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Aerodynamic characteristics of the Provox low-resistance indwelling voice prosthesis

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Summary. The use of various prostheses for voice rehabilitation after total laryngectomy has become widely accepted in recent years. Two different types of prostheses can be distinguished: non-indwelling devices, which can be removed and replaced by the patient, and indwelling voice prostheses, which have to be removed and replaced by a physician. In this report we describe the in vitro measurement of the airflow dynamics of the recently developed Provox low-resistance, indwelling voice prosthesis. Airflows used in these experiments varied from 0.05 to 0.4 $l s^{-1}$. With increasing flows, the trans-device air pressure against airflow rates increased from 0.28 kPa to 1.36 kPa, while the mean airflow resistance decreased from 5.6 to 3.4 kPa l^{-1} s^{-1}. From these data and by comparison with data for other prostheses, the Provox voice prosthesis shows favorable airflow characteristics.

Key words: Total laryngectomy – Voice rehabilitation – Voice prosthesis – Airflow resistance

Introduction

Results of voice rehabilitation after total laryngectomy have improved significantly in recent years due to the introduction of various voice prostheses. Since the introduction of the first Blom-Singer voice prosthesis [11], several other useful devices have been developed [5, 9, 10]. Prosthetic voice rehabilitation is now widely used in clinical practise, and can be considered the most successful form of voice restoration currently available [4, 19].

The success of prosthetic voice rehabilitation depends not only on surgical and patient factors such as the tonicity of the pharyngoesophageal (PE) segment [12, 13], primary versus secondary placement of the prosthesis [1], and the patient's dexterity, but also on device factors, most importantly the airflow resistance of the prosthesis itself [18]. The original prostheses were primarily designed as one-way valves, preventing leakage of fluids from the alimentary tract into the trachea [9–11]. Thereafter, it became clear that a low airflow resistance of the prosthesis could markedly improve the results of voice rehabilitation [17]. This led to the design of a new generation of low-resistance prostheses [17, 20]. Unfortunately, the adjective "low-resistance" is relative.

The airflow resistance of the low-resistance Blom-Singer and Groningen prostheses is indeed approximately half that of the standard versions [14, 20]. This is not true, however, for the Panje prostheses, in which no constant difference could be measured between the two versions now available [16]. Furthermore, there appear to be considerable differences in the reported resistance values; the comparable Blom-Singer devices show significant lower airflow resistance values than do their Panje or Groningen counterparts [18, 20].

In general, two main types of prostheses can be distinguished, i.e. non-indwelling and indwelling types. The former devices can be removed and replaced by the patient; the latter stay in place permanently and have to be removed and replaced by the physician at the end of the device's life, as determined by leakage of fluids or increased airflow resistance.

Recently, we reported the results obtained in 79 patients with a newly developed voice prosthesis, *Provox*, which was purposely designed as a low-resistance indwelling device [5]. The prosthesis is made of medical-grade silicon and is reinforced with a fluoroplastic insert. The in vitro opening pressure of this prosthesis is very low (0.03 kPa). The in vivo intratracheal pressure measurements showed values between 1.0 and 3.8 kPa (mean 1.9 kPa), which compares favorably with those reported by other investigators [8, 17].

In this paper, we will present the results of the in vitro airflow measurements of the Provox voice prosthesis. Results are compared with the airflow characteristics of the Blom-Singer duckbill, Blom-Singer/Bivona low-resistance, Groningen standard and Groningen low-resistance prostheses under similar experimental conditions.

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Materials and methods

The Provox voice prosthesis is shown schematically in Fig. 1 and is a bi-flanged medical-grade silicon device in which the hinged valve, in contrast to that of the Blom-Singer/Bivona low-resistance prosthesis, is molded in one piece with the shaft. The valve closes against an internal valve seat which consists of a rigid fluoroplastic ring inserted and fixed within the shaft to reinforce the prosthesis, preventing distortion of the valve by compression in the tracheo-esophageal fistula and/or esophagus. During the manufacturing process of the prosthesis, the hinged valve is preloaded to improve its closure against the valve seat even further.

The Provox prosthesis has an esophageal flange, which is more rigid than the tracheal flange, to prevent inadvertent spontaneous dislodgment into the trachea. This also means that the prosthesis is an indwelling device, which has to be removed and replaced by a physician using a special guide wire that is included in the package [5]. The prosthesis is available in three shaft lengths, i.e. 6, 8 and 10 mm (Fig. 2).

Airflow measurements were carried out on five Provox voice prostheses that were obtained directly from the manufacturers. For comparison, the airflow resistances of the Blom-Singer duckbill, Blom-Singer/Bivona low-resistance, Groningen standard, and Groningen low-resistance prostheses were also tested.

The dimensions of the Provox prosthesis are shown in Fig. 1. The Blom-Singer duckbill prosthesis had an inner diameter of approximately 3.5 mm (outer diameter 16F) and a shaft length of 33 mm. The Blom-Singer/Bivona low-resistance prosthesis had an inner diameter of 4.8 mm (outer diameter 20F) and a shaft length of 33 mm. Both Groningen buttons had an inner diameter of 5 mm and a 7 mm (standard version) or 9 mm (low-resistance version) shaft length.

Airflow was assessed against pressure differential in all prostheses. The measurements of the Provox device were carried out five times, using the 6-mm and 8-mm versions twice each and the 10-mm version once (Fig. 2).

The airflow transducer used was a RT-200 calibration analyzer (Allied Healthcare Products, St. Louis, Mo., USA) and the pressure transducer was a DP-200 digital manometer (Mecotec, Meerbusch, Germany). The airflow transducer has an automatic compensation for temperature and is calibrated for normal air. The experimental setup is shown schematically in Fig. 3. Thus, compressed air at room temperature passes through a pressure reducer that acts as an airflow control as well. The air enters a cylinder made of Perspex, which consists of two threaded halves. Between the two halves a disc is placed and sealed with a rubber ring. A hole in the disc mounts the prosthesis for testing. To achieve an airtight fit without distortion of the prosthesis, a different disc was manufactured for each prosthesis. The pressure transducer measured the pressure difference across the prosthesis. The outlet of the cylinder is connected through a hose with the airflow transducer. After setting the airflow to a given value, the corresponding pressure differential can be read.

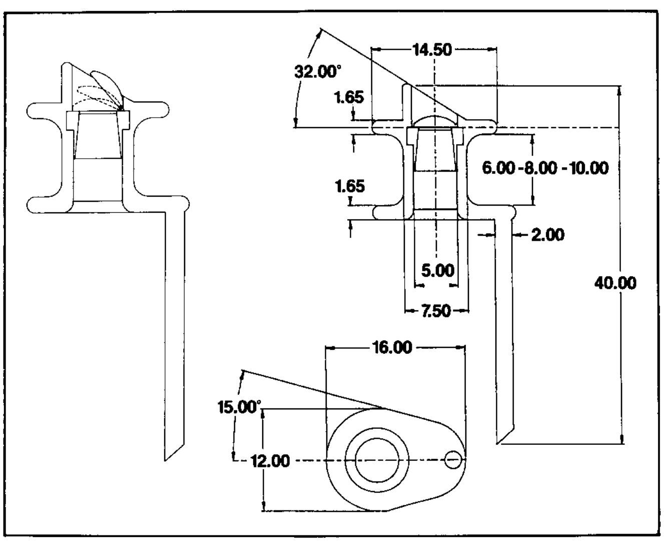

Fig. 1. Schematic illustration of the Provox voice prosthesis. Dimensions are given in millimeters and in degrees (°)

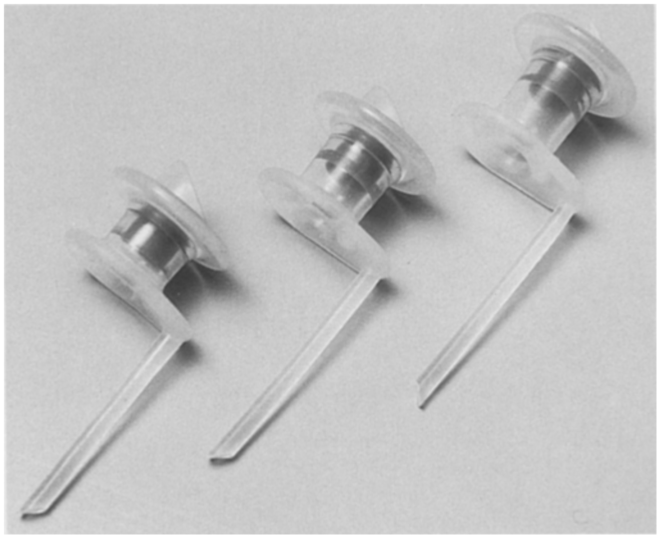

Fig. 2. The three different Provox voice prostheses available, with shaft lengths of 6, 8 and 10 mm

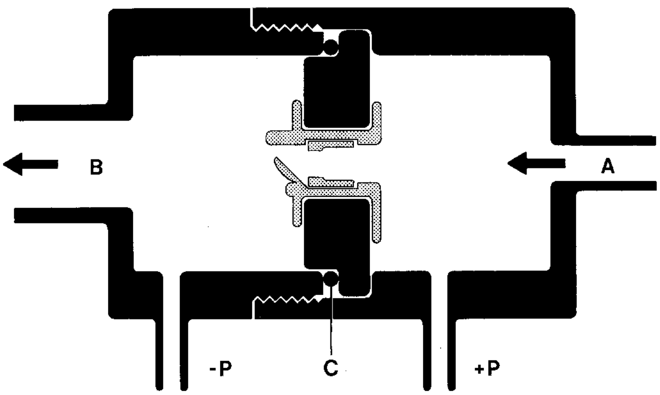

Fig. 3. Schematic setup of airflow resistance measurements: *A*, Airflow control; *B*, airflow transducer; $+P$, positive inlet of pressure transducer; $-P$, negative inlet of pressure transducer; *C*, rubber ring

Airflow resistance is calculated as the ratio of the transdevice pressure loss and the airflow rate in kilopascals per liter per second. The airflow resistance is calculated for eight known flows, ranging from 0.05 to 0.4 ls^{-1} with intervals of 0.05 ls^{-1}.

Results

The comparison of transdevice air pressure against airflow rates for the different prostheses is shown in Fig. 4. For the Provox voice prosthesis, the mean of the five measurements is given (with the standard deviation varying between 0.06 and 0.13 kPa). The values for the Provox and the low-resistance Blom-Singer/Bivona prostheses were comparable and considerably lower than those

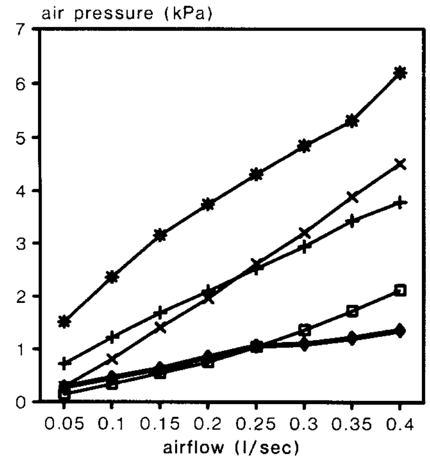

Fig. 4. Transdevice air pressure against airflow rates. The *abscissa* shows the airflow plotted in liters per second and the *ordinate* shows the pressure differentials across the prostheses in kilopascals (1 kPa = 10 mb = approx. 10 cmH_2O). ♦, Provox low-resistance prosthesis; +, Groningen low-resistance button; *, Groningen standard button; □, Blom-Singer/Bivona low-resistance prosthesis; ×, Blom-Singer duckbill prosthesis

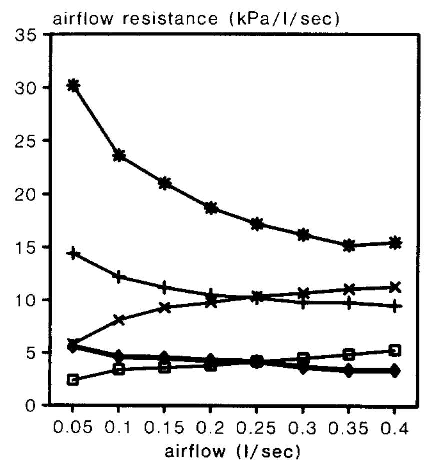

Fig. 5. Airflow resistance. The *abscissa* shows the airflow plotted in liters per second, and the *ordinate* shows airflow resistance in kilopascals per liter per second. Symbols as in Fig. 4

found for the other three devices. The Provox prosthesis showed the least increase in air pressure, from 0.28 to 1.36 kPa, vs 0.14 to 2.12 kPa (Blom-Singer/Bivona low-resistance), 0.29 to 4.51 kPa (Blom-Singer duckbill), 0.72 to 3.78 kPa (Groningen low-resistance) and 1.51 to 5.31 kPa (Groningen standard). At the supposedly physiological airflow of 0.15 ls^{-1} [6], values were: 0.67 kPa (Provox), 0.54 kPa (Blom-Singer/Bivona low-resistance), 1.40 kPa (Blom-Singer duckbill), 1.68 kPa (Groningen low-resistance) and 3.15 kPa (Groningen standard).

The relation between airflow resistance and airflow is depicted in Fig. 5. The Provox and Groningen prostheses showed a decrease in airflow resistance with increasing flows, whereas both the Blom-Singer duckbill and the Blom-Singer/Bivona low-resistance prostheses showed a clear increase in airflow resistance with increasing flows. For airflows increasing from 0.05 to 0.4 ls^{-1}, the Provox prosthesis showed airflow resistance values decreasing from 5.6 to 3.4 kPa $l^{-1}s^{-1}$. The Blom-Singer/Bivona low-resistance and Blom-Singer duckbill prostheses showed an increase from 2.4 to 5.3 kPa $l^{-1}s^{-1}$ and from 5.8 to 11.3 kPa $l^{-1}s^{-1}$, respectively. The Groningen low-resistance and the Groningen standard buttons showed decreases from 14.4 to 9.5 kPa $l^{-1}s^{-1}$ and from 30.2 to 15.5 kPa $l^{-1}s^{-1}$, respectively. At the "physiological" airflow of 0.15 ls^{-1}, the airflow resistances were 4.5 kPa $l^{-1}s^{-1}$ (Provox), 3.6 kPa $l^{-1}s^{-1}$ (Blom-Singer/Bivona low-resistance), 9.3 kPa $l^{-1}s^{-1}$ (Blom-Singer duckbill), 11.2 kPa $l^{-1}s^{-1}$ (Groningen low-resistance) and 21.0 kPa $l^{-1}s^{-1}$ (Groningen standard).

Discussion

Prosthetic voice rehabilitation after total laryngectomy has become widely used in recent years. To improve further on the early promising results with the Blom-Singer duckbill prosthesis, research has focused on surgical, patient and device factors.

Surgical research has led to a better understanding of the importance of the constrictor pharyngeus muscles in obtainaing a fluent voice [12]. Tonicity of the PE segment can be "controlled" by neurectomy and/or myotomy [2, 12, 13]. Timing of the introduction of the voice prosthesis also appears to be of significance. Primary placement during laryngectomy leads to a higher success rate than does delayed secondary placement [1]. The development of indwelling voice prostheses seems to have reduced the importance of patients' dexterity and thus improves the long-term success of voice rehabilitation by avoiding inadvertent dislodgement or improper replacement of the prosthetic device [4, 5, 9]. This may also explain the somewhat lower complication rates found with indwelling voice prostheses [6].

Research on device factors has focused mainly on airflow resistance and proper function of the valve in preventing leakage of fluids. Ideally, the airflow resistance of a voice prosthesis together with that of the PE segment should be comparable to or at least not significantly exceed that of the normal larynx and pharynx. Reported airflow resistance values during phonation for the normal larynx vary between 3.5 and 4.3 kPa $l^{-1}s^{-1}$ [15]. The airflow resistance of the Provox voice prosthesis, at the physiological airflow of 0.15 ls^{-1}, of 4.5 kPa $l^{-1}s^{-1}$ appears to be in the same range.

Among the prostheses studied, only the 20-F Blom-Singer/Bivona low-resistance device met the same standard in showing an airflow resistance of 3.6 kPa in our experiments under similar circumstances. However, in contrast to the latter, the Provox voice prosthesis showed a decrease in airflow resistance with increasing flows, down to 3.4 kPa $l^{-1}s^{-1}$. This is easy to understand, as the valve of the Provox prosthesis opens further with increasing airflow, thus increasing the effective diameter of the device. The most likely explanation for the opposite phenomenon in the Blom-Singer devices seems to be the opening on the side and the longer shaft of the prostheses, leading to higher air velocities at a given flow. This causes turbulence to start at a lower flow [3].

The somewhat higher resistance of the Provox voice prosthesis in low flows when compared with the low-pressure Blom-Singer/Bivona device is probably due to the preloading of the valve in the former. This preloading ensures optimal closure of the valve against the valve seat, improving the leak-proof characteristics of the prosthesis, but at the same time increases to a minor extent the opening pressure of the device.

The airflow resistance values found in our experimental setup appeared to be fully comparable with the values reported in the literature [14, 18, 20]. This indicates that, in contrast to other findings [8], the humidity and temperature of the air used have little influence.

The airflow resistance of the Provox device at the physiological airflow of $0.15\,ls^{-1}$ proved to be 60% lower than that of the low-resistance Groningen button and almost 80% lower than that of the standard Groningen button, which are comparable indwelling devices. In contrast to recently expressed expectations [19], these differences indicate a considerable improvement, reducing the airflow resistance of the device to only a small percentage of the combined resistance of the prosthesis and the PE segment [20]. The PE segment is not necessarily the major contributor to the overall airflow resistance in prosthetic speech.

The reported transdevice pressure losses for the Groningen buttons are 1.5 and 3.5 kPa at the supposedly physiological airflow rate of $0.15\,ls^{-1}$ [20]. Values measured in this study were 1.68 and 3.15 kPa. The in vitro pressure differential across the Provox prosthesis at this airflow is 0.67 kPa. These values have to be added to the pressure losses in the PE segment. In vivo, we found that intratracheal pressures determined in 30 consecutive laryngectomized patients using a Provox device were between 1.0 and 3.8 kPa (mean 1.9 kPa) when producing an "A" at a comfortable loudness level [4].

Assuming that findings with the Provox device correspond with the normal flow rate mentioned above, this means that the pressure loss across the PE segment varies from 0.3 to 3.1 kPa. Thus, the pressure losses across the Groningen prostheses (1.68 and 3.15 kPa respectively) contribute to a higher degree to the total pressure needed for phonation than that across the Provox device. This is in accordance with the subjective judgment of patients, who in general reported a considerably decreased effort needed for phonation with the Provox prosthesis compared to the standard Groningen button [4].

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References

1. Annyas AA, Nijdam HF, Escajadillo JR, Mahieu HF, Leever H (1984) Groningen prosthesis for voice rehabilitation after laryngectomy. Clin Otolaryngol 9:51–54
2. Baugh F, Lewin JS, Baker SR (1990) Vocal rehabilitation of tracheoesophageal speech failures. Head Neck 12:69–73
3. Ben Jebria A, Henry C, Petit J, Gioux M, Devars F, Tressac L (1987) Physical and aerodynamic features of the Bordeaux voice prosthesis. Artif Organs 11:383–387
4. Hilgers FJM, Balm AJM (1993) Long term results of vocal rehabilitation after total laryngectomy with the low-resistance, indwelling Provox™ voice prosthesis system. Clin Otolaryngol (in press)
5. Hilgers FJM, Schouwenburg PF (1990) A new low-resistance, self-retaining prosthesis (Provox™) for voice rehabilitation after total laryngectomy. Laryngoscope 100:1202–1207
6. Manni JJ, Broek P van den (1990) Surgical and prosthesis-related complications using the Groningen button voice prosthesis. Clin Otolaryngol 15:515–523
7. Nieboer GLJ, Schutte HK (1987) Aerodynamic properties of buttons and button-assisted oesophageal speech. In: Hermann IF (ed) Speech restoration via voice prostheses. Springer, Berlin Heidelberg New York, pp 87–91
8. Nieboer GLJ, Schutte HK (1987) The Groningen button: results of in vivo measurements. Rev Laryngol 108:121–122
9. Nijdam HF, Annyas AA, Schutte HK, Leever H (1982) A new prosthesis for voice rehabilitation after laryngectomy. Arch Otorhinolaryngol 237:27–33
10. Panje WR (1981) Prosthetic voice rehabilitation following laryngectomy: the voice button. Ann Otol Rhinol Laryngol 90:116–120
11. Singer MI, Blom ED (1980) An endoscopic technique for restoration of voice after laryngectomy. Ann Otol Rhinol Laryngol 89:529–533
12. Singer MI, Blom ED (1981) Selective myotomy for voice restoration after total laryngectomy. Arch Otolaryngol 107:670–763
13. Singer MI, Blom ED, Hamaker RC (1986) Pharyngeal plexus neurectomy for alaryngeal speech rehabilitation. Laryngoscope 96:50–53
14. Smith BE (1986) Aerodynamic characteristics of Blom-Singer low-pressure vioce prostheses. Arch Otolaryngol Head Neck Surg 112:50–52
15. Smitheran JR, Hixon TJ (1981) A clinical method for estimating laryngeal airway resistance during vowel production. J Speech Hear Dis 46:138–146
16. Weinberg B (1982) Airway resistance of the voice button. Arch Otolaryngol 108:498–500
17. Weinberg B, Moon J (1984) Aerodynamic properties of four tracheoesophageal puncture prostheses. Arch Otolaryngol 110:673–675
18. Weinberg B, Moon JB (1986) Airway resistances of Blom-Singer and Panje low-pressure tracheoesophageal puncture prostheses. J Speech Hear Disord 51:169–172
19. Williams SE, Watson JB (1987) Speaking proficiency variations according to method of alaryngeal voicing. Laryngoscope 97:737–739
20. Zijlstra RJ, Mahieu HF, Lith-Bijl JT van, Schutte HK (1991) Aerodynamic properties of the low-resistance Groningen button. Arch Otolaryngol Head Neck Surg 117:657–661