Chapter 3

Design and Test of a New Tracheostoma Valve Based on Inhalation

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Abstract
Tracheostoma valves are used to make hand-free speaking possible for persons who have undergone a laryngectomy. To design and test a new tracheostoma valve to improve existing tracheostoma valves. The tracheostoma valve closes by means of strong inhalation so that all the air that is exhaled is available for phonation. The device automatically stays in the “speak-position” until the patient deliberately changes the device to the “breathing position” by a fast expiration. If all the air that has been exhaled has been consumed during phonation, the patient can inhale again, without changing the device, because a small valve automatically opens, thus allowing phonation without time limits. An experimental setup with a computer-based acquisition program was used to measure the pressure at which the valve opened and the flow at which the valve closed. The pressure and flow needed to open and close the magnetic adjustable valve were measured for different positions and contained in the computer through a data acquisition program. Also, the airflow resistance coefficients for inhaling and exhaling were measured. The airflow necessary to close the tracheostoma valve ranges from 1.6 to 3.8 l/s. The opening pressure of the valve ranges from 1 to 7 kPa. The airflow resistance coefficient is $2.9 \times 10^6 \ [Pa \cdot s^2 \cdot l^{-2}]$ for inhalation and $4.3 \times 10^6 \ [Pa \cdot s^2 \cdot l^{-2}]$ for exhalation. The device appears to function well in physiological ranges and is optimally adjustable. The airflow resistance coefficient lies in the range of the entire airway resistance ($1.2 \times 10^6 - 4.7 \times 10^6 \ [Pa \cdot s^2 \cdot l^{-2}]$) in quiet breathing.

3.1 Introduction

Severe cancer in the laryngeal or hypopharyngeal region often requires a total laryngectomy. After this operation, voice restoration usually takes place by tracheoesophageal puncture and the insertion of a shunt valve in the puncture. By closing the tracheostoma manually, air flows through the shunt valve to an air chamber enclosed by soft tissue at the top of the oesophagus (pseudoglottis), which starts to vibrate and acts as new “vocal folds”.

One of the major problems for the patient who has undergone a laryngectomy and voice rehabilitation concerns the tracheostoma. The stoma attracts attention, especially when the patient has to close it with a thumb or finger in order to speak. Also, stoma closure can be unhygienic and impractical when the patient’s hands are dirty. Stoma closure is also impossible during certain activities, eg, while driving a car, eating, or participating and sports. Several tracheostoma valves (TSVs) have been developed in an attempt to overcome this problem.

The Blom-Singer TSV was the first TSV described in the literature.\(^1\) It consists of a valve diaphragm that closes when the expiratory flow is stronger than in normal breathing. Decreasing expiratory flow reopens the diaphragm. The valve diaphragm is available in 4 thicknesses, therefore, the flow to close the TSV can be adjusted to the individual patient. The TSV is fixed in a convex flexible housing that is glued around the stoma with special adhesives.

Herrmann and Koss\(^2\) described their experience with the ESKA-Herrmann TSV (ESKA Implants, Lübeck, Germany). This device has a metal plate in it that contacts a magnet in the housing. An increase of expiratory flow closes the valve to allow speech. By rotating the valve, the contact area between magnet and plate can be changed to make the moment of valve closure adjustable during use. The TSV is fixed by a surgical technique that requires the creation of a chimney on top of the trachea. A close fit between the trachea and the TSV is necessary to prevent leakage.

In 1987, Singh\(^3\) described a rectangular TSV that can be fixed in a stoma button. A movable flap in the TSV closes when the patient wants to speak. The flap has an angle of inclination, which can be adjusted with a screw, thus regulating the flow needed to close the valve.

In 1992, a new, adjustable Blom-Singer TSV\(^4,5\) with a silicon diaphragm became available. The opening of the diaphragm can be adjusted and with it the flow needed to close the valve. This valve is connected in the same way as the first-generation TSV.
Verkerke et al.\textsuperscript{6} published a report on the design and test of a TSV that makes coughing possible. This device consists of 2 valves: a speech valve that makes speech possible, using the same mechanism as the ESKA-Herrmann TSV, and a cough valve. Both valves can be adjusted individually according to the patient’s wishes. Geertsema et al.\textsuperscript{7} described an improved version of this valve. The Blom-Singer flexible housing was used to connect the TSV to the stoma.

All these existing TSVs have to be closed by an extra spurt of expiratory air. They would be improved by a valve that can be closed by an extra spurt of inspiratory air instead of by and exhalation. The advantage of such a device is that all expiratory air is available for speech. Moreover, inhalation precedes speaking, which makes speech more natural.

The ability to inhale during phonation has a further advantage. The TSV can stay automatically in the "speak-position", until the patient deliberately changes it to the "breathing position" by a fast expiration. Inhalation during speaking allows the patient to extend the duration of speech indefinitely. This article provides information on the design and in vitro test of a new TSV, based on the above-mentioned improvements.

3.2 Materials and methods

3.2.1 TSV design

The TSV, which is shown in Figure 1, is 2 cm high and 2.5 cm wide. It is made of polycarbonate, a very strong but very light, size- and form-fixed material that resists weak acids very well and does not absorb liquid. The TSV can be attached to the stoma by housing it in a fixation ring, which is attached to the skin with adhesives, double-sided foam or tape disks, and glue\textsuperscript{5}. It consists of a large valve that can be moved in a housing (Figure 2). The large valve comprises an integrated small valve and a ring with magnets around the lower side of the large valve. The large valve can be put in 2 positions: the breathing position and the speaking position.

When the patient wants to speak, he or she has to inhale strongly while the TSV is in breathing position and the large valve will close (speaking position). When the stoma is closed, air will flow through the shunt valve between the trachea and the oesophagus to the pseudoglottis, thereby enabling the patient to speak. After all the air for speaking has been consumed, the patient can inhale again, which opens the small valve. This inhalation makes it possible for the patient to speak as long
as he or she wants to without the necessity of changing the valve system. To stop speaking, the patient can reopen the large valve again by a strong exhalation.

Figure 1: Tracheostoma valve with open valve (breathing position, left) and with closed valve (speaking position, right).

The flow for closing the large valve and the pressure for opening it are adjustable. A ring around the large valve has magnets at its upper and lower side. The housing incorporates metal plates at the top and bottom. The metal plates are formed in such a way that the area of the plates is shaped from small to large. The contact area between metal plate and magnet determines the closing and opening force of the large valve. Rotating the metal plate by rotating the outside of the housing can change these forces.

Figure 2: Drawings of the tracheostoma valve in the breathing, speaking and inhaling-during-speech positions.
3.2.2 Setup

The in vitro setup to measure the flow values necessary to close the large valve and the pressure values necessary to open the valve after speaking is illustrated in Figure 3. The apparatus consists of 2 different flow tube setups: flow tube setup 1 measures the flow and pressure values necessary to respectively open and close the large valve; flow tube setup 2 measures the airflow resistance coefficient (ARC). This term will be explained below. Both setups have a flow head to measure the flow and a pressure transducer to measure the pressure. The measured data were imported in the computer with a data acquisition program (Labview for Windows 3.01, National Instruments, Austin, U.S.A.). The airflow, which is produced by blowing directly in the tube by mouth, was measured with a flow head (Lilly flow head, Mercury Electronics, Glasgow, Scotland); the flow head was calibrated with a flow meter (Tube type R-8M-25-4F, Float No. 8-RS-14, Brooks Instrument, Veenendaal, The Netherlands) and the pressure was measured with a pressure transducer (Model 267BC, Hewlett Packard, Waltham, U.S.A), which was calibrated against a water manometer.

![Diagram of setup](image-url)
3.2.3 Measuring method

The flow necessary to close the large valve and the pressure necessary to open the large valve were measured. The flow range to close the large valve was subdivided in 8 positions with equal steps between positions 1 and 8. Position 1 of the valve was the most difficult position to close. The pressure range to reopen the large valve was subdivided in 7 positions, with position 1 being the most difficult position to open. Five measurements per position were performed. Additional measurements were performed to calculate the ARC of the TSV during breathing. The ARC was previously calculated as follows by Geertsema et al.\textsuperscript{7}

\[ p_1 - p_2 = ARC \cdot F^2, \]

where \( p_1 - p_2 \) is the pressure difference (before and after placement of the TSV), \( R_C \) is the ARC with dimensions \([Pa \cdot s^2 \cdot l^{-2}]\); and \( F^2 \) is the squared flow.

Measurements were executed by generating an increasing flow through the flow tube, whereas the pressure difference (before and after placement of the TSV) and the flow were registered simultaneously. To determine the ARC of the TSV, the pressure was plotted against the squared flow. A straight line was calculated with linear regression approach, and the slope of the straight line represents the ARC. The ARC of the TSV was established for a flow range of –2.3 to 2.4 L/s. The value of the ARC for inhaling will differ from that for exhaling, as the small silicon valve will only open during inhalation, which reduces the ARC. Accordingly, the ARC is calculated separately for inhaling and for exhaling.

3.3 Results

The flow values necessary to close the large valve are shown in Figure 4. The range of these flow values is about 1.7 to 3.8 L/s. The flow values decrease in nearly linear fashion, except for positions 3 and 4. The standard deviation (SD) appears to be low for position 3 through 8, which means that these measurements are reproducible. This low SD is in contrast to the higher SD of the values correlating to positions 1 and 2.

The pressure values necessary for opening the large valve are shown in Figure 5. These values also decrease nearly linearly and have a range of approximately 0.8 to 7.2 kPa. All the positions display low SD values, indicating that the pressure needed to open the valve is quite reproducible.
Design and test of a new TSV based on inhalation

Chapter 3

Valve position

Flow (l/s)

1 2 3 4 5 6 7 8

Figure 4: Flow required for closing the large valve, obtained for different valve positions (mean values and SDs [error bars], based on 5 measurements per position).

The results of the ARC, measured in flow tube setup 2 (Fig. 3), are presented for inhaling and exhaling respectively in Figure 6 and Figure 7, where the pressure difference measured is plotted against the squared flow. The value of ARC when inhaling, $ARC_{\text{inhaling}}$, is:

$$ARC_{\text{inhaling}} = 2.9 \cdot 10^2 \left[ \text{Pa} \cdot \text{s}^2 \cdot \text{l}^{-2} \right]$$

The value of ARC when exhaling, $ARC_{\text{exhaling}}$, is:

$$ARC_{\text{exhaling}} = 4.3 \cdot 10^2 \left[ \text{Pa} \cdot \text{s}^2 \cdot \text{l}^{-2} \right]$$

3.4 Discussion

In contrast to existing TSVs, the new TSV closes the stoma by an extra spurt of inhaled air, which probably enables the patient to speak longer on 1 inhalation. Another improvement, in comparison with existing devices, is that air can be inhaled very easily during phonation. The new TSV also allows a more physiological way of speaking, as an inhalation is necessary to initiate phonation. In general, all these improvements make it easier for the patient to speak.

The flow necessary to close the large valve of the TSV ranges nearly linearly from 1.7 to 3.8 L/s, but position 4 shows a sudden increase of the flow, indicating that the interaction between magnet and metal plate is not yet ideal. The measured flow
range is comparable to that of other devices measured in the past \textsuperscript{6,7}, but those devices are controlled by a spurt of exhaled air, which is attained more easily. Nevertheless, healthy persons were able to attain the flow values necessary to close this new TSV, although it was difficult to close the large valve in positions 1 and 2. Patient tests have to prove if this range is appropriate.

![Figure 5: Pressure values required for opening the large valve, obtained for different valve positions (mean values and SDs [error bars], based on 5 measurements per position).](image)

The pressure to reopen the large valve ranges from 0.8 to 7.2 kPa. The TSVs that have a cough valve that opens by the generation of air pressure, show a similar range \textsuperscript{6,7}. This range means that it is possible to adjust the large valve to such a position that it will not open during phonation when different voice prostheses, such as the Groningen low-resistance button, the Blom-Singer duckbill prosthesis, or the Provox low-resistance prosthesis, are being used \textsuperscript{8,9}.

In general, the use of magnets and shaped metal plates makes it possible to generate ranges for linear flow and pressure. Experiences of patients using this TSV can optimise ranges for flow and pressure. Also, the ARC for inhaling and exhaling makes low-resistance breathing possible, as the ARC lies in the range of the entire ARC of a healthy person, which is $1.2\cdot10^2$ to $4.7\cdot10^2 \, [Pa\cdot s^2\cdot l^{-1}]$. On the other hand, the ARC of the new TSV is rather high compared to existing TSVs, which have lower ARCs. The ARC for exhaling is especially high. Again, patient tests should be conducted to see if ARCs for inhaling and exhaling are suitable.
Finite element method studies could suggest ways for optimise the design for the ARC.

Figure 6: Pressure values plotted against the squared flow values during inhalation. The straight line is obtained by linear regression. The slope of this line represents the airflow resistance coefficient.

Figure 7: Pressure values plotted against the squared flow values during exhalation. The straight line is obtained by linear regression. The slope of this line represents the airflow resistance coefficient.
The new TSV is much smaller than other TSVs and does not protrude from the skin surface as much; accordingly, it will attract less attention, especially when the patient is wearing clothes over it, and is less likely to disconnect from the tracheostoma. In contrast to other TSVs that are often used, the TSV does not have to be removed from the stoma during coughing. It is adapted in such a way that it fits in a fixation ring that is also used for the Blom-Singer TSVs\(^5\). The fixation ring is less loaded, because the valve can be closed by a strong inhalation. The closing of other TSVs is achieved by a spurt of exhalation, which can accelerate the fixation to disconnect from the skin around the tracheostoma. Also, the reopening action will occur less frequently than the closing action of TSVs that are based on the mechanism of exhalation. Thus, the inhalation principle is likely to extend the useful life of attachment (such as doublesided foam, tapedisks, and glue) of the fixation ring to the skin.

References