INTRODUCTION

After total laryngectomy, voice rehabilitation becomes a very important issue. Tracheoesophageal speech is currently the best method of postlaryngectomy voice rehabilitation. A voice prosthesis is positioned in a tracheoesophageal puncture. The prosthesis consists of a one-way valve that allows air to pass from the trachea to the esophagus, inducing resonance and thereby facilitating speech. One of the drawbacks of voice prosthesis speech is that it requires digital tracheostoma occlusion.

In 1982, Blom et al. introduced the first tracheostoma valve that eliminated the need for digital tracheostoma occlusion. This tracheostoma valve is contained in a special housing that is glued to the peristomal skin. Using the tracheostoma valve helps the patient regain considerable freedom, because it leaves both hands free. Further, the patient acquires more spontaneous speech and draws less attention to the stoma from the listener. Since the initial introduction of the first Blom-Singer tracheostoma valve, other tracheostoma valves have been introduced.

Unfortunately, not all laryngectomized tracheoesophageal speakers are successful in using a tracheostoma valve. Successful tracheostoma valve use is dependent on patient factors, physician and speech pathologist factors, and tracheostoma valve factors. As reported earlier by our group, important patient factors are phlegm production prior to valve use, back-pressure, age, motivation, etc. Teaching the patient how to use the tracheostoma valve may certainly influence his or her ability to work with the device. Valve-related factors such as the aerodynamics, price, and availability may be important for successful use, also.

A tracheostoma valve needs to meet certain aerodynamic characteristics. During normal respiration, the tracheostoma valve must remain open to allow air to pass through. At the same time, the resistance of the tracheostoma valve needs to be relatively low so it will not cause discomfort. When a patient wants to speak, the tracheostoma valve must close through forced expiration, enabling the air to pass through the voice prosthesis to the esophagus.

To date, aerodynamic characteristics of the three commercially available tracheostoma valves have not been investigated. Knowledge of the valves’ aerodynamics may help to determine which valve best suits a specific patient.

In this article, we present the various aerodynamic characteristics of the Tracheostoma Valve I (hereinafter referred to as the ’Bivona I’; Bivona Medical Technologies, Gary, Ind), the Blom-Singer Adjustable Tracheostoma Valve (’Blom-Singer ATV’; In- health Technologies, Carpinteria, Calif), and the Tracheostoma Valve II large (’Bivona II’; Bivona Medical Technologies). Dynamic flow and pressure mea-
Fig 1. Photograph of tested tracheostoma valves. Size ratio 1:1. A) Bivona I (light). B) Blom-Singer Adjustable Tracheostoma Valve at ±90°. C) Bivona II large (15-g spring).

measurements were performed on each of these valves and their subtypes.

MATERIALS

Three different commercially available tracheostoma valves were evaluated. These valves were the Bivona I, the Blom-Singer ATV, and the Bivona II. These three tracheostoma valves were tested in four subtypes as described below.

**Bivona I.** The Bivona I (Fig 1A) valve consists of a plastic housing with a silicone diaphragm. The valve has four subtypes that are determined by the thickness of the silicone diaphragm. This valve is not adjustable, so when a patient requires different valve characteristics, a change of valve is required. The thicker the silicone diaphragm, the higher the closing pressure. The subtypes are called ultralight, light, medium, and firm.

**Blom-Singer Adjustable Tracheostoma Valve.** The Blom-Singer ATV is a relatively new valve that was introduced in 1992 (Fig 1B). There is one configuration of this valve, and it is adjustable by rotating the faceplate, thereby determining the position of the silicone diaphragm. The position of the silicone diaphragm determines the valve aerodynamic characteristics. The Blom-Singer ATV is the only valve that facilitates the use of a heat and moisture exchanger (HME; Humidi-filter). To allow comparison between the three valves, we excluded this HME option during the valve measurements because of its possible influence on the valve aerodynamic characteristics.

The measurements of this valve were performed with the faceplate at 0°, 30°, 60°, and ±90° rotation, resulting in four different valve conditions (0° being the most open valve position).

**Bivona II,** The Bivona II valves consist of a flat valve with a spring mechanism (Fig 1C). The strength of the spring determines the closing pressure. Four different springs are provided with the valve, i.e., 15, 20, 25, and 30 g. The Bivona II valves have a pressure relief mechanism that should keep the valve from malfunctioning during high-pressure occurrences, e.g., coughing. The pressure relief mechanism was not tested in this study.

METHODS

Figure 2 is a schematic drawing of the experimental setup. A valve was placed in the universal valve housing before each measurement. The valve housing was of the same type used in the patient.

The airflow for the measurements was generated by a variable electric air pump. A pressure transducer (Statham) and a pneumotachograph (Siemens) were connected in front of the tracheostoma valve, as illustrated in Fig 2. The pressure and flow meters were linked to an IBM-compatible computer through an analog-digital (AD) interface, sampling the analog transducer outputs at 100 Hz. A software data acquisition program was used. The raw signal, containing an excess of high-frequency components, was low-pass-filtered after the measurements.

The airflow rate was increased gradually while the pressure and flow were simultaneously registered. The airflow rate was increased until the valve closed, instantly reducing the flow of air to zero. The resis-
MAXIMUM AIRFLOW RATES AND Pressures OF THREE TRACHEOSTOMA VALVES AND THEIR SUBTYPES

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Maximum Flow (L/s)</th>
<th>SD</th>
<th>Closing Pressure (cm H20)</th>
<th>Opening Pressure (cm H20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biv I firm</td>
<td>3.41</td>
<td>0.05</td>
<td>27</td>
<td>21.5</td>
</tr>
<tr>
<td>Biv I med</td>
<td>2.68</td>
<td>0.05</td>
<td>16</td>
<td>10.2</td>
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<tr>
<td>Biv I light</td>
<td>2.50</td>
<td>0.13</td>
<td>17</td>
<td>9.0</td>
</tr>
<tr>
<td>Biv I ultra light</td>
<td>2.31</td>
<td>0.06</td>
<td>10</td>
<td>7.1</td>
</tr>
<tr>
<td>ATV 0°</td>
<td>2.38</td>
<td>0.02</td>
<td>18</td>
<td>12.5</td>
</tr>
<tr>
<td>ATV 30°</td>
<td>2.24</td>
<td>0.05</td>
<td>18</td>
<td>12.5</td>
</tr>
<tr>
<td>ATV 60°</td>
<td>1.72</td>
<td>0.01</td>
<td>18</td>
<td>12.5</td>
</tr>
<tr>
<td>ATV 90°</td>
<td>1.68</td>
<td>0.02</td>
<td>18</td>
<td>12.5</td>
</tr>
<tr>
<td>Biv II 30 g</td>
<td>1.67</td>
<td>0.02</td>
<td>12</td>
<td>6.9</td>
</tr>
<tr>
<td>Biv II 25 g</td>
<td>1.94</td>
<td>0.06</td>
<td>10</td>
<td>5.2</td>
</tr>
<tr>
<td>Biv II 20 g</td>
<td>1.39</td>
<td>0.04</td>
<td>6</td>
<td>4.2</td>
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<tr>
<td>Biv II 15 g</td>
<td>1.28</td>
<td>0.04</td>
<td>4.5</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Maximum flow - maximum airflow rate through tracheostoma valve, SD - standard deviation of repeated measurements of maximum flow of valves, closing pressure - pressure needed to result in complete valve closure, opening pressure - pressure at which valve opens spontaneously, Biv I - Bivona Tracheostoma Valve I, ATV - Blom-Singer Adjustable Tracheostoma Valve, Bivona Tracheostoma Valve II large.

RESULTS

The aerodynamic characteristic curves derived from these measurements allow calculation of the maximum airflow through the devices, the resistances at given airflow rates, and the closing pressures.

Maximum Airflow. These values indicate the maximum airflows that these tracheostoma valves allow to pass through without closing. The Table contains the averaged maximum flow rates (in liters per second) of the valves tested and their standard deviations. The results show a high reproducibility, as indicated by the low standard deviation. The Bivona allows the highest airflow (3.41 L/s) through the device before closing; the Bivona II with the 15-g spring shows the lowest maximum airflow (1.28 L/s).

Resistance. The resistances of these tracheostoma valves were calculated for the patient-relevant airflow rates (rest and mild exercise breathing). The resistances (pressure/flow) of all valves at 1/4, 1/2, 3/4, and 1 L/s airflow rate are shown in Fig 3. In all the graphs, the standard deviation is also illustrated. These values are highly reproducible.

Closing Pressure. This closing pressure (in centi-

Fig 3. Resistances of various valves with subtypes measured at 1/4, 1/2, 3/4, and 1 L/s. Bivona I - Bivona Tracheostoma Valve I, ATV Blom-Singer Adjustable Tracheostoma Valve, Bivona II -- Bivona Tracheostoma Valve II large. Standard deviation is shown in each graph.
The maximum airflow rate represents the total pressure needed to result in complete tracheostoma valve closure (see Table). This pressure is an indication of the expiratory effort the patient needs for achieving tracheostoma valve closure to allow phonation. The closing pressure is a summation of the opening pressure and the pressure needed to overcome the resistance of the tracheostoma valve an instant before closure. The measurements during the closing phase are less reproducible because of their highly transient nature and because of the resonance of silicone valves (Bivona I and Blom-Singer ATV) during this phase.

**Opening Pressure.** The opening pressure (in centimeters of H2O) represents the pressure at which the valve opens spontaneously after being closed (see Table). The clinical meaning of this value is that when the endotracheal pressure (back-pressure) drops to this value, the valve will open spontaneously, making speech impossible. The Table shows a considerable difference in opening pressure between the tracheostoma valves and the subtypes of the Bivona I. The opening pressure of the Blom-Singer ATV is the same for all subtypes, as is inherent to its design. Adjustability is achieved, not by changing the valve compliance, but by merely changing the position of the diaphragm.

**DISCUSSION**

The results of this study indicate that there were significant differences in aerodynamic characteristics between tracheostoma valves and their respective subtypes. These differences are not unexpected, because of the differences in valve construction.

**Maximum Airflow Rate.** The maximum airflow rate represents the maximum airflow rate that a tracheostoma valve will allow without closing. This maximum airflow rate represents the threshold that a patient can breathe without closing the valve. During exercise, the patient can breathe up to this threshold without having unwanted spontaneous valve closure. Patients need to be able to reach this maximum airflow rate during forced expiration, however, to make valve closure possible when wanting to speak. Therefore, a very high threshold does not necessarily identify a better valve, since it may require much effort by the patient to close the valve. A low threshold may be disadvantageous because of the tendency for spontaneous closure during normal daily activities, even though speech would be relatively effortless.

Knowledge of the maximum airflow rates can help the clinician deal with patient complaints about unwanted spontaneous closure during exercise or, conversely, complaints about valve closure that requires too much effort.

The Blom-Singer ATV and Bivona II are adjustable valves. The former is adjusted by simple rotation of the faceplate, and the latter, by replacing the spring within the valve. For a patient with a Bivona I valve, changing the maximum flow characteristics involves changing of the valve to another subtype.

The maximum airflow rate of the Bivona II with the 25-g spring is unexpectedly higher than that with the 30-g spring. Comparison of die springs revealed that the 30-g spring is shorter than the 25-g spring. The springs were not erratically exchanged, since the pressures needed for total closure of the valves are in accordance with their relative strengths (Fig 3C). The 30-g spring does require a higher pressure for total closure than the 25-g spring; approximately 12 cm H2O versus 10 cm H2O, respectively.

The reproducibility of the maximum airflow rates is good, as can be seen from the standard deviations in the Table.

**Resistance.** We looked at the resistance (pressure/airflow) of the tracheostoma valves using four different airflow rates (1/4, 1/2, 3/4, and 1 L/s). These airflow rates were used because they represent airflow rates from rest to mild exercise for healthy individuals.

The resistances of the tested valves are shown in Fig 3. The reproducibility is good for the resistances measured, as illustrated by the standard deviations in Fig 3.

For reference, we looked at the reported expiratory resistance of the upper airway in the literature. Even though the patient is no longer able to breathe through the nose, the comparison is logical. Cole et al report the upper airway (larynx, pharynx, and nose) expiratory resistance at rest to be 4.1 cm H2O per liter per second, in healthy individuals. Wheatley et al report an expiratory nasal resistance of 3.2 and 2.0 cm H2O per liter per second at rest and during exercise, respectively. This comparison with the upper airway is important, because the tracheostoma valve should not exceed the upper airway resistance. When the resistance of a tracheostoma valve is too high, the patient will experience discomfort such as dyspnea. No data are available indicating at what airflow resistance discomfort is experienced, and there is certainly great interpatient variability.

The Bivona I and the Blom-Singer ATV at 0° bath have the lowest air resistances. When the Blom-Singer ATV is turned to the most closed position
(±90°), the resistance increases, as can be seen in Fig 3. The inner diameter of the Blom-Singer ATV is considerably smaller at 90° than at the 0° position, accounting for the increase in resistance. The Bivona II has, on average, a higher resistance for all its subtypes compared to the other valves.

All valves have resistances well below the reported resistance of the nose, for the four flow rates measured.

**Closing Pressure.** The closing pressure (in centimeters of H2O) serves as an indication of the effort needed for tracheostoma valve closure. The closing pressure is a combination of the airflow resistance through the device just before closure and the pressure needed to overcome the silicone diaphragm compliance. The closing pressure is one parameter that indicates the ease of tracheostoma valve closure. The higher the closing pressure, the more effort a patient needs to use to close the tracheostoma valve.

Each Bivona I subtype has a different silicone diaphragm thickness. These different thicknesses result in different compliances and therefore different closing pressures. The Bivona I valve (firm subtype) has the thickest silicone diaphragm and, as a result, the highest closing pressure of the valves tested (approximately 27 cm H20).

The Blom-Singer ATV has one closing pressure for all of its subtypes, consistent with its design. The adjustability of the Blom-Singer ATV is achieved by altering the position of the silicone diaphragm. This positioning does not affect the compliance of the diaphragm itself; therefore, the closing pressure of the Blom-Singer ATV remains unaltered.

The closing pressure of the Bivona II is determined by the strength of the spring used within it. The 30-g spring has the highest closing pressure.

**Opening Pressure.** The opening pressure (in centimeters of H2O) represents the pressure at which the valve opens spontaneously after being closed (see Table). The clinical meaning of this value is that when the endotracheal pressure (back-pressure) drops to this value, the valve will open spontaneously, making speech impossible. A patient should not be given a tracheostoma valve with an opening pressure that exceeds the phonation pressure (endotracheal pressure needed to phonate). The phonation pressure is determined by the resistance of the voice prosthesis, the resistance of the pharyngoesophageal segment, hypopharynx, and mouth, and the loudness of phonation. A phonation pressure of 20 to 30 cm H20 is generally accepted as being desirable. The Bivona I is the only tracheostoma valve that may exceed the phonation pressure in certain patients, because its opening pressure is 21.5 cm H20. If the opening pressure is higher than the phonation pressure, the patient would be unable to phonate, because of unwanted spontaneous opening of the tracheostoma valve. The other tracheostoma valves have a sufficiently low opening pressure that this problem should not occur.

**Additional Valve Factors.** There are other factors to be considered when choosing a tracheostoma valve. The Blom-Singer ATV currently is the only valve that allows the use of an HME. Heat and moisture exchangers help to condition the inspired air, 7, 8 The air inspired through an HME is warmer and has a higher humidity, somewhat like air inspired through a normal nose. Phlegm production can often be reduced by an HME. 2 Using the HME with the Blom-Singer ATV does, however, increase the airflow resistance of the valve. Whether the combined air resistance of the Blom-Singer ATV with an HME will be higher than the airflow resistance of the normal nose is unclear at this point.

All tracheostoma valves produce noise while closing, and this noise influences the intelligibility of the laryngectomized patient. 9 The extraneous noise level produced by the valves during closure was not simultaneously measured in this study. Our clinical experience with these valves does indicate differences; the Bivona valves appear to make more noise during closure. Currently, the extraneous noise production of the tracheostoma valves is under investigation.

The Bivona valves could be improved by clearly indicating the subtype. The Bivona I would be improved by having the silicone diaphragm thickness printed on the valve or on the silicone diaphragm itself. The Bivona II would be improved by having insertable springs in different colors. With these small changes, the patient would be visually assisted in determining what valve subtype he or she is using, which is difficult at the present time.

**Clinical implications.** There are numerous complaints expressed by laryngectomized patients that are related to aerodynamic tracheostoma valve factors. However, the most frequent complaints are related to nonaerodynamic factors, like peristomal fixation problems of the valve housing. Nonetheless, aerodynamic-related complaints can be dealt with by using the presented data from this study. The two most frequently heard complaints in this category are unwanted spontaneous closure and complaints of too high a resistance of the tracheostoma valve during normal breathing, resulting in shortness of breath.
Figure 4 can assist the clinician when the tracheoesophageal speaker complains about unwanted spontaneous closure or difficulty closing the valve during speech. Figure 4 displays the maximum airflow ranges for the three tracheostoma valves. When unwanted spontaneous closure occurs frequently, a tracheostoma valve should be chosen that is located further to the right in Fig 4 compared to the valve currently being used (higher maximum airflow rate). When the patient is frequently unable to close the tracheostoma valve for speech, the opposite applies (lower maximum airflow rate). A valve with a high closing pressure sometimes also results in complaints of speech that takes too much effort. The Table shows the closing pressures for the different tracheostoma valves and subtypes.

If the patient complains about too high a resistance, a valve is needed that has a lower resistance. Figure 3 gives guidelines on what valves have a low resistance during resting breathing and which have a relatively high resistance. Some patients experience shortness of breath as soon as a tracheostoma valve is in place over the stoma, even with valves with low airflow resistances. This population may not be able to work with any tracheostoma valve at present.

Spontaneous frequent opening of the tracheostoma valve during speech is uncommon, but may theoretically occur with the Bivona I. The Table shows all the opening pressures; alternative tracheostoma valves may be tried.

CONCLUSION

Knowledge of the aerodynamics of the tracheostoma valves, as presented in this report, combined with good understanding of the patient’s needs such as daily physical activity, pulmonary status, peak flow capabilities, and phlegm production, may increase the success rate of tracheostoma valve use. In our clinic, the valve usage success rate is approximately 66%. Aerodynamic characteristics of tracheostoma valves, however, are additional factors that need to be considered in the attempt to optimize the process of speech without digital occlusion. It is very important to identify factors that will allow broader use of tracheostoma valves for laryngectomized patients and allow them to regain considerable freedom and more spontaneous speech. Successful voice rehabilitation involves not only assisting the laryngectomized patient with speech, but also improving the ease and quality of speech.

A clinical study is needed to further evaluate the contribution of valve aerodynamics relative to the individual patient factors that determine successful tracheostoma valve use.

REFERENCES


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