Experimental comparison between Staffieri and new tracheo-oesophageal prostheses

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Abstract

Phonatory valves are prostheses for the voice rehabilitation of patients that have lost the vocal function due to a total laryngectomy operation. The prosthesis is positioned in a fistula and recreates a communication via between the airway and the digestive tract, realising a one-way valve.

In this paper the experimental results obtained with Staffieri and new tracheo-oesophageal prostheses are presented. The valves have been experimentally tested under different conditions of airflow through the valve and tracheal side pressure; the data have allowed to calculate the airflow resistance, the parameter usually used to compare the performance of valves. The valves have also been experimentally tested under different condition of fluid flow through the valve and oesophageal side dynamic pressure; the use of a dynamic pressure better reproduce the real functioning of the valve.

Comparing the airflow resistance of the Staffieri and new tracheo-oesophageal prostheses with different angular extension of the razor thin slit $\alpha$ it has been observed that the parameter $\alpha$ has a significant influence on flow characteristics; while the influence of the shape of the hat is negligible for smaller $\alpha$ and became important for the bigger $\alpha$ considered.

Regarding the reverse flow, it is pointed out that for most of the valve (Staffieri and new prosthesis), at different oesophageal pressures the fluid flow is smaller than the flow that can be tolerated by the patients without giving problems.

Keywords: total laryngectomy, voice rehabilitation, voice prosthesis, voice button, phonatory valve, low resistance.

1. Introduction

Phonatory valves are prostheses for the voice rehabilitation of patients that have lost the vocal function due to a total laryngectomy operation. [1-20]

The prosthesis is positioned in a fistula and recreates a communication via between the airway and the digestive tract, which have been separated by the total laryngectomy. In this way the pulmonary air activates a vibrating segment at the level of the cervical oesophagus capable of producing a sound which is in its turn modulated by the supraglottal structures (buccal cavity, nasal cavities, tongue, teeth and lips).

The prosthesis must realise a one-way valve which thus permits the passage of air from the trachea to the oesophagus (direct flow) and prevents the passage of liquids and foodstuffs in the opposite direction (reverse flow).

The production of the voice depends on both the resistance exerted against the airflow by all anatomic structures upstream of the trachea and the resistance of the voice button. In particular the airflow resistance of the valve has a great influence on voice production. An optimum phonatory valve allows to the expiratory air to pass freely from the trachea and hypopharynx-oesophagus (which after the operation are not distinguishable) and provides an easy phonation for the patient, i.e. not too much effort and low resistance to the flow.

The purpose of this paper is to evaluate the aerodynamic behaviour of two types of valves: Staffieri and new tracheo-oesophageal prostheses. The most important geometrical difference between the two types of valves is the shape of the hat in the oesophageal side. For the two types of valves different values of the angular extension of the razor-thin slit have been taken into account.

The experimental tests have required special attention to the apparatus, both with regards to the direct air flow characteristics and the reverse fluid flow.
characteristics, in order to have a system capable to compare the behaviour of the different type of valves. Relatively to the direct air-flow characteristics, the flow-rate through the valve and the pressure drop $\Delta p$ (difference between the tracheal side pressure and the oesophageal side pressure) have been measured. The airflow resistance has been calculated as the ratio of pressure drop $\Delta p$ to the flow-rate.

For the reverse flow, or reflux, the leakage of water that pass from the hypopharynx-oesophagus to the trachea has been measured, as a function of the oesophageal pressure. In particular the tests have been carried out using an oesophageal dynamic pressure to simulate the situation of liquid and foodstuffs swallow.

In fact is important to evaluate the flow that the patient can eliminate without medical problems.

All the valves performance in terms of airflow resistance and reverse flow have been compared and this information allows to evaluate the valves.

The results obtained with Staffieri and new prototype valves establish that the razor thin slit extension has an important influence on the performance, and the airflow resistance is lower if the slit extension increase; but also the shape of the hat influence the performance of the valve.

2. Design of the valves

The design and the working of the phonatory valve can be explained referring to figure 1. The valve consists in a tracheal entry 1, whereby an endotracheal retention collar 2 is connected to the tracheal mucosa (tracheal flange); an hollow cylindrical tube 3 that connects the trachea to the hypopharynx-oesophagus; an endoesophageal flange 4; a dome (or hat) 5 closing the proximal endoesophageal end of the tube; the hypopharynx-oesophagus exit (or razor thin slit) 6 is realised at the base of the hat and can have different angular extension.

By way the razor thin slit 6 the hat enables a flow passage from the trachea to the oesophagus when there is a positive differential pressure, and it prevents the reverse flow of liquids when the differential pressure becomes negative.

For the two valves considered the slit 6 has been realised at the base of the hat and can have different dimensions (or angular extension $\alpha$).

Figure 2 shows the Staffieri prosthesis a) and the new prosthesis b). It is possible to note that the most important differences between the two types of valves are the shapes of tracheal flange and hat.

For the Staffieri valve the hat is hemispherical while for the new prosthesis the shape of the hat has been studied [21] to have a deflector for the food (bolo or saliva) in the oesophagus side. The tracheal flange of the new valve does not allow the valve rotation when the valve is positioned in vivo.
Figure 3 shows the longitudinal section of the two valves together. The valves have internal diameter equal to 4 mm, length of the hollow cylindrical tube equal to 5 mm, walls thickness equal to 1 mm. It is possible to note that the most important parameter that can influence the performance of the valves could be the shape of the hat.

![Figure 3. Longitudinal section of the two valves](image)

The valves have been realised using the vacuum casting technique useful to produce a small quantity of valve made in biocompatible silicone. The razor thin slit has been realised subsequently with a properly test rig. The slit has been realised fixing the valve and the bistouty, that could be rotate by hand but not moved; in this way is possible to realise the razor thin slit with a certain precision the angular extension.

In this study has been evaluated the influence of the length of the razor-thin slit on flow characteristics; in particular six different angular extensions α have been considered (180°, 210°, 240°, 270°, 290°, 310°). For each type of valve (Staffieri valve SV and new valve NV) and each α four valves (nominally equal) were experimented tested, in order to determine the experimental repeatability.

**3. Measurement of direct flow characteristics**

The flow-rate characteristics were obtained through experimental tests using a specially made testing apparatus, whose schema is shown in figure 4.

![Figure 4. Test bench for direct flow characteristics measurements](image)

The range of flow-rate has been identified taking into account that, usually, to compare the performance of the valves an average airflow equal to 0.15 dm³/s (ANR) [22] is used [1-20].

The airflow resistance (ratio of pressure drop to the flow-rate) is shown in the graphs as a function of the flow-rate.

The experimental plan considers all type of valves (SN and NV), with six angular extensions α of the slit; for each possible combination four valves were tested.

Figures 5 and 6 show the pressure vs. flow-rate curves corresponding to the different angular extension of the slit α for SV and NV respectively. For each value of α the plotted curve corresponds to the average curve obtained considering the results of the four valves.

To compare the behaviour of the valves, with different hat and α, a statistical approach has been used. The experimental result is not a single value but a curve, thus it is not possible to apply directly the classical technique of analysis of variance. Consequently, the analysis has been carried out by calculating, for every experimental configuration (hat and α) the average curve and the range of one standard deviation (±σ). Observing if the scattering bands are superposed or separate it is possible to assess if the experimental configurations are significantly distinguished or not.

Figure 7 and figure 8 show the pressure vs. flow-rate for SV α=180° and NV α=240° respectively. Each of the four dashed curves corresponds to a valve; the continuous line is the mean curve and the vertical bars show ± one standard deviation range.
The results can be also compared at equal angular extension of the slit α, and varying the shape of hat. In this case for α less than 270° the flow characteristics are superimposed, while for α=290° and α=310° the influence of the hat is significant.

Figure 5. Pressure vs. flow-rate for Staffieri valves SV

Figure 6. Pressure vs. flow-rate for new valves NV

Figure 7. Pressure vs. flow-rate for Staffieri valves SV α=180°

Figure 8. Pressure vs. flow-rate for new valves NV α=240°

Figure 9. Resistance vs. flow-rate for Staffieri valves SV

Figure 10. Resistance vs. flow-rate for new valves NV

Figure 9 and 10 show the airflow resistance (pressure to flow-rate ratio) vs. flow-rate, for each α, for SV and NV respectively; also in this case for each α, the average curve has been shown. It is possible to note that for very small flow-rate (until 0.05 dm³/s) there is not a significant difference between the two types of
valves. For the smaller values of $\alpha$ (180°, 210°, 240° and 270°) the resistance of SV and NV are not significantly different, while for wider angular extension $\alpha$ (290° and 310°) the behaviour of the resistance are different.

Figure 11 shows the resistance vs. flow-rate for $\alpha$=180° and $\alpha$=310°, for SV and NV. Taking into account the physiological flow (equal to 0.15 dm$^3$/s ANR) it is possible to observe that the shape of the hat for $\alpha$=180° is not influent while for $\alpha$=310° is important, and the SV has a smaller resistance.

![Figure 11. Comparison of resistance between SV and NV](image)

### 3. Measurement of reverse flow characteristics

In choosing a phonatory valve one must asses the airflow resistance to the passage from the trachea to the oesophagus and the reverse flow quantity (or backflow or reflux), i.e. the tendency of fluid (food or saliva) to pass from the oesophageal to the tracheal part of the valve.

It is essential, however, to assess the amount of fluid, at the oesophageal pressure inversion, which can pass into the trachea, even if the best results is to have no flow passage.

Some authors [3] refer a test methodology for measuring the maximum oesophageal pressure which the valve is capable of bearing before opening to let an unspecified flow pass in the trachea.

Other authors [1] have realised a test rig to evaluate both pressure and flow-rate, using a statical pressure. The test rig used in this paper allow to subject the oesophageal part of the valve to a dynamic pressure, and the leakage of fluid (especially water) that passes through the valve can be measured.

Figure 12 and 13 show the experimental results obtained with SV and NV respectively, in terms of leakage vs. pressure. Each figure shows the mean value obtained for each group of the four valves considered. The valves with $\alpha$=180° and $\alpha$=210° have zero leakage in the pressure range considered.

The dashed line (green colour) represents the quantity of liquid that can be easily eliminated by the patient coughing, without the fluid reaching the lungs and causing problems. For all NV (and every $\alpha$) the fluid passage is lower than the reference value; for SV with $\alpha$=240° and $\alpha$=270° the fluid passage is lower than the reference value; for $\alpha$=290° and $\alpha$=310° the fluid passage is greater than the reference value.

![Figure 12. Leakage vs. pressure for Staffieri valve SV](image)

![Figure 13. Leakage vs. pressure for new valve NV](image)

### 4. Conclusions

This paper reported the experimental measurement of airflow resistance and reverse flow for two types of voice prostheses. The results have been analysed considering the airflow valve resistance has great...
influence on voice production and that the valve must prevent the passage of fluid from the oesophagus to the trachea.
The performance of Staffieri and new prosthesis have been evaluated, assessing that the angular extension of the slit $\alpha$ has a significant influence on the airflow characteristics, while the effect of the shape of the hat can be distinguished from experimental errors only for certain values of $\alpha$.

With regards to the reverse flow, the amount of fluid which can be tolerated (i.e. can be eliminated by the patient coughing) has been taken into account. From this point of view all new prostheses have negligible or acceptably low fluid passage, while for the Staffieri $\alpha=290^\circ$ and $\alpha=310^\circ$ the reverse flow is greater than the acceptable level.

The use of dynamic pressure experimental test simulates the real situation of the patients have allowed to know some interesting information about the valves performance, but it would interesting to evaluate also the reverse characteristics knowing the in vivo oesophageal pressure.

In choosing a phonatory valve one must assess the airflow resistance and the reverse flow. Accounting for both parameters is possible to conclude that:

- the value of $\alpha$ is the parameter that most influences the performance of the valve;
- increasing $\alpha$ (from $180^\circ$ to $310^\circ$) for SV and NV results in a significant reduction of airflow resistance;
- for greater $\alpha$ the NV has a higher resistance;
- the SV gives a good performance relatively to the reverse flow, except for $\alpha=290^\circ$ and $\alpha=310^\circ$;
- the NV gives a better performance relatively to the reverse flow, for each $\alpha$.

To improve the evaluation of the prosthesis it would be necessary to perform fatigue test, to establish the influence of the number of opening/closure cycles of the hat on the airflow parameter.

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References

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