Chapter 5:

Discussion and conclusions
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Even though tracheo-esophageal prosthesis-assisted speech signified a major breakthrough in post-laryngectomy voice rehabilitation techniques, ample room for further improvements remains. Current research within this field focuses on several aspects such as variations within the used surgical techniques - be it at the time of the laryngectomy (primary) or during post-laryngectomy (secondary) procedures-, prosthesis-related improvements and analysis of the influences of the prosthetic environment.

Exploration of these concepts with a thorough determination of those aspects meriting further attention or improvement formed the scope of this thesis and hence the title “New concepts in prosthetic voice rehabilitation in the laryngectomized patient”.

A thorough analysis of new developments within the technique of tracheo-esophageal fistula creation (tracheo-esophageal puncture, TEP) as well as in the type of prosthesis used during this procedure rendered several issues in need of improvement.

Whereas TEP was initially intended as a secondary voice rehabilitation technique, it soon saw many variations of which immediate insertion of an indwelling prosthesis during laryngectomy (primary TEP) has become the most popular one. If opted for primary TEP with immediate prosthesis insertion, the traditional use of a backloading and indwelling device has long since proven to be a safe choice. These sturdy backloading devices are able to withstand possible dislocating forces such as edema at the freshly created tracheo-esophageal fistula site. However, a current tendency among surgeons to insert supplier new generation frontloading prostheses into the freshly created tracheo-esophageal fistula is observed. Although these new prostheses are a worthwhile improvement over the traditional backloading types, - specifically if the improved insertion method enabling easy non-cumbersome outpatient replacement and aerodynamic aspects are taken into account- we consider their use within fresh edematous fistulas to be unsafe. Because of the very supple materials of which these devices are manufactured, they are less adept at withstanding local dislocating forces and have a considerable risk of dislocation into the trachea. Furthermore, the method used for insertion of these frontloading prostheses into the fistula tract requires blind
introduction into the freshly created tracheo-esophageal fistula and we believe this blind insertion method to behold other potential risks.

One such risk is formed by the possible creation of a fausse-route when the device is maneuvered blindly into the freshly created and therefore not yet well formed fistula tract. Also, because of the blind frontloading insertion into the fresh fistula, disruption of tissue structures forms a potential other risk and should be yet another reason to ensure refining from the use of frontloading prostheses during primary TEP.

In view of the aforementioned factors we strongly advise against the use of frontloading prostheses during TEP procedures and thus opt for a more traditional backloading device. This, however, forms a dilemma as these traditional backloading devices have been shown to have less desirable characteristics when compared to the new generation frontloading devices. These characteristics mainly vary in the less cumbersome replacement in the outpatient clinic and the more favorable aerodynamic qualities of the modern frontloading devices.

Because of these considerations the VoiceMaster Primo prosthesis was designed and developed in our clinic. This backloading device has an incorporated ball-valve and thus combines the desired sturdiness with favorable aerodynamics. A preliminary in-vivo study with the Primo prosthesis was conducted in our clinic and the achieved encouraging average life span of 2.2 months encouraged us to promote the use of this device in other European countries.

Some professionals may consider the backloading insertion of the Primo prosthesis to be a drawback, specifically when outpatient replacement methods (cumbersome backloading versus less cumbersome frontloading replacement) are taken into account. However, the relatively cheap production of this all-silicone prosthesis may very well render it the affordable device for voice rehabilitation in countries with a less prosperous economical situation.

Bearing economical aspects in mind, we developed a variation of the currently used secondary TEP technique, tailoring it into a simple technique with local anesthesia suitable for out-patient use. The costs of hospitalization -necessary for regular secondary TEP with general anesthesia- as well as the commonly encountered frustrating problem
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of waiting lists can thus be bypassed. We achieved excellent results with this new technique and view it to be a valid alternative in those cases of necessary TEP after extensive laryngo-pharyngeal surgery or previous fistula related problems. Also, it could be the ideal means of providing an affordable TEP-procedure for a large world-wide group of patients whom have not yet been able to benefit from prosthetic voice rehabilitation.

A new concept within prosthetic voice rehabilitation, more specifically a new concept within voice prosthetic design is another amply discussed topic within the presented work of this thesis. Analysis of accumulated experiences with several types of prosthesis – both in literature as through personal experience – allows for a careful consideration as well as a clear definition of favorable characteristics for any type of voice prosthesis. These favorable characteristics for indwelling voice prostheses comprise easy frontloading insertion into the tracheo-esophageal fistula, a low resistance to airflow and a resistance to Candida yeast induced dysfunction. With these favorable characteristics in mind, the VoiceMaster voice prosthesis was designed and developed by Professor Paul F. Schouwenburg. Over the past few years, ongoing development of the VoiceMaster voice prosthesis has been a gratifying issue of research, both in our own clinic as well as in a multi-center setting.

A preliminary study conducted in our clinic, in which the very first pre-production (prototype) models of the VoiceMaster prosthesis were used, generated very encouraging results. Of course, as with any new product, points in need of improvement were detected.

One such point was the sticking of the ball-valve to the valve seat. This sticking greatly influenced the aerodynamic characteristics of the prosthesis as increased pressure is needed to open the valve for phonation. Analysis of this problem showed it to be complex, finding its basis in both the local anatomy at the tracheo-esophageal fistula site as well as the design of the valve seat itself. Another issue encountered within the use of the pre-production models was snapping of one of the ball-valve suspension springs upon hyperextension of the prosthesis during frontloading insertion into the tracheo-esophageal fistula. Careful examination of these snapped suspension springs, revealed
that the snapping always took place in the hinge of the suspension spring. Although this snapping was of course bothersome - as it renders the prosthesis useless - it had no consequences to safety as attachment of the prosthesis to the insertion aid is independent of the ball-valve suspension mechanism.

Even though the above mentioned points in need of improvement were detected, it is our opinion that the most important conclusions of this preliminary VoiceMaster study should be that no complications were observed and the prosthesis proved to be safe in use.

Based on the results of the preliminary study, further detailing of the VoiceMaster took place. Specifically, the valve seat was redesigned and the snapping of suspension springs was dealt with through revision of the production mould and production process. These changes resulted in the currently available VoiceMaster prosthesis.

This redefined VoiceMaster prosthesis was put to the test in a consecutive, larger multi-center study. Whereas the preliminary study generated an average prosthesis life span of 2.1 months, the average device life span ranged up to 4.8 months with the new design. Of course, not only life span should be seen as a measure for prosthesis viability, but other factors such as ease of use and specific characteristics should also be taken into account.

One of such specific VoiceMaster characteristics is the unique possibility of removal for inspection, cleaning and re-insertion of the same device. Analysis of the accumulated patient data showed a marked increase in life span if this characteristic was applied. In the individual case, a life span increase of many months could easily be achieved. However, not all professionals working with the device were willing to invest the minimal amount of time needed for this unique aforementioned action, or perhaps busy outpatient clinics or an insufficient familiarity with this new prosthesis played a role.

Analysis of the multi-center results also led to a clear definition of factors influencing VoiceMaster insertion into the tracheo-esophageal fistula. These factors include tracheostoma size - the stoma size should obviously allow for accommodation of the prosthesis - as well as the position of the tracheo-esophageal fistula. As frontloading of the VoiceMaster requires the prosthesis to be stretched into a spindle shape, space
within the esophagus to accommodate this elongated prosthesis is necessary. Therefore, the fistula is ideally in the upper quadrants of the posterior tracheo-esophageal wall, hence allowing for the desired upward (cranioposterior) direction of insertion. In view of these factors influencing successful VoiceMaster insertion, an active evaluation of the tracheostoma and fistula site is required before use. Motivated professionals using the VoiceMaster demonstrated an evident learning curve in assessing patients for VoiceMaster use.

Skeptics amongst those professionals active in voice prosthetic rehabilitation may very well consider this necessary active evaluation of the fistula site before insertion of the VoiceMaster a definitive negative factor, and this could very well cause them to refrain from use of this prosthesis.

Although it is certainly true that active fistula assessment requires some effort and additional skills and also that not all sizes (as in other types of prostheses) are currently available, we think several of these skeptics may very well reconsider their position in view of the achieved long-term results of VoiceMaster use.

The long-term evaluation of VoiceMaster use was performed within our laryngectomized patient group and reflected an average device lifetime of 6.5 months. This lifetime places the VoiceMaster device amongst the best-cited prosthesis lifetimes as stated in literature today.

Another prosthesis-related issue dealt with within this thesis is that of the often encountered and bothersome fistula dilation, resulting in leakage of esophageal contents into the trachea. Voice prosthesis induced mechanical trauma is often suggested to be a contributing dilation factor. Therefore, increasing votes for a decrease in prosthesis size are heard amongst prosthesis users as a decrease in size would cause a decrease in mechanical trauma at the fistula site.

We conducted in-vitro research to assess the possibilities of such a decrease. If any prosthesis were to be decreased in size, this would of course imply a decrease in both outer and inner diameter. Changes in diameter are of course of influence to the aerodynamic characteristics of the prosthesis, more specifically the effective inner diameter. Our in-vitro testing demonstrated a decrease of the effective inner diameter of the prosthesis by 1.0-mm (from the regular 5.0 to 4.0-mm) to be possible without
significant aerodynamic consequences. Of course, all tests were conducted within the average laryngectomized phonation airflow range to allow for extrapolation to an in vivo setting.

A smaller prosthesis diameter also implies a lesser weight and as a possible consequence less trauma to the tracheo-esophageal fistula. If a decrease of the regular prosthesis diameter with 1-mm (from the regular 5.0 to 4.0-mm) were to be performed this would also lessen the prosthesis weight with 18\%\). We believe these findings to be of importance if manufacturers are to seriously consider prosthetic downsizing in the future.

Finally, the issue of frequent prosthesis dysfunction necessitating frequent prosthesis replacement is addressed. The need for frequent prosthetic replacements can be a genuinely frustrating issue for many laryngectomized patients as well as their treating physicians. Not only the frequency in which the prosthesis has to be replaced but also - perhaps even specifically- the unpredictability of the prosthesis life span ensures a wide range of research focusing on this issue.

Candida yeasts and changes in the local micro-environment have been shown to play a predominant role within this prosthesis dysfunction. In order to assess the influence of Candida within our laryngectomized patient group, an analysis of the biofilm present on the surface of dysfunctioning voice prostheses was performed. A predominance of Candida Albicans and commensal oral microflora was seen within our microbial cultures. Our series supports other such findings as cited in literature and also represents the largest cultured prosthesis series. The effects of radiation therapy, specifically the radiation therapy induced xerostomia, shortened the lifetime of the first inserted prosthesis in particular. This finding can be readily explained by the known increase in Candida concentration in irradiated patients occurring simultaneously with a thinner protective salivary film on the prosthetic surface.

Several strategies have been developed over the years in order to reduce local Candida concentration. One such frequently employed strategies -although non-scientifically supported- is the local application of anti-mycotic drugs and does not take other possible mechanisms contributing to the local micro-environment into account.
We think gastro-esophageal reflux disease (GERD) - an often present entity in head and neck cancer patients - to be one such factor that should very definitively be taken into consideration when dealing with frequent Candida induced prosthesis dysfunction. Previous research in literature has shown viable Candida to be present within the stomach and given the known GERD predominance we therefore believe a sole focus of anti-Candida therapy on the local fistula site to represent a shortcoming. To analyze this possible role of GERD a small pilot-study was conducted within a select group of patients with a higher than average prosthesis replacement rate. The majority of these patients had reflux related complaints, whilst not all of them were on anti-reflux medication. Upon replacement of the prosthesis, matched samples of the prosthetic surface biofilm and as well as gastric contents were obtained. A morphological comparison of the Candida species present rendered positive matches for each pair of samples. This renders credibility to our belief that GERD should be taken into account. Furthermore, when those patients within our group who had no previous anti-reflux therapy started regular anti-reflux medication an increase in prosthesis life time was seen. Of course we realize that the presented data are those of only a very small pilot-study within a selected patient group, but we believe the results to be of such importance that they merit a place within this thesis and further future research.