1 Gray = 100 rad.

The overall judgement of both the shunt and the non-shunt method is based upon a weighed evaluation of three criteria groups:
1. Phonatory skills.
2. Additional factors.
3. General impression of the judge.

For each criteria group a three point scale was used: good, moderate and poor.
The criteria of the first criteria group are listed in table 6.3.
The judgement in this first criteria group is based on:

a) Availability of the esophageal voice.
   Is the esophageal voice always readily available, or only occasionally available, or infrequently/not available? Is the period between request to phonate and phonation onset longer or shorter than five seconds?
b) Maximal phonation time.
   Longest sustained phonation of the vowel /a/ for the shunt esophageal voice and of this same vowel preceded by a plosive consonant for the non-shunt esophageal voice.
c) Dynamic range of vocal intensity.
   The vocal intensity difference between the loudest and the softest phonation, measured with a dB meter at a mouth-to-microphone distance of thirty centimeters.
d) Voice pitch modulation.
e) Speech rate.
   The number of syllables per minute registered while reading a standard text aloud.
f) The number of syllables per intake of air.
   Is the speech fluent (high number of syllables per intake of air) or is frequent interruption for air intake required?

In the judgement of the second criteria group, factors concerning:

a) Audible stoma noise
b) Air-charging noises
c) Excessive movements of head, neck or hand during voice production or stoma occlusion are taken into account.

The third criteria group consists of more subjectively judged qualities:

a) Is the voice relaxed or tense
b) Is the sound agreeable and pleasant to listen to
c) Is the speech intelligible?

The overall judgement is also expressed in the terms: good, moderate, and poor. The overall judgement *'good'* is given when no more than three moderate qualifications are given. All other qualifications have to be good.
The overall judgement *'moderate'* is given when no more than two aspects were considered poor in different criteria groups. All other qualifications have to be at least moderate.
The overall judgement *'poor'* is given when two qualifications poor are given in one criteria group or when more than two poor qualifications are given in any of the criteria groups.

Table 6.3 Judgement of phonatory skills in esophageal speech (criteria group I).

Availability of voice	SHUNT	NON-SHUNT
Good	always immediately on request (voice onset delay < 5 sec)	always immediately on request (voice onset delay < 5 sec)
Moderate	occasionally, voice onset delay >5 sec following request	occasionally, voice onset delay > 5 sec following request
Poor	not	not
Maximal phonation time		
Good	> 10 sec	> 2 sec
Moderate	4-9sec	0.5-2 sec
Poor	< 3 sec	< 0.5 sec
Dynamic range of vocal intensity		
Good	> 25 dB	> 15 dB
Moderate	16-24dB	6-14 dB
Poor	< 15 dB	< 5 dB
Voice modulation		
Good	adequate pitch variation	adequate pitch variation
Moderate	little pitch variation	little pitch variation
Poor	monotonous	monotonous
Speechrate (syllables per minute)		
Good	> 200	> 150
Moderate	150–200	100–150
Poor	< 150	< 100
Fluency of speech (syllables per air intake)		
Good	> 19	> 5
Moderate	10–18	2–4
Poor	< 9	< 1

6.3 **RESULTS**

6.3.1 **Early voice acquisition**

Esophageal voice production with the shunt method immediately during the first session in the speech rehabilitation program was acquired by sixty-two (89 per cent) of the seventy laryngectomees following a primary puncture procedure, and by fourteen (74 per cent) of the nineteen laryngectomees following a secondary procedure (table 6.4). Esophageal voice production with the non-shunt esophageal method was rarely obtained during the first session of the speech rehabilitation program.

Table 6.4 Early voice acquisition with shunt method (during first speech therapy session).

	N	Yes	No
		in percentages	
primary puncture	70	89	11
secondary puncture	19	74	26
total	89	85	15

6.3.2 **Primary mode of voice production**

The different modes of substitute voice which were used at the end of the follow-up period are listed in table 6.5.

Table 6.5 Primary mode of voice production.
(in percentages)
N = 89

non-shunt esophageal	33
shunt esophageal	33
electrolarynx	10
shunt and non-shunt esophageal	22
shunt esophageal and electrolarynx	2

Twenty-nine laryngectomees (33 per cent) used the non-shunt esophageal method as the primary method of substitute voice production.
The same number of laryngectomees (33 per cent) primarily employed the shunt method.
All nine laryngectomees (10 per cent) who used only the electrolarynx had undergone the puncture procedure before the first of January 1983 and six of them had undergone the puncture as a secondary procedure, two years or more after laryngectomy (6.3.7).
The two laryngectomees (2 per cent) who used both the shunt method, and an electrolarynx, have hypersensitive tracheostomas, which prevents continuous use of the shunt method.
The twenty laryngectomees (22 per cent) who use both the shunt and the non-shunt esophageal method, mostly used the non-shunt method at home in conversation with

their relatives, and the shunt method for telephone conversation, conversation in a noisy environment, and in other circumstances which require a louder and better intelligible speech.

6.3.3 **Quality of speech**

In speech quality evaluation it is important to realize that the criteria used here for the shunt and for the non-shunt esophageal method differ enormously, so that what is considered good for the non-shunt method is moderate or even poor for the shunt method.
Of seven laryngectomees it was not possible to obtain an overall judgement at the correct moment, three months after the start of speech therapy, because at that time one of the patients had already died, and the six others had chosen for permanent prosthesis removal. Four of them had undergone a secondary puncture without satisfying result.
Of all seven laryngectomees, a reasonable estimation of the quality of speech using both the non-shunt and the shunt method of esophageal voice was obtained before the end of the three month period. This estimated speech quality was used instead of the overall judgement three months after starting voice therapy for these seven laryngectomees.
The results of the speech quality judgement are summarized in table 6.6.

Table 6.6 Esophageal speech quality three months after starting voice therapy.

		SHUNT METHOD			in percentages	NON-SHUNT METHOD		
	N	good	moderate	poor		good	moderate	poor
primary puncture	70	83	10	7		41	23	36
secondary puncture	19	63	16	21	16		16	68
no puncture	49	—	—	—		43	35	22

Of the seventy laryngectomees who had undergone a primary puncture, fifty-eight (83 per cent) had developed good speech with the shunt method, while only twenty-nine (41 per cent) had developed good speech with the non-shunt esophageal method.
Of the nineteen laryngectomees who had undergone a secondary puncture these numbers are respectively twelve (63 per cent) and three (16 per cent).
As a comparison the speech quality results are given of a control group of patients who were laryngectomized during a two year period before the introduction of the Groningen button valve prosthesis. No other shunt operations were performed at that time, so that only results of the non-shunt esophageal method were obtained for these fourty-nine laryngectomees, using the speech quality criteria as described in 6.1.
Twenty-one of the laryngectomees (43 per cent) in the control group had developed good non-shunt esophageal speech. This result is similar to the non-shunt esophageal speech result obtained by laryngectomees who have undergone a primary puncture procedure and valve prosthesis placement.
No correlation could be found between radiation therapy and the quality of speech with either shunt or non-shunt method after three months. It was, however, obvious that those laryngectomees who received postoperative radiotherapy, had a temporary decrease of speech quality with both shunt and non-shunt method, which lasted for a few weeks following the radiotherapy.

Furthermore, no correlation could be found between the type of initial surgery (laryngectomy with or without neck dissection) and the speech quality of either shunt or non-shunt method.
No correlation was found between age and speech quality for the shunt method. There seemed to be a slight tendency towards a poorer speech quality with the non-shunt esophageal method in those laryngectomees who were seventy years or older. The younger laryngectomees' speech was, however, not significantly better.

6.3.4 **Replacement of the prosthesis**

After some time most laryngectomees require replacement of the valve prosthesis. During the follow-up period 522 prostheses have been replaced. The mean device life-time was 3.9 months (range: 0.2 – more than 41 months).
The reasons for replacement of the prosthesis are listed in table 6.7.

Table 6.7 Reasons for prosthesis replacement. (in percentages) N = 522.

leakage of valve	52
high air flow resistance	28
spontaneous dislocation	7
temporary prosthesis removal	4
various reasons	9

The first and second most frequent reasons for prosthesis replacement were leakage of the valve (52 per cent) and a high air flow resistance (28 per cent), both are signs of a malfunction of the valve mechanism, and are most likely caused by deterioration of the valve prosthesis (4.2 and 4.3)
Concerning the thirty-six *spontaneously dislocated* prostheses (7 per cent), it is interesting to consider that this occurred twenty-six times involving sixteen laryngectomees in the starting period, and only ten times involving five laryngectomees (three of whom had also experienced this earlier and are included in the group of sixteen from before January 1st, 1983) after the starting period. At the end of the starting period a slightly modified Groningen button had been developed, with a thicker and consequently stiffer tracheal flange, which reduces the possibility of dislocation towards the esophagus. Spontaneous dislocation into the trachea has never been observed. Furthermore, in the starting period, the puncture was either performed with a scalpel or a cutting forceps and not with the puncture instrument which is used presently. A slightly large incision could thus result in a shunt which was too large for the prosthesis. This may also have facilitated dislocation towards the esophagus.
Reasons for *temporary removal* of the prosthesis were shunt insufficiency, infections of the shunt or severe hypertrophy of the tracheal mucosa.
The most frequent among the *various reasons* for replacing the valve prosthesis was that the prosthesis situated at that moment was already much longer in place than the previous one had been. Consequently the laryngectomee feared that although the prosthesis was still functioning properly at that moment, leakage would occur soon.

The replacement procedure seldom presented problems. In three patients with a

hypopharyngeal stenosis, replacement was occasionally performed under general anaesthesia. Sometimes in these cases, the small silicone string, which connects the prosthesis to the flexible metal wire (5.1 and 5.3), broke at the moment that the prosthesis was pulled through the stenosis. This can be prevented by securing the prosthesis to the metal wire with a separate thread, tied around the tracheal flange. Furthermore, occasionally the flexible metal wire turned in the hypopharynx and was advanced towards the stomach. With some external manual pressure applied to the neck, the wire could be redirected towards the mouth.

6.3.5 **Permanent removal of the prosthesis**

In thirty-two laryngectomees the valve prosthesis was removed permanently from the tracheo-esophageal shunt, on their own request. This involved twenty-four (34 per cent) of the laryngectomees following primary puncture and eight (42 per cent) of the laryngectomees following secondary puncture.
Only one of the nine laryngectomees who had undergone the secondary puncture procedure within a year after total laryngectomy, requested permanent prosthesis removal. From the group of ten laryngectomees who had undergone the secondary puncture procedure later, seven requested permanent prosthesis removal.
The reasons for permanent removal, summarized in table 6.8, were:

A. The valve prosthesis is no longer used because of a preference for the non-shunt esophageal voice. This involved thirteen laryngectomees all after primary puncture, all with a very good non-shunt esophageal voice, but with an even better shunt esophageal voice. All of these laryngectomees stated that the valve prosthesis had been very helpful in the beginning, when they still were depending on the shunt method of esophageal voice production. At the moment they decided to have the prosthesis permanently removed, none of the laryngectomees regretted the initial decision to undergo a primary puncture procedure and valve prosthesis placement.
B. Failure to acquire a good esophageal voice with the shunt method, or other reasons for considering this type of substitute voice production a failure. This involved sixteen laryngectomees, nine following primary puncture. All but one of these sixteen laryngectomees had undergone the puncture procedure during the starting period.
C. Problems concerning infection of the shunt or severe shunt insufficiency with recurrent leakage through the shunt around the valve prosthesis. This involved three laryngectomees.

Table 6.8 Reasons for permanent prosthesis removal.

	A	B	C	removed
primary puncture	13	9	2	24
secondary puncture within a year	—	1	–	1
secondary puncture after more than a year	—	6	1	7
total	13	16	3	32

A = Good non-shunt esophageal voice
B = Failure shunt esophageal voice
C = Infection or shunt insufficiency

After removal of the prosthesis, a transnasal feeding-tube was introduced for at least one week, to await spontaneous closure of the tracheo-esophageal shunt. Only sixteen laryngectomees had a tracheo-esophageal shunt which closed spontaneously within ten days after removal of the prosthesis. One shunt closed spontaneously after four weeks. The remaining fifteen laryngectomees had to undergo a surgical shunt-closing procedure. The initially performed surgical shunt-closing procedure with shunt excision and twin-layer suturing was often not successful. Therefore, since 1983 a technique with the interposition of a dermal graft is employed, as is described by Annyas and Escajadillo (1984). All eleven dermal graft shunt-closing procedures were successful. The tendency towards spontaneous closure is higher when the period between the puncture procedure and the permanent prosthesis removal is shorter (table 6.9).

Table 6.9 Shunt closure after permanent prosthesis removal.

Time since puncture:	N	spontaneous closure	surgical closure
less than 6 months	13	11	2
6-12 months	9	5	4
more than 12 months	10	1	9
total	32	17	15

In the laryngectomees who had spontaneous closing shunts the mean period between the puncture procedure and the time of permanent prosthesis removal was 4.9 months (range: 2-14 months). For the laryngectomees who required a surgical shunt closure, this mean period was 14.2 months (range: 2-39 months). Nine out of ten laryngectomees who had the shunt for more than a year, required surgical closure. While only two out of the thirteen laryngectomees who had the shunt for less than six months, required surgical closure.

6.3.6 **Complications**

During the follow-up period sixteen laryngectomees died. None of these deaths could be attributed to the puncture procedure, the tracheo-esophageal shunt or the valve prothesis.

No early complications due to the primary puncture procedure were observed. In one secondary puncture procedure (performed in the starting period) the incision for the shunt was made too large. The prosthesis was lost during the procedure and could not be retrieved. It either passed down the esophagus into the stomach or it was displaced into the mediastinum. After suturing part of the too large shunt, a new prosthesis was fitted without further complications. The patient recovered without problems, but the voice rehabilitation was unsuccessful, as a result of P-E segment hypertonicity.
No other early complications due to the secondary puncture procedure were observed. The late complications due to the long-term use of the Groningen button valve prosthesis are listed in table 6.10.

Table 6.10. Late complications associated with long-term use of the Groningen button. (in percentages of all observed laryngectomees with a prosthesis, N = 89).

severe hypertrophic tracheal mucosa	4
infection of shunt	8
other infections	2
shunt insufficiency	18
dislocation of prosthesis	20/5*
inadvertent shunt closure	1
aspiration of prosthesis	0
persisting shunt after removal	17
swallowing disorders	3
pulmonary problems	0

* corrected for situation after 1 January 1983: 5 per cent, for explanation see text.

Minor hypertrophy of the tracheal mucosa was found in twenty-six laryngectomees. Since it was asymptomatic, caused no discomfort and required no treatment, this situation was not regarded as a complication. Minor modifications of the prosthesis consisting of slightly rounded tracheal and esophageal flanges (introduced in 1984), seemed to result in a tendency towards less hypertrophy of the tracheal mucosa. Treatment of *severe hypertrophy* of the tracheal mucosa was occasionally required because of possible airway interference. In one of the four laryngectomees involved (4 per cent), the prosthesis was temporarily removed, resulting in a sufficient decrease of the hypertrophic mucosa. In the other three laryngectomees the prostheses were replaced by longer ones to reduce mechanical irritation of the tracheal mucosa. With additional application of nitras argenti a decrease of hypertrophic mucosa was achieved. Figures 6.1 and 6.2 show examples of the result of such a treatment.

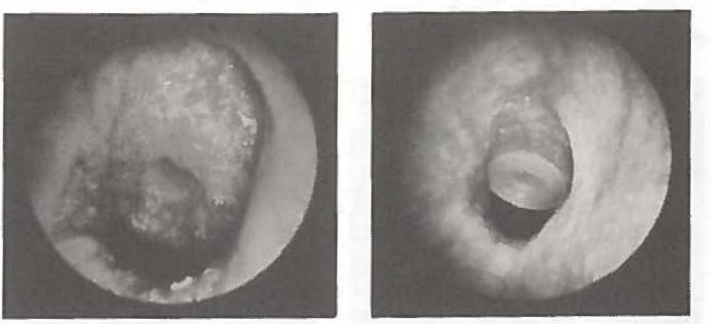


Fig. 6.1

Left:
hypertrophic mucosa in the trachea partly obstructing the tracheostoma and the view on the prosthesis.
Right:
same patient fourteen days following replacement of the prosthesis by a longer one.

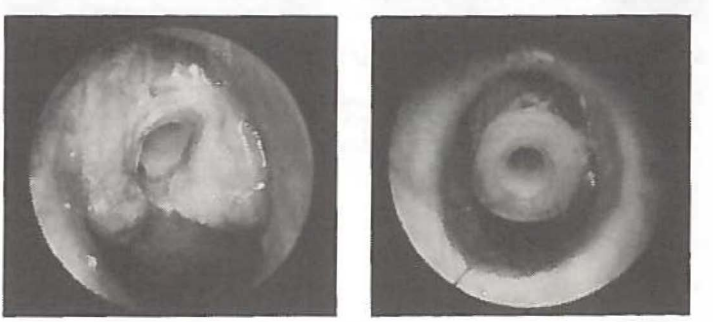
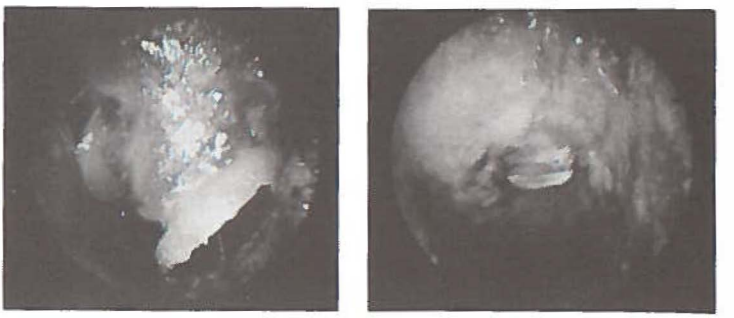


Fig. 6.2

Left:
hypertrophic mucosa in the trachea partly covering the prosthesis.
Right:
same patient three weeks following replacement of the prosthesis by a longer one and additional nitras argenti application.

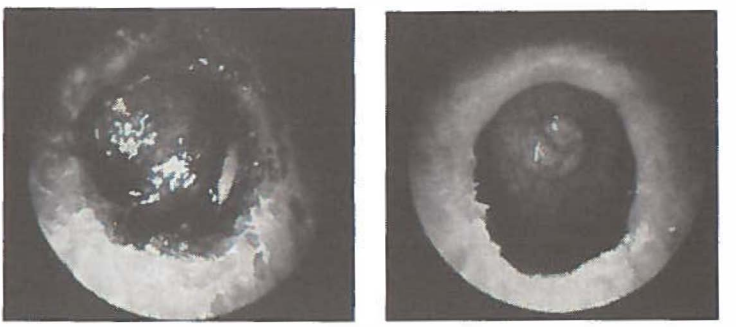
Infection of the shunt occurred in seven patients (8 per cent), twice requiring temporary prosthesis removal and in one case permanent removal (this patient had already considered permanent removal prior to the infection). In six of these laryngectomees *Staphylococcus aureus* was isolated in the culture from the shunt and in the other patient who had already been under antibiotic (amoxicillin) treatment for five days only *Candida albicans* was cultured. The last finding is understandable in the light of recent observations (4.2). At that time, the *Candida albicans* was considered to be the pathogenic organism. Retrospectively, however, we must assume that another microorganism, possibly *Staphylococcus aureus* had caused the infection, but due to the amoxicillin treatment this microorganism could not be isolated from the culture. All patients were effectively treated with cefradin and amphotericin B respectively. Figures 6.3 and 6.4 show examples of a shunt infection.

Fig. 6.3



Left: infection of tracheo-esophageal shunt with extrusion of the prosthesis towards the trachea.
Right: same patient one week after prosthesis removal and antibiotic treatment. Tracheo-esophageal wall at the site of the shunt. The shunt has closed.

Fig. 6.4



Left: infection of tracheo-esophageal shunt with extrusion of the prosthesis, obstructing the tracheostoma.
Right: same patient one week after prosthesis removal and antibiotic treatment. Only a small granulation at the site of the tracheo-esophageal shunt remained. Another week later the granulation had also disappeared and a new prosthesis could be introduced in the still open shunt.

The two patients (2 per cent) with other infections both had a Candida esophagitis. Both were treated with ketoconazol, because amphotericin B lozenges (4.3) were at that time not yet available.

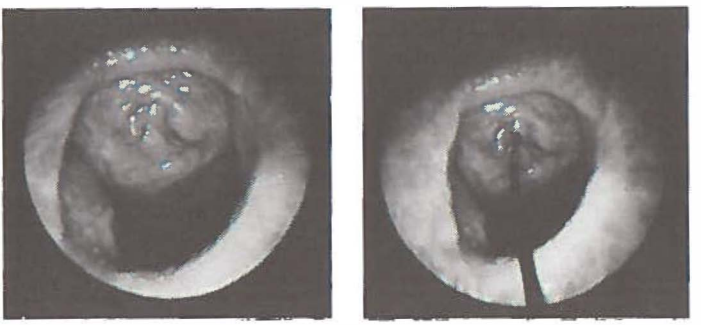
Sixteen patients (18 per cent) had *shunt insufficiency*, as a result of a widening of the tracheo-esophageal shunt, which resulted in minor or severe intermittent leakage of esophageal contents, around the prosthesis through the shunt. Eleven of these sixteen patients had undergone the puncture procedure in the starting period, when the puncture was still performed with a scalpel or a cutting forceps. A slightly thicker Groningen button has been developed with a tube diameter of eight millimeters. By inserting this 'thick' prosthesis into the insufficient shunt, the leakage around the prosthesis was stopped. This treatment proved to be sufficient in nine laryngectomees (10 per cent), but the other seven laryngectomees (8 per cent) developed intermittent leakage around the thicker prosthesis as well. In these seven cases, which may be considered to have a severe shunt insufficiency, the prosthesis was temporarily removed to allow spontaneous reduction of the shunt diameter, which usually occurred within a few days. Subsequently, a normal prosthesis could be inserted again. This was initially effective in all seven laryngectomees, but four of them later had a recurrency of the problem, which was successfully treated the same way, in two patients. In the other two patients it was eventually decided to remove the prosthesis permanently. One of these two patients was heavily irradiated (100 Gy) and has already been described (5.4.1).

Spontaneous dislocation of the prosthesis towards the esophagus occurring in eighteen laryngectomees (20 per cent), has been already discussed in 6.3.4, together with the possible explanations for the different frequencies of this problem during and after the starting period. Only two (5 per cent) out of thirty-seven laryngectomees who underwent a puncture procedure after the starting period, experienced a dislocated prosthesis. Most laryngectomees who suffered dislocation of prostheses, also had problems with shunt insufficiency. Two laryngectomees had experienced recurrent dislocation of the prosthesis. This was effectively prevented by tying one end of a thread around the tracheal flange and taping the other end to the peritracheal skin, thus securing the prosthesis in the shunt.
Most laryngectomees who experienced spontaneous dislocation towards the esophagus, reported to have 'lost' the prosthesis during 'exaggerated' swallowing action. When the tracheal flange can no longer be seen in the tracheostoma, spontaneous dislocation is likely to have occured. This, however, should be verified by thorough inspection of the shunt before reinsertion of a new prosthesis. Hypertrophic tracheal mucosa may hide the tracheal flange. Figure 6.5 shows an example of such a 'lost' prosthesis which proved to be still in place but was covered by hypertrophic mucosa.
In one patient no thorough examination of the shunt was performed before reinserting a new prosthesis, and the new prosthesis was placed inside the old one, which resulted in a failure to produce shunt esophageal voice.
In one case the shunt had inadvertently closed after spontaneous dislocation. A repuncture procedure similar to the secondary puncture procedure was performed without complications and no recurrency of prosthesis dislocation occured.
Aspiration of the prosthesis has never been observed, apparently all spontaneous dislocations occured towards the esophagus.

The problems concerning *persisting shunts* after permanent prosthesis removal have

already been discussed in 6.3.4.

Fig. 6.5

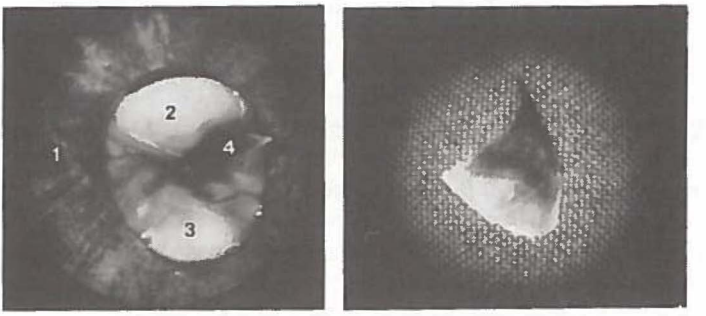


Left: tracheostoma with seemingly disappeared prosthesis and closed shunt. The laryngectomee was no longer able to speak with the shunt method.
Right: palpation with a metal probe reveals that the prosthesis is still in place and the shunt is still open, but that they are covered with hypertrophic mucosa. Replacement of the old prosthesis by a longer one again enabled shunt esophageal sound production.

Swallowing disorders have been reported by ten laryngectomees. In seven of them this was caused by hypopharyngeal stenosis or a hypopharyngeal pouch. The complaints disappeared after treatment of the underlying cause, and therefore, it is assumed that in these cases no relationship between the swallowing disorder and the prosthesis existed. Three laryngectomees (3 per cent) reported swallowing problems which appeared to be associated with the prosthesis. Two of them had no actual impairment of swallowing, but occasionally had the feeling of a small lump in the throat. After removal of the prosthesis this lump feeling disappeared. The other patient had been speaking with the shunt esophageal method for over a year without any complaint, before he started mentioning higher pressures required for phonation and swallowing difficulties. Swallowing was painful, food passed poorly, liquids presented no problems. Radiographic examination revealed no pathology and endoscopy was performed to exclude local tumor recurrency. A foreign body was found to be lodged in the valve of the prosthesis (Fig. 6.6). It proved to be a small part of the skin of a pine-apple. After removal of this foreign body, voice production and swallowing returned to normal.

Contrary to the expectations expressed by Schultz-Coulon and co-workers (1980) we did not observe pulmonary problems, even though occasionally extremely high intratracheal pressures during phonation with the shunt method have been recorded. An elderly laryngectomee (67 years), who had developed an excellent substitute voice with the shunt method, for example, built up an intratracheal air pressure of more than 25 kPa during sustained phonation. In contrast, the subglottic air pressure of normal laryngeal subjects during sustained phonation, vary from 0.15 kPa to 3 kPa (Schutte 1980). This laryngectomee displays no signs of fatigue or of pulmonary or cardiac problems, during or after phonation. This finding is in agreement with the publications of Blechschmidt and co-workers (1982) and Brendebach and co-workers (1986), who found normal lung function values in laryngectomees using the shunt method of esophageal voice production.

Fig. 6.6



Left: endoscopic view of esophageal flange of Groningen button valve prosthesis with foreign body lodged in the valve.
Right: foreign body (peel of pineapple) after removal.
1 = inner surface of endoscope, 2 = esophageal flange of Groningen button, 3 = posterior esophageal wall, 4 = foreign body.

6.3.7 **Patient satisfaction**

At the end of the first year or during the second year following the puncture procedure, the laryngectomees were asked to give their opinion as to whether speech rehabilitation with the Groningen button had been satisfactory or not. The laryngectomees who had already chosen for permanent prosthesis removal were included in this questionnaire study. Eight laryngectomees had died before the end of the first year. But five of these deceased laryngectomees had already expressed their opinion in the earlier follow-up period. These opinions were also taken into account. The other three laryngectomees had died without expressing their opinion and are listed in the category 'no opinion', together with patients who did not have, or did not want to express, an opinion. The results concerning the laryngectomees' satisfaction are given in table 6.11, in which a differentation is made between puncture procedures performed before and after the first of January 1983.

Table 6.11 Laryngectomees satisfied with the Groningen button (in percentages).

	puncture procedure '80-'82	'83-'84
Satisfied		
yes	55	89
no	35	3
no opinion	10	8
	N = 52	N = 37

The majority of the eighteen dissatisfied laryngectomees (35 per cent) from the first period can be divided into two groups:

1. Laryngectomees who had persisting shunts after permanent prosthesis removal (6.3.5). Before the dermal graft shunt closing procedure was being used, several unsuccessful attempts of surgical closure have been undertaken. Furthermore, in the beginning spontaneous shunt closure was awaited for a much longer period than the one to two week period which is presently considered the maximal time to allow spontaneous shunt closure. In nine laryngectomees this initial awaiting policy resulted in a persisting shunt, and consequently in using a nasogastric feeding tube, for a mean period of eighteen weeks (range: 3-40 weeks). At the moment of permanent prosthesis removal, still six of these nine laryngectomees were satisfied that initially a puncture had been performed and the prosthesis had been placed. They had requested prosthesis removal because of a very well developed non-shunt esophageal speech. It is understandable that they were no longer satisfied with the whole procedure after having experienced the discomforts of a persisting tracheo-esophageal shunt and a nasogastric feeding tube for several months.
2. The second major group of dissatisfied laryngectomees consists of those who had undergone a secondary puncture procedure two years or more after laryngectomy.

In table 6.12 the laryngectomees' satisfaction after secondary puncture is presented, related to the period elapsed between the laryngectomy and the secondary puncture. Six of the seven laryngectomees, who had undergone a secondary puncture procedure two years or more after laryngectomy (all performed in 1981), were dissatisfied. All six experienced their shunt esophageal voice as a failure, although two of them were able to produce speech which was judged as being moderate by the speech therapists. The other four were judged as having a poor or failed shunt esophageal speech.

Table 6.12 Number of laryngectomees satisfied with the Groningen button after secondary puncture procedure.

	period between laryngectomy and puncture		
	first year	second year	after 2 years or more
Satisfied			
yes	9	2	1
no	–	–	6
no opinion	–	1	–

N = 19

6.4 **DISCUSSION**

6.4.1 **Early voice acquisition**

The shunt method of esophageal voice production using a valve prosthesis is a great asset to laryngectomee voice rehabilitation considering the large number of laryngectomees who can immediately produce esophageal sound with this method. Even many of those laryngectomees who later decided to have the prosthesis permanently removed, found this early voice production ability to be a great advantage. The psychological and social advantages of early voice acquisition have already been discussed(3.3.2). This is the main reason why we advocate the performance of a primary puncture procedure.

6.4.2 **Primary mode of voice production**

The rather negative results of the secondary puncture procedures performed before 1983 obviously influence the percentage of patients using an electrolarynx at the end of the observation period. Before 1983 no adequate patient selection for secondary prosthesis placement was performed. Preoperative insufflation tests and fluoroscopic studies of the P-E segment were not performed until after this starting period.
Despite this negative influence the shunt method, alone or in combination with another substitute voice method, is the primary mode of voice production in 57 per cent of all patients after a mean follow-up period of twenty-three months.
In a recent prospective study performed by Blom and co-workers (1986), 83 per cent of fourty-seven laryngectomees were reported to still use their valve prosthesis after one year, which was applied as the criterion for long-term success. This, however, only involved laryngectomees who had undergone a secondary puncture procedure and who had been preoperatively strictly selected by means of insufflation tests. Since the laryngectomees in Blom's study obviously had problems in acquiring non-shunt esophageal voice, they had little alternative but to use the shunt method.
In our population, which consists mainly of laryngectomees who have undergone a primary puncture, 33 per cent preferred the use of the non-shunt method, although most of them were able to produce very good, mostly even better, esophageal voices with the shunt method as well. These laryngectomees cannot be classified as being failed shunt esophageal speakers, although they no longer use the valve prosthesis. If they would not have the alternative of the non-shunt esophageal voice, then they would also use the shunt esophageal voice as their primary mode of voice production.
Consequently, the long-term success rate as defined by Blom would then be much higher for the Groningen button as well.

6.4.3 **Quality of speech; successful speech acquisition**

Few studies concerning laryngectomee speech acquisition have been prospectively conducted.
As Gates and co-workers (1982a) suggested, many of the reports of successful esophageal speech acquisition may be inflated because the investigations were retrospective, tending to exclude high-risk or poor-outcome patients who are unavailable or unwilling to be assessed. Their prospective study evaluated fourty-seven laryngectomees from time of diagnosis through six months of treatment following total laryngectomy. On completion of the treatment only 26 per cent of the patients had successfully acquired a non-shunt esophageal voice. If in our study, which was conducted prospectively, the judgements moderate and good are considered to indicate successful esophageal voice acquisition, we can present much more favourable figures than Gates and co-workers did. In the control laryngectomee group without a puncture procedure we found a non-shunt esophageal speech success rate of 78 per cent, three months after starting voice and speech therapy. After one year this success rate is even slightly higher with 55 per cent good and 28 per cent moderate non-shunt esophageal speakers.
The success rate of non-shunt esophageal speech in the group who had undergone a primary puncture is slightly lower than in the control group. This is probably due to the fact that fewer laryngectomees are motivated to acquire a non-shunt esophageal voice, because they can already speak with the shunt esophageal voice. On the other hand they are under less pressure to learn the non-shunt esophageal voice, which results in a more

relaxed, and therefore better attitude towards voice and speech therapy.

The success rate of the shunt method is higher than that of the non-shunt method, even with the higher voice quality standard of the shunt method. The superior quality of the shunt esophageal voice as compared to the non-shunt esophageal voice, which is so apparent in this study, is also demonstrated by our other, more basic, studies on esophageal voice quality. Extensive presentation of these, as yet unpublished, acoustical and perceptual studies is beyond the scope of this work. The most relevant results can, however, be summarized as follows:
Concerning all aspects of voice and speech quality which were investigated (speechrate, maximal voice duration, vocal intensity, speech intelligibility, long-term average spectral analysis of the speech signal, and correlates of speech acceptability), the shunt esophageal speech samples are significantly better than the non-shunt esophageal speech samples.
Furthermore, concerning some aspects of speech quality (speechrate and speech intelligibility), the shunt esophageal speech samples approached the quality of normal laryngeal speech samples. The assessment methods of quality employed in the present study, the overall speech proficiency judgement of experienced listeners, proved to be highly correlated with the results of most above mentioned assessment methods and aspects of voice and speech quality. Therefore, it was deemed sufficient to present here only these overall speech proficiency judgements.

The 79 per cent success rate of the secondary puncture group is remarkably lower than the 93 per cent of the primary puncture group. The most obvious reason for this difference is the fact that fifteen of the nineteen secondary punctures were performed during the starting period, without the preoperative tests, which are presently considered indispensable for patient selection.
Some other reports also mention lower success rates after secondary punctures than after primary punctures (Casiano, Maniglia and Lundy 1985; Manni, van den Broek and de Groot 1986). Singer and Blom (personal communication 1986) did not find differences in success rates after primary or after secondary punctures. Nor did they find a negative correlation between successful voice acquisition and the period which had elapsed between laryngectomy and the time of secondary puncture, which is so apparent in our data.

6.4.4 **Replacement of the prosthesis**

The mean life-time of the Groningen button is higher than that reported for the Blom-Singer prosthesis and for the Panje voice button. In 80 per cent of the cases the Groningen button had to be changed because of a dysfunction of the valve mechanism of the prosthesis, either leakage or increased air flow resistance. Presently, we know that this is caused by deterioration of the valve, most likely as a result of *Candida* vegetations (4.2). It has already proved feasible to prevent this deterioration of the valve prosthesis by decontaminating the oropharynx (4.3).

6.4.5 **Permanent removal of the prosthesis**

The correlation between early permanent prosthesis removal and spontaneous closure of the shunt clearly supports the notion that when permanent removal is considered, it can best be performed within the first six months following the puncture.

The development of a dermal graft shunt closing procedure has greatly contributed to overcoming the problem presented by a persisting shunt.
When a patient presently requests permanent removal of the prosthesis, we await spontaneous closure for one or two weeks at the most. If the shunt has not closed spontaneously by then, a prosthesis is reinserted to prevent leakage through the shunt and a surgical closure with a dermal graft interposition is planned. This strategy has proven to be acceptable for most patients.

6.4.6 **Complications**

Contrary to the complications, mentioned in the literature, during or shortly following the puncture procedures (Silver, Gluckman and Donegan 1985; Andrews et al 1987), we did not observe such early complications.
Especially the high incidence of infectious complications shortly following primary punctures, as mentioned in other reports (Casiano, Maniglia and Lundy 1985; McConnel and Duck 1986), is in contrast to the total absence of this complications in our population. This may be a result of our prophylactical antibiotic treatment (1.1).
Although several late complications have been observed, which present more or less discomfort, none can be considered to be very severe. This is illustrated by the high percentage of satisfied patients in the last years. Some complications may be difficult to prevent, such as the infection of the shunt as a late complication. Others, however, seem to be avoidable, or their frequency of occurrence could at least be diminished.
Modification of the puncture procedure for instance seems to have had a positive influence on the occurrence of shunt insufficiency and spontaneous prosthesis dislocation. The severe shunt insufficiency which was observed in 8 per cent of our patients, can be considered to be the most serious and discomforting complication.
The problem of shunt insufficiency is mentioned in other publications as well. It is reported to occur in 8 to 12 per cent of the patients (Wetmore, Johns and Baker 1981, 1985a; Hamaker et al 1985; Silver, Gluckman and Donegan 1985; Andrews et al 1987).
Singer also recognizes this problem and suggests a staged muscle flap interposition and repuncture to overcome this complication (personal communication 1986).
Surgery is, however, not a very attractive solution in an already irradiated and operated patient population and so far our more conservative treatment of temporary prosthesis removal has been acceptable to the patients involved. Remacle (personal communication 1988) proposes an interesting and seeming simple solution by locally injecting collagen into the insufficient shunt.
Comparison of complication rates mentioned in different studies should be undertaken with caution, because of the differences in follow-up intensity and follow-up period. Nevertheless the present study, which has a long and intensive follow-up period, shows a relatively low complication-rate in the use of a valve prosthesis, both considering the number and the severity of the complications. Most other studies have a shorter and less intensive follow-up period, and many of them report a higher complication rate.

6.4.7 **Patient satisfaction**

The relatively high number of dissatisfied patients from the period before 1983 can be attributed to the absence of preoperative patient selection for secondary puncture procedures and to the problems associated with persisting shunts following permanent prosthesis removal. An additional factor will undoubtedly have been the initial inexperience of the rehabilitation team with a valve prosthesis situated in a tracheo-

esophageal shunt. This is probably an important factor influencing the success rate in many studies.
Considering the period since 1983 in which only one patient (3 per cent) expressed dissatisfaction, we can state that voice rehabilitation with the Groningen button is a method with a very high patient acceptance rate.
There is always the question of how to measure the success of a voice rehabilitation method. The success can not be measured only by speech acquisition rates, voice quality judgements or complication rates. A combination of all factors mentioned determines whether or not a voice rehabilitation method can be considered to be successful, and this accumulates in the satisfaction of the patients.

6.5 COMMENT ON THE RESULTS WITH THE GRONINGEN BUTTON

In our five years experience with the Groningen button valve prosthesis, it has proved to be an effective and reliable asset to laryngectomee voice rehabilitation. Not only reports from the Netherlands (Nijdam et al 1982, 1986a, 1986b; Hilgers, Schouwenburg and Scholtens 1983; Annyas et al 1984; Manni et al 1984; Manni, van den Broek and de Groot 1985, 1986; Mahieu and Annyas 1985; Mahieu, Annyas and Nijdam 1986b; Mahieu 1987), but also reports from other countries (Escajadillo, Annyas and Leever 1984; Meyer-Breiting 1985; Heger and Richter 1986; Hochleitner et al 1986) mention good results. Furthermore, our data show that the shunt esophageal voice rehabilitation with the Groningen button is a very safe method, especially when compared to some reports of other valve prostheses.
The advantages of the Groningen button valve prosthesis when compared to some other types of valve prostheses are mainly:
- the self retaining quality,
- the relatively long device lifetime,
- no need for maintenance by the patient and consequently,
- no need for intermittent replacement by the patient,
- minimal interference with respiration and deglutition,
- safety and low complication rate.

The main disadvantages of this valve prosthesis when compared to some other devices are:
- replacement requires medical personnel and special instruments,
- hypopharyngeal stenosis may interfere with replacement procedure.

The quality of the substitute voice with the shunt method using a valve is superior to other methods of substitute voice production, and is in some aspects, even comparable to laryngeal voice production.
Another important asset of shunt esophageal voice production with a valve prosthesis, is the almost immediate availability of the substitute voice, which is so important for the further rehabilitation of the laryngectomee. Therefore, even those laryngectomees who will later only use the non-shunt esophageal voice, benefit from a primary puncture procedure and valve prosthesis placement.
Undoubtedly, the shunt esophageal method of substitute voice production with a valve prosthesis will not be the final solution for the voice and speech problems of the laryngectomee. However, at present it is the best method available. Further improvements of this type of subsitute voice production are to be expected, especially as a result of research concerning functional P-E segment surgery, low resistance prosthesis design and prevention of valve prosthesis deterioration.

Chapter VII

SUMMARY AND CONCLUSIONS

Total laryngectomy is a surgical procedure, which entails the total removal of the larynx and the creation of a permanent tracheostoma.
The laryngectomized state has serious consequences for the laryngectomee's personal and social life. The most distressing of these consequences of total laryngectomy is generally considered to be the loss of vocal functions. Voice and speech restoration with a substitute voice is therefore one of the most important aspects of the rehabilitation process. Valve prostheses inserted into a tracheo-esophageal shunt are a new and very promising development in laryngectomee voice rehabilitation. The main objective of this study is to evaluate the long-term results achieved with such a valve prosthesis (the Groningen button). Furthermore, the major problems associated with this type of substitute voice production have been identified and some factors which may improve this substitute voice production have been investigated.

In Chapter II various methods of substitute voice production are described. Phonation with a substitute voice, analogous to normal laryngeal phonation, requires an energy source, a sound source and a resonator.
Pharyngeal and buccal voice production are considered undesirable methods of substitute voice production.
Mechanical sound sources, either pneumatically or electrically powered, have a long history in substitute voice production. The resulting substitute voice is rather monotonous and conspicuous, and is consequently regarded as a less desirable alternative, which is applied only when other methods of substitute voice production have failed.
Many surgical voice rehabilitation procedures have been described, most of which consist of creating a shunt between the airway and the upper digestive tract. The majority of these shunts enter the digestive tract just below the level of the pseudoglottis, a structure situated in the esophagus entrance. This pseudoglottis can act as a sound source and produces the esophageal voice. The esophageal voice, which can be achieved with surgical voice rehabilitation procedures is generally of a very good quality. However, complications associated with these surgical procedures, largely consisting of aspiration of esophageal contents through the shunt and stenosis of the shunt, limit the use of these methods of substitute voice production. Most of these complications can be prevented by inserting a one-way valve into the shunt, which forms the most recent development in laryngectomee voice rehabilitation.
Esophageal voice can also be produced without a surgically created shunt. This *non-shunt* esophageal voice has, until very recently, been considered to be the most desirable method of substitute voice production, although the *shunt* esophageal voice is often of a better quality.

In Chapter III both the non-shunt and the shunt esophageal voice production are discussed in detail.
Esophageal voice resembles the sound accompanying belching, and is produced using the pseudoglottis as sound source. The pseudoglottis is situated in the pharyngo-esophageal (P-E) segment and consists of the musculature of the pharynx and esophagus entrance and the mucosa covering these structures. Surgical manipulations in the P-E

segment area during the laryngectomy are critical with respect to the phonatory function of the pseudoglottis. Especially voluntary controlled coordination, relaxation and tonicity adjustments of the P-E segment are essential for esophageal voice production. The power source, which generates vibrations in the pseudoglottis, is formed by pressurized air contained in an air reservoir which is located in the upper part of the esophagus. This air periodically escapes superiorly through the pseudoglottis and sets the air in the resonator (vocal tract) into vibration (= sound).
Prior to esophageal sound production the air reservoir will have to be filled with air. Four different methods of air intake into this air reservoir can be distinguished:
1) swallowing method, 2) inhalation method, 3) injection method, 4) shunt method.
Only the last method uses respiratory air which is shunted through a surgically created shunt from the trachea into the subpseudoglottic air reservoir.
To fill the air reservoir using the first three methods, the air will have to pass downwards from the oral and pharyngeal cavities through the P-E segment, before it can be redirected outwards again.
Various factors can interfere with the acquisition of esophageal voice production, but hypertonicity of the P-E segment is by far the most important.
The shunt esophageal voice production method is the quickest and most easy method to learn and has the lowest voice acquisition failure rate.
Valve prostheses inserted into surgically created tracheo-esophageal shunts have made it possible to achieve the good substitute voice results of the shunt esophageal method while avoiding most of the complications often associated with such surgical voice rehabilitation procedures without prostheses.

Some of the more interesting and widely used types of valve prostheses and their associated methods of creating a tracheo-esophageal shunt are presented in Chapter IV, with their respective advantages and disadvantages.
Most types of valve prostheses are made of silicone material, which is known to deteriorate as a result of colonization with *Candida* species.
Prevention of this colonization by means of a selective oropharyngeal decontamination using a locally applied antimycotic agent, results in a better functioning valve prosthesis and consequently less intratracheal air pressure is required for shunt esophageal phonation. For those laryngectomees requiring frequent prosthesis replacement because of valve malfunctions or for those who have problems building up sufficient intratracheal air pressure to phonate, treatment with antimycotic lozenges is advocated.

In Chapter V the Groningen button valve prosthesis, developed in the ENT-department of the University Hospital of Groningen, is described. A detailed instruction of the tracheo-esophageal puncture procedures to create a shunt either at the time of laryngectomy (primary puncture) or in an already laryngectomized patient (secondary puncture) is given.
Furthermore the technique of a modified myotomy of the P-E segment, performed at the time of laryngectomy to prevent hypertonicity of this P-E segment, is described. Since this myotomy procedure is being performed a further reduction of the already low, shunt esophageal voice acquisition failure rate has been observed. In addition such a myotomy facilitates shunt esophageal phonation, because less intratracheal air pressure is required for phonation.

Chapter VI contains the results and complications observed with the Groningen button valve prosthesis in the ENT-department of the University Hospital of Groningen since 1980, involving eighty-nine laryngectomees with a mean follow-up period of

twenty-three months. The vast majority of laryngectomees was able to speak immediately with the shunt esophageal method during the first voice therapy session; with the non-shunt esophageal method none were able to speak immediately.
At the end of the follow-up period one-third of the laryngectomees used the shunt esophageal method as the primary method of voice production, one-third the non-shunt esophageal method and one-quart both methods.
One-third of the laryngectomees, a large number of whom had acquired a good non-shunt esophageal voice, had during the follow-up period chosen for permanent valve prosthesis removal and they no longer used the shunt esophageal voicing method.
The quality of the shunt esophageal voicing method was superior to the quality of the non-shunt esophageal voicing method, even in those laryngectomees who had chosen for permanent prosthesis removal.
The complications observed as a result of the valve prosthesis were not severe and most of them could be effectively treated with simple measures. The satisfaction rate among laryngectomees using the valve prosthesis was high.

Conclusions
Voice rehabilitation following laryngectomy using a valve prosthesis fitted in a tracheo-esophageal shunt is at this moment the best available voice rehabilitation method. The results achieved with the Groningen button, demonstrate that it is a competent valve prosthesis, with a high patient satisfaction rate. The tracheo-esophageal puncture is best performed at the time of laryngectomy, so that the speechless period of the laryngectomee is reduced to its minimum.
For a secondary puncture procedure and valve prosthesis placement the most important indication is based upon a positive insufflation test during fluoroscopic examination.
Furthermore, this study indicates that performance of a modified myotomy of the P-E segment and prevention of *Candida* colonization can improve the efficiency of the shunt esophageal phonation by requiring less intratracheal air pressure.
The voice and speech rehabilitation program following laryngectomy and primary tracheo-esophageal puncture should involve the teaching of both shunt esophageal and non-shunt esophageal voice production, so that the laryngectomee can later choose which voicing method he prefers to use.

STEM EN SPRAAK REVALIDATIE NA LARYNGECTOMIE

SAMENVATTING EN CONCLUSIES

Totale laryngectomie is een chirurgische procedure, die de totale verwijdering van de larynx en het aanleggen van een permanent tracheo-stoma behelst.
De gelaryngectomeerde status heeft ernstige consequenties voor het persoonlijke en sociale leven van de gelaryngectomeerde. Het verlies van de stem wordt algemeen beschouwd als de meest ingrijpende consequentie van een laryngectomie. Stem en spraak revalidatie middels een vervangende stemgeving is derhalve één van de meest belangrijke aspecten van het revalidatie proces.
Ventiel protheses geplaatst in een tracheo-oesophageale shunt vormen een nieuwe en veelbelovende ontwikkeling in de stemrevalidatie van de gelaryngectomeerde. Het hoofddoel van deze studie bestaat uit de evaluatie van de lange termijn resultaten die met een ventielprothese (de Groninger button) bereikt worden. Voorts zijn de belangrijkste problemen geidentificeerd welke bij deze methode van stemrevalidatie kunnen ontstaan en tevens zijn enkele factoren onderzocht die de vervangende stemgeving zouden kunnen verbeteren.

In hoofdstuk II worden de verschillende methoden van vervangende stemgeving beschreven. Analoog met normale laryngeale stemgeving, vereist ook fonatie met vervangende stemmen een energiebron, een geluidsbron en een aanzetstuk.
Pharyngeale en buccale stemgeving worden beschouwd als ongeschikte methoden van vervangende stemgeving.
Mechanische geluidsbronnen, hetzij pneumatisch, hetzij electrisch aangedreven, hebben een lange voorgeschiedenis met betrekking tot vervangende stemgeving. De stemgeving die met deze methode bereikt wordt is vrij monotoon en opvallend, en wordt derhalve als een minder goed alternatief beschouwd, welke alleen maar wordt toegepast wanneer andere methoden van vervangende stemgeving gefaald hebben.
Er zijn vele chirurgische stemrevalidatie procedures beschreven. De meeste van deze procedures bestaan uit het aanleggen van een verbinding (shunt) tussen de ademweg en het bovenste deel van de spijsweg. Het merendeel van deze 'shunts' heeft zijn verbinding met de spijsweg juist onder het niveau van de pseudoglottis, een structuur gelegen in de slokdarmingang. Deze pseudoglottis kan als geluidsbron gebruikt worden en brengt de oesophagusstem voort. De oesphagusstem die bereikt kan worden met chirurgische stemrevalidatie methoden is over het algemeen van een zeer goede kwaliteit. Echter de met deze chirurgische methoden samenhangende complicaties, vooral bestaande uit aspiratie van slokdarminhoud door de shunt en stenose van de shunt, hebben het gebruik beperkt. Deze complicaties kunnen voorkomen worden door het plaatsen van een ventiel in de shunt, hetgeen de meest recente ontwikkeling in de stemrevalidatie van gelaryngectomeerden vormt.
De oesophagusstem kan ook opgewekt worden zonder chirurgisch aangelegde shunt. Tot voor kort werd deze *non-shunt* oesophagusstem beschouwd als de meest geschikte methode van vervangende stemgeving. Dit ondanks dat de *shunt* oesophagusstem vaak van een betere kwaliteit is.

In hoofdstuk III worden zowel de non-shunt als de shunt oesophagusstem uitgebreid besproken.
De oesophagusstem vertoont gelijkenis met het geluid dat gepaard gaat met opboeren.

Het wordt gevormd door gebruik te maken van de pseudoglottis als geluidsbron. De pseudoglottis is gelocaliseerd in het pharyngo-oesophageale (P-E) segment en bestaat uit: de musculatuur van de pharynx, de musculatuur van de oesophagusingang en het slijmvlies dat deze structuren bekleedt.
Chirurgische manipulaties in de regio van het P-E segment, tijdens de laryngectomie oefenen een belangrijke invloed uit op de latere stemgevende functie van de pseudoglottis. Vooral de willekeurig gecontroleerde coördinatie, relaxatie en toniciteitsveranderingen van het P-E segment zijn essentiëel voor oesophageale stemgeving.
De energiebron die trillingen in de pseudoglottis opwekt wordt gevormd door de samengeperste lucht welke zich bevindt in een luchtreservoir, in het bovenste gedeelte van de slokdarm. Op periodieke wijze ontsnapt deze lucht naar boven, langs de pseudoglottis, waardoor de lucht in het aanzetstuk in trilling wordt gebracht (= geluid).
Voorafgaande aan de oesophageale stemgeving moet het luchtreservoir met lucht gevuld worden. Vier verschillende methoden van luchtinname in dit reservoir, kunnen worden onderscheiden:
1) slikmethode,
2) inhalatiemethode,
3) injectie methode,
4) shunt methode.
Alleen de laatste methode maakt gebruik van uitademingslucht, die via een chirurgisch aangelegde shunt, van de luchtpijp naar het, onder de pseudoglottis gelegen, luchtreservoir geleid wordt. Om met behulp van de eerste drie methoden het luchtreservoir te vullen, zal de lucht allereerst vanuit de mond-keelholte, langs de pseudoglottis, naar beneden gebracht moeten worden, voordat deze lucht opnieuw naar buiten gestuwd kan worden.
Verschillende factoren kunnen het opgang komen van de oesophagusstem verhinderen, maar hypertoniciteit van het P-E segment is verreweg de belangrijkste oorzaak.
De snelste en gemakkelijkste methode om aan te leren is de shunt oesophagus stemgeving. Deze methode heeft het hoogste percentage van goed opgang gekomen stemgeving. Door het plaatsen van ventielprotheses in de shunts is het mogelijk geworden om de goede vervangende stemgevingsresultaten van de shunt methode te behalen, zonder dat de complicaties optreden, welke anders zo frequent gezien worden bij deze stemrevalidatie methode.

De meest interessante en meest gebruikte ventielprotheses, de daarbij behorende methoden om een tracheo-oesophageale shunt aan te leggen en de respectivelijke voor- en nadelen worden in hoofdstuk IV besproken.
Het merendeel van de ventielprotheses is vervaardigd uit siliconenmateriaal, waarvan bekend is dat het aangetast kan worden door *Candida* species. Preventie van colonisatie met deze *Candida* species door selectieve oropharyngeale decontaminatie met een locaal toegediend antimycoticum, resulteert in een beter functionerende ventielprothese, waardoor minder intra tracheale luchtdruk nodig is voor shunt oesophageale stemgeving. Er wordt geadviseerd om een behandeling met antimycotische zuigtabletten in te stellen, wanneer de ventielprothese frequent vervangen moet worden in verband met een dysfunctie van het ventielmechanisme, òf wanneer de gelaryngectomeerde moeite heeft om voldoende luchtdruk in de trachea op te bouwen om een shunt oesophageale stem te produceren.

In hoofdstuk V wordt de Groninger button ventielprothese, die in de KNO kliniek van de Rijks Universiteit Groningen ontwikkeld is, beschreven. Tevens wordt een

gedetailleerde instructie gegeven omtrent de tracheo-oesophageale punctieprocedures voor het aanleggen van een shunt, hetzij tijdens de laryngectomie (primaire punctie), hetzij bij een al eerder gelaryngectomeerde patient (secundaire punctie).
Voorts wordt de techniek van een gemodificeerde myotomie van het P-E segment ten tijde van de laryngectomie beschreven. Deze myotomie kan hypertoniciteit van dit P-E segment voorkomen. Sedert de invoering van een dergelijke myotomie is een verdere afname geconstateerd van, het op zich al geringe aantal, niet op gang gekomen shunt oesophageale stemgevingen. Bovendien wordt de shunt oesophageale stemgeving door de myotomie vergemakkelijkt, omdat er minder intratracheale luchtdruk nodig is voor de stemgeving.

Hoofstuk VI bevat een beschrijving van de resultaten en de complicaties die gevonden werden bij het gebruik van de Groninger button ventielprothese in onze kliniek sedert de invoering van dit ventiel in 1980.
Er werd onderzoek verricht naar een groep van negenentachtig gelaryngectomeerden die gemiddeld gedurende een observatie periode van drieëntwintig maanden gevolgd werden. De overgrote meerderheid van deze gelaryngectomeerden was in staat om direct tijdens de eerste logopedische sessie te spreken met de shunt oesophageale stem; met de non-shunt oesphageale methode was geen enkele patient direct in staat om te spreken.
Aan het einde van de observatieperiode bleek één derde deel van de gelaryngectomeerden de shunt oesophageale stemgeving als de voornaamste stemgevingsmethode te gebruiken, één derde deel gebruikte overwegend de non-shunt oesophageale stemgevingsmethode en één kwart gebruikte beide methoden ongeveer evenveel.
Eén derde van de gelaryngectomeerden, waarvan een groot aantal een goede non-shunt oesophagus stemgeving had verworven, koos voor definitieve ventielprothese verwijdering, omdat zij de shunt oesophageale stemgevingsmethode niet meer gebruikten. De kwaliteit van de shunt oesophageale stemmen was echter superieur aan de kwaliteit van de non-shunt oesphageale stemmen, ook bij die gelaryngectomeerden die voor definitieve ventielprotheseverwijdering hadden gekozen.
De waargenomen complicaties van het gebruik van de ventielprotheses waren niet ernstig van aard en het merendeel kon met eenvoudige middelen effectief worden behandeld. Het aantal gelaryngectomeerden dat tevreden was over de ventielprothese was groot.

Conclusies
Stemrevalidatie van gelaryngectomeerden met behulp van een ventielprothese in een tracheo-oesophageale shunt is momenteel de beste stemrevalidatiemethode. De resultaten van de stemrevalidatie met de Groninger button tonen aan dat dit een goede ventielprothese is, die een groot aantal patiënten tevreden stelt. De tracheo-oesophageale punctie kan het beste ten tijde van de laryngectomie worden verricht, zodat de stem- en spraakloze periode van de gelaryngectomeerde tot het minimum beperkt blijft. De indicatiestelling voor een secundaire tracheo-oesophageale punctie en ventielprotheseplaatsing lijkt het beste gebaseerd te kunnen worden op een positieve insufflatietest, verricht onder doorlichting. Voorts toont dit onderzoek aan dat zowel het verrichten van een gemodificeerde myotomie van het P-E segment als de preventie van colonisatie van de ventielprothese met *Candida* soorten, bijdragen tot een efficiëntere shunt oesophageale stemgeving met behulp van een ventielprothese.
In het stem- en spraakrevalidatie programma na laryngectomie en primaire

tracheo-oesophageale punctie dient het aanleren van zowel de *shunt* oesophagus stemgeving als ook de *non-shunt* oesophagus stemgeving nagestreefd te worden, zodat de gelaryngectomeerde later kan kiezen welke methode hij wenst te gebruiken.

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