New concepts in prosthetic voice rehabilitation in the laryngectomized patient
Erenstein, S.E.J.

Citation for published version (APA):
Chapter 1:

Introduction to prosthetic voice restoration
Introduction

Although only five percent of all malignancies occur at sites in the head and neck - with an even smaller percentage of these tumors occurring at laryngeal level - the origins, treatment and consequences of laryngeal cancer are an issue of major concern for many involved.

Currently, the performance of a total laryngectomy is the accepted treatment of choice in cases of extensive laryngeal cancer or cancer recurrence after i.e. laser treatment, partial laryngectomy and/or curative dose radiotherapy. Although the overall five-year survival rate varies from 55 to 85%, it comes at the toll of loss of natural voice.19

In 1873, the first successful total laryngectomy was performed; it gave way to an era in which varying techniques for voice restoration were developed and ever so often promptly abandoned.19-21 Amongst the various techniques, esophageal speech, air-shunting methods and electromechanical artificial larynxes generated good results; of these, the air-shunting methods are the most satisfactory in voice fluency.17-18

Air-shunting methods are based on the principal of shunting pulmonary air - through a tracheo-esophageal fistula - into the pharyngo-esophageal segment, where it can be used to generate voice. Several shunting techniques were developed over the years. However, leakage of esophageal contents through the created shunt and stenosis of the fistula tract constituted recurrent problems influencing the results and popularity of shunting procedures.19-22

A major breakthrough came in 1979 when Blom, Singer and Hamaker introduced a new endoscopic fistula-creating technique and a new silicone prosthesis to be inserted into the fistula. With this prosthesis, named after its characteristic duckbill shape, laryngectomized patients generated fluent speech and no leakage of esophageal contents was noted through the created fistula.23, 24 The duckbill prosthesis was of the non-indwelling type, meaning that it did not remain fixed into the tracheoesophageal fistula and it could be easily removed for cleaning or replacement purposes. Owing to these non-indwelling characteristics, this prosthesis had the potential chance of spontaneous dislocation as well as not so favorable aerodynamic properties.
As a consequence, the development of a new generation of prostheses with a modified fixation method was triggered. These modifications, as first introduced by Panje, mainly consisted of the addition of a retaining esophageal flange allowing for better fixation into the tracheoesophageal fistula. In Europe, more specifically the Netherlands, this concept was further refined and generated bi-flanged prostheses such as the Groningen, Provox and Nijdam devices. Also other European countries participated in the prosthesis development, with the Traissac, Staffieri and Hermann as the most noticeable devices. Owing to their bi-flanged concept, these new generation prostheses were suitable for permanent indwelling insertion into the tracheoesophageal fistula until replacement of the device because of prosthesis dysfunction was due.

Eventually, this prosthesis dysfunction - noticeable through leakage of esophageal contents through the device and eliciting bouts of patient coughing at the intake of fluids - marks the end of the device life span. The unpredictability of the moment in time at which dysfunction occurs constitutes one of the enigmas of prosthetic use. Prosthesis life span has an inter- and intra-patient variability of weeks to many months and the currently accepted general life span for any type of voice prosthesis averages ninety days.

One of, if not the major factor contributing to prosthesis dysfunction, is the colonization of and consequently the deterioration of the device by mainly Candida yeasts. Yeasts and bacteria are omnipresent in the oropharyngeal microflora of all humans. Due to environmental factors, such as irradiation in laryngectomized patients, the yeast concentration in the microflora can be increased and thus contribute to the Candida colonization of the prosthesis. Different methods for influencing the local microflora, such as the use of anti-mycotic drugs or specific dietary measures, have contributed to a prolongation of life span but these do not constitute an ideal long-term solution and research on this issue continues.

Where Candida induced deterioration causes unwanted leakage through the prosthesis, leakage around the prosthesis because of gradual tracheo-esophageal fistula dilation is yet another of the frequently encountered problems in voice prosthesis using
laryngectomized patients. Solutions to this problem are often temporary and eventually the best option is the creation of a new fistula after closing the problematic one. Creating a new fistula does not differ from the initial post-laryngectomy situation in which Blom-Singer introduced their endoscopic puncture technique. Over the years, several variations of this technique, with and without immediate insertion of a voice prosthesis, have come into use. Currently, particularly in Western Europe, puncture of the fistula during laryngectomy (primary puncture) and immediate prosthesis insertion is the method of choice whereas secondary procedures are less frequently performed.

Although secondary puncture is a minor procedure, it is always performed in general anesthesia and patient admittance into the hospital is required, thus enhancing the patient burden.

Another topic of ongoing research is formed by the prosthetic aerodynamic qualities; the desired situation being one of a minimal amount of pressure needed for fluent, effortless speech. As all prostheses are essentially the same - a bi-flanged cylinder of varying lengths and a more or less constant diameter - aerodynamic improvements are to be sought in the valve mechanism. Until recently, flap and slit valves of different materials and dimensions were the only used valve types.

Gradually, through years of experience with the different types of prostheses, a clear definition of the desirable characteristics for any prosthesis took form. Ideally, any prosthesis should be of the frontloading insertion and replacement type, be indwelling, have favorable aerodynamic qualities, be easy to maintain and be less susceptible to Candida deterioration.

With all of these characteristics in mind, the frontloading VoiceMaster prosthesis was designed and developed. Favorable aerodynamic characteristics are achieved due to the unique and separately assembled ball valve that allows for Candida resistant materials to be incorporated. It is the only prosthesis that can be removed and consequently reinserted after inspection or cleaning.
As the VoiceMaster underwent further development and tests in our clinic, we have been using the device since the first prototypes and our experiences with this device will be presented in this thesis.

All of the aforementioned prosthesis related issues are amply discussed in this thesis, as well as research of new concepts within the various prosthetic voice related issues. The following issue-based chapters are included:

In *chapter 2*, several issues relating to tracheoesophageal puncture and voice prosthesis use are dealt with. The question is raised which considerations should be taken into account when performing tracheoesophageal puncture and which local factors influence the function of the freshly inserted prosthesis. Furthermore, whether the modern frontloading prostheses are capable of withstanding possible dislocating factors at the fistula site and whether it is safe to insert these devices during laryngectomy or whether one should opt for the use of a more traditional type of backloading device. Also, if a more traditional backloading type of prosthesis is called for whether it would be possible to develop such a prosthesis that incorporates both the sturdiness of the backloader with the more favorable aerodynamic characteristics of a new generation frontloading device. Finally the question is raised if there remains room for improvement within the techniques of tracheoesophageal punctures, more specifically, the question if it would be possible to modify the current general anesthesia techniques to one suitable for outpatient use in local anesthesia.

In *chapter 3*, the specific factors defining prosthesis function are defined. Given these factors, the possibilities for design and development of a new prosthesis (the VoiceMaster) in which all of these factors are incorporated are explored. The results obtained with this new prosthesis, both in our own patient population as well as in a multi-center study, are presented and an analysis of the factors influencing use and results of the device is made. Also, the question if this new prosthesis merits a place within the currently available array of prostheses is dealt with. Finally, this chapter also
focuses on the issue of further changes within standard prosthetic design, more specifically if it is possible to decrease regular prosthesis diameter, hence dealing with this issue of increasing popularity within post-laryngectomy voice rehabilitation.

In chapter 4, the issue of Candida related prosthesis dysfunction is dealt with. The question is raised if the applied contemporary solutions for this often encountered problem in which the focus lies on the local eradication of Candida, should not be revised if other possible contributing factors such as gastro-esophageal reflux (GERD) are taken into account.

In chapter 5, the discussion and conclusions of this thesis are to be found. A summary of the presented research in this thesis is given in English and in Dutch in chapter 6.
References

20. Staffieri M. Neue chirurgische möglichkeiten zur rehabilitation der stimm nach total


