Clinical aspects of postlaryngectomy voice prosthetic rehabilitation
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The most important task after a total laryngectomy is rehabilitation of voice. Tracheoesophageal speech with the use of valved silicone rubber prostheses gives laryngectomized patients the immediate ability to restore their voice after surgery. Tracheoesophageal speech is known to be superior to alternative methods, such as esophageal speech and artificial laryngeal speech.

Indwelling tracheoesophageal voice prostheses need to be replaced due to leakage of esophageal fluids into the trachea or increased airflow resistance. Both leakage and airflow resistance of a voice prosthesis are determined by both the design of the prosthesis, including the valve, and the degree of colonization of the esophageal side of the prosthesis by bacteria and yeast. This biofilm formation on the esophageal site of the voice prostheses primarily determines the device lifetime. On average, proper functioning of these prostheses varies from 3 to 4 months, but in some patients the device lifetime is remarkably shorter. Frequent replacements are harmful to the tracheoesophageal fistula causing granulations, scar tissue formation and insufficiency or stenosis of the fistula. Furthermore, frequent replacements are unpleasant for the patients and can lead to high costs in health care.

Biofilm formation is a complex process starting from the moment the voice prosthesis is placed in the tracheoesophageal fistula. Several internal and external factors influence the formation of the biofilm, e.g. previous radiation, the microflora in the neopharynx and dietary components. Due to its composition reduction of a biofilm is difficult as microbial resistance is one of its survival mechanisms.

In this thesis several products capable to interfere in the biofilm formation process are tested in vitro and in vivo and possibilities to increase the in situ lifetime are discussed. The second aim is to improve the quality of life of laryngectomized patients and to reduce the health care costs for this group of patients.

In Chapter 2 the artificial throat model was modified to a model comparable to the clinical situation. As patients may consume a food product immediately after replacement of a prosthesis, test products must be added from the onset of the biofilm formation in the artificial throat in stead of on an existing biofilm. Buttermilk, Yakult Light fermented milk drink and N-acetylcysteine prevented biofilm formation in this artificial throat model. Next to their known reductive effect on biofilm formation, these products are very promising for a clinical study to evaluate their effect on the in situ lifetime of the voice prostheses.

In Chapter 3 the effect of buttermilk and Yakult Light fermented milk drink on the lifetime of Provox® voice prostheses was tested both in vitro and in vivo. In vitro results showed a reduction of bacteria in the biofilm, but a stimulation of the amount of yeast. The in vivo part of the study showed a reduction of both bacteria and yeast after consumption of Yakult Light fermented milk drink and, concurrently, a significant increase of the in situ lifetime. Buttermilk reduced only the amount of yeast and stimulated bacterial growth. As a consequence, the in situ lifetime did not significantly decrease. Although yeasts are considered to be responsible for valve failure, a reduction of only the amount of yeast did not influence the in situ...
lifetime. This observation supports the theory that biofilm formation is a complex process in which both bacteria and yeast play an important role and in which both species are responsible for dysfunction of the voice prosthesis.

In Chapter 4 the influence of N-acetylcysteine on the integrity of the biofilm and the in situ lifetime of Provox®2 voice prostheses was assessed in vitro and in vivo. The importance of extracellular polymeric substances (EPS) or slime in the biofilm was discussed. EPS glues the biofilm together and to the surface and is considered to be responsible for the lack of influence of antimicrobial drugs on biofilm formation. N-acetylcysteine is a mucolytic drug which disrupts the disulfide bridges in mucus and therefore may disrupt the integrity of the biofilm. The biofilm on the voice prostheses removed from the artificial throat showed a reduction of both bacteria and extracellular polymeric substances. In contrast to the in vitro study, the in situ lifetime of the prostheses in the clinical part of the trial did not increase. As it is generally known that a reduction of biofilm formation will positively effect the lifetime of tracheoesophageal voice prostheses, NAC still remains a promising drug for the prolongation of the in situ lifetime. The negative effect on the lifetime is possible a dose-related effect as it is known that a certain amount of biofilm is necessary to seal off the valve of the Provox®2 prosthesis. As dose-related effects of NAC have been reported before, further research is necessary to determine the ideal dosage of NAC in Provox®2 voice prostheses.

In Chapter 5 the effect of biofilm formation in Provox®2 voice prostheses on airflow parameters was evaluated in vivo by comparing airflow parameters of new and of dysfunctional, biofilm covered Provox®2 voice prostheses, when the voice prosthesis is in situ. The majority of patients needed a new voice prosthesis because of leakage through the voice prostheses and only 9% of the patients had problems because of an increased airflow resistance. Previous in vitro studies showed an increased airflow resistance as a consequence of biofilm formation. In this study in situ measurements showed a significant decrease of airflow resistance with a biofilm present in relation to new clean voice prostheses without a biofilm present. The discrepancy between ex situ and in situ measurements can be explained because of the multiplicity of factors influencing the voice and speech within patients. In the specific patients group in which prosthesis replacement was necessary due to increased phonatory efforts also decreased airflow resistances were measured. The major cause of these remarkable results is obviously not found in a dysfunctional device but may be explained by problems in the neopharyngeal pouch in relation to the esophageal flange of the prosthesis. As aerodynamic problems only account for a small part of the reasons for replacement of voice prostheses, reduction of biofilm formation still remains a very relevant factor prolonging the in situ lifetime of voice prostheses.

In Chapter 6 the Groningen frontloading system was clinically evaluated. The aim of this study was twofold. First, to evaluate and validate a new, comfortable method of insertion for the Groningen voice prostheses as compared to the Provox
anterograde method. Second, to evaluate the lifetime of the Groningen Ultra Low Resistance (ULR). With the use of structured questionnaires, the opinion of both patients and physicians about this new method and voice prosthesis was registered. In the majority of cases physicians were very pleased about the use of this new method, and considered it adequate and friendly in use. The physicians preferred this new method in 84% of the patients. The patients reported no differences in comfort compared to the Provox anterograde method and no differences in effort to speak with the Groningen ULR compared to the Provox®2. The lifetime of the Groningen ULR was 150% of the lifetime of the Provox®2 and, as a consequence of these positive results, only 12% of the patients preferred the Provox®2 anterograde method. With this new method a major reduction of health care costs can be achieved as the cost of a Groningen ULR is approximately one third of a Provox®2 and the in situ lifetime is 1.5 times the lifetime of a Provox®2. In conclusion, we created a frontloading system comparable to the Provox®2 anterograde system and provided one standardized method of replacement for the Groningen Low Resistance and ULR voice prostheses. Important advantages of the Groningen frontloading system are a possible major reduction of health care costs and an improvement of the quality of life of laryngectomized patients by increasing the lifetime of their voice prostheses.

In Chapter 7, the general discussion of this thesis, the reasons to prolong the in situ lifetime of voice prostheses is discussed. The need to explore other products in stead of antimicrobial drugs to prevent biofilm formation is discussed. Furthermore, several suggestions are made to improve the quality of life of laryngectomized patients and to lower the health care costs for this specific patient group.