Chapter 7

Summary and conclusions

The larynx plays a crucial role in speech, breathing and swallowing. It has three important functions: control of the airflow during breathing, protection of the airway and production of sound for speech.

When a cancer in the laryngeal region is in an advanced stage and cannot successfully be treated by other methods like irradiation therapy, surgical treatment is necessary. This sometimes leads to a total laryngectomy. This life-saving operation consists of the surgical removal of the larynx including vocal folds and epiglottis. The trachea is cut from the larynx and is led outside to the neck, where it is sutured to the skin forming a tracheostoma. Breathing is now performed via the tracheostoma, as the airway tract is completely separated from the alimentary tract. To restore voice, the surgeon usually creates a shunt between trachea and esophagus. A silicone rubber valve is then placed in this shunt. Closing the tracheostoma with a thumb or finger forces the air through the shunt valve into the oesophagus. On top of the oesophagus the oesophageal sphincter starts to vibrate thus functioning as new vocal folds (pseudoglottis). Hands-free speaking can be realised by placing a tracheostoma valve (TSV) on the tracheostoma.

For these laryngectomized patients, a project called “Artificial Larynx” (Eureka project EU 72310) started in 1992 in Groningen. The subject of this thesis is to study parts of this artificial larynx: a valve system to switch between breathing and speaking and a new fixation method, the tissue connector (TC). The valve system can already be applied as a TSV. The TC can be used to improve existing fixation methods of TSVs and shunt valves.

In chapter 2 the design and in vitro test of an improved Groningen TSV, better known as the Adeva Window®, is described. The Window® consists of a “cough” valve with an integrated (“speech”) valve, which closes for phonation. The cough
valve opens as the result of pressure produced by the lungs during a cough. The speech valve closes by the airflow produced by the lungs, thus directing air from the lungs into the esophagus at a deliberately chosen moment.

An experimental set-up with a computer-based acquisition program (Labview for Windows) was developed to measure the pressure at which the cough valve opened and the flow at which the speech valve closed. In addition, the airflow resistance coefficient (ARC) of the TSV was defined and measured with an open speech valve. Both dry air from a cylinder and humid expired air were used.

Results showed a pressure range of 1-7 kPa to open the cough valve and a flow range of 1.2-2.7 L/s to close the speech valve. These values were readily attained during speech, while the flow range occurred above values reached in quiet breathing. The ARC is $1.2 \times 10^2 \text{ Pa} \cdot \text{s}^2 \cdot \text{ l}^{-2}$, which lies in the range of the entire airway resistance ($1.2 \times 10^2 - 4.7 \times 10^2 \text{ Pa} \cdot \text{s}^2 \cdot \text{ l}^{-2}$) in quiet breathing.

The device appeared to function well in physiological ranges and was optimally adjustable to an individual setting. No significant differences were measured between air from a cylinder and humid expired air.

The ADEVA Window® has already been brought to the market by ADEVA Medical (Lübeck, Germany) and is now being tested in a series of patients in the ENT clinics of Würzburg and Stuttgart.

The methods used to obtain the aerodynamic characteristics of the designed TSVs can be used as a reference method for comparing aerodynamic characteristics of various TSVs. This method can also be used for shunt valves, voice-producing prostheses and Heat and Moisture Exchangers.

The design and test of a new TSV is presented in chapter 3. The TSV is made of polycarbonate and consists of a large round valve with a small integrated one-way valve. The large round valve can be moved in a round housing. This new TSV is based on the mechanism of inhalation to improve existing TSVs. The TSV closes by inhaling strongly (instead of exhaling), so all exhaling air is available to speak. The device stays in “speak-position” automatically, until the patient deliberately changes the device to “breathing position” by a strong expiration. If the patient has consumed all exhaling air for speech, he can inhale again, without changing the device, because the small valve automatically opens, thus allowing him to speak as long as he wants.
The experimental set-up described in chapter 2 was used to measure the pressure at which the valve opened and the flow at which the valve closed. Pressure and flow needed to open and close the adjustable valve were measured for different positions. Also, the ARC values for inhaling and exhaling were measured.

The airflow necessary to close the TSV ranges from 1.6-3.8 L/s. The opening pressure of the valve ranges from 1-7 kPa. The ARC for inhaling is $2.9 \times 10^2 \ [Pa \cdot s^2 \cdot l^{-2}]$ and for exhaling is $4.3 \times 10^2 \ [Pa \cdot s^2 \cdot l^{-2}]$. The device appears to function well in physiological ranges and is optimally adjustable. The ARC values lie in the range of the entire airway resistance (1.2 $\times 10^2$ - 4.7 $\times 10^2 \ [Pa \cdot s^2 \cdot l^{-2}]$) in quiet breathing.

To decrease the ARC value and prevent slanting, an improved TSV (the Inhalation TSV) based on the inhalation mechanism is portrayed in chapter 4. The Inhalation TSV is made of polycarbonate. The TSV consists of a housing with an eccentric axis and a large valve, which revolves on this axis. A small half-moon shaped silicon one-way (inhale) valve is integrated in the large valve making inhalation during speaking possible.

The experimental set-up described in chapter 2 was used to measure the pressure at which the valve opened and the flow at which the valve closed and to measure the ARC values. A new in vivo set-up was developed to measure the performance of the Inhalation TSV in patients. The Inhalation TSV was compared in vivo with existing TSVs for the parameters; air volume to close TSVs, speaking time of the TSVs and speaking volume of the TSVs.

The device is optimally adjustable, as the airflow to close the valve ranges from 1.2 to 3.8 L/s and the opening pressure ranges from 1.2 to 7.1 kPa. The ARC value of the Inhalation TSV during breathing is $0.6 \times 10^2 \ [Pa \cdot s^2 \cdot l^{-2}]$ and the ARC value for inhaling in speaking position is $22.7 \times 10^2 \ [Pa \cdot s^2 \cdot l^{-2}]$. The Inhalation TSV is an improvement regarding to existing devices. The Inhalation TSV makes inhalation in the "speaking position" possible and saves up to 22% of the total exhalation volume for speaking compared to existing TSVs.

This Inhalation TSV has been patented by ADEVA Medical and will be brought to the market.

In chapter 5, the biocompatibility of a novel tissue connector (TC) is tested. This new TC has been developed to improve the fixation method of tracheostoma.
valves and shuntvalves. It basically consists of a ring that will be integrated into surrounding tracheal soft tissue. The valves can be placed in the ring.

To test the principle of the TC a prototype consisting of a subcutaneous polypropylene mesh and a percutaneous titanium stylus was implanted into the backskin of 10 rats by a two-stage surgical procedure. We reasoned that if a firm connection can be realized with the skin, a firm connection with the trachea will also be possible. The subcutaneous part was implanted first, followed by the percutaneous part after 6 weeks. The complete TC with surrounding tissue was removed 8 weeks later and examined histologically.

The principle of the new TC proved to be effective: hardly any epithelial downgrowth appeared, and adhesion of soft tissue was demonstrated. No infection or severe inflammation reaction was detected. The TC seems appropriate for its intended use.

The next step, testing the novel TC in the trachea is reported in chapter 6. Two experiments were performed.

In experiment 1, a polypropylene mesh was implanted around the trachea of 4 goats. The mesh was removed after 6 and 12 weeks.

In experiment 2, the actual TC consisted of 2 titanium rings (inner ring and outer ring) that were both executed as a quarter ring, fixed on each other, and clamp a polypropylene mesh like a sandwich in between. The titanium inner ring was placed in an incision between 2 tracheal rings thus penetrating the trachea with the mesh around the trachea and the fixed titanium outer ring on the outside of the trachea. The TCs were removed after 12 weeks.

Histological examination of experiment 1 showed that the mesh was entirely infiltrated by host tissue. Inflammatory cells and high vascularity were observed in 3 of 4 implants.

In experiment 2, the mesh was completely incorporated by mature connective tissue. At some areas cartilage tissue had been developed. In 3 of 4 implants the titanium inner ring is overgrown by epithelial tissue. Some cell debris and inflammatory cells were detected between the titanium rings.

In conclusion, the TC was firmly embedded in the trachea thus being appropriate for its intended use. Overgrowth of epithelium and inflammatory cells can probably
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be prevented by redesigning the titanium rings and by sealing up the space between them.

Consequently, this new TC seems appropriate for its intended use. To apply this TC clinically a couple of steps must be taken. The next step is the implantation of a TC consisting of a complete titanium ring. The TC should also be tested in long-term experiments. Another recommended experiment is radiation of the laryngeal area preceding implantation of the TC. This latter step is necessary, as laryngectomees usually have been radiated.

Finally, both applications of a tissue connector and the developed tracheostoma valves will form an external artificial larynx, which will improve quality of life of laryngectomees. The external artificial larynx is a first stage in the development of the ultimate goal: a totally implantable artificial larynx.