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In vitro comparison of the Groningen high resistance, Groningen low resistance and Provox speaking valves

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Abstract
This paper compares the physical parameters of the newer Groningen low resistance and Provox indwelling laryngectomy prostheses with the established and original Groningen device.

In vitro pressure/flow profiles were determined, using specially designed apparatus, in 44 standard Groningen high resistance (GHR), 37 Groningen low resistance (GLR) and 19 Provox tracheo-oesophageal prostheses prior to insertion. GHR valves had significantly higher forward opening pressures than both the newer valves and the GHR was significantly higher than the Provox ($p<0.01$: Mann-Whitney U-test). The mean forward resistance of GHR was significantly higher than that of both; the Provox valve was significantly lower than that of GLR ($p<0.0001$: Mann-Whitney U-test). This may be of relevance with respect to patient acceptability, voice quality and effective duration of valve action.

Key words: Laryngectomy; Larynx, artificial

Introduction

Effective vocalization following laryngectomy is one of the most challenging areas of rehabilitation for the otolaryngologist, patient and speech therapist. Some patients rely on an 'artificial larynx' or vibrator which can produce loud enough but monotonous, machine-like speech. This consists of a vibrating plate which transmits motion to the floor of mouth so that the resulting vibrations can be articulated into recognizable speech. This method can be used reasonably effectively very soon after the operation. A more natural type of voice can be produced by the flow of air up through the neopharynx or pharyngo-oesophageal (PE) segment. This sound can, in a similar fashion, be articulated into recognizable speech. In this way oesophageal speech uses regurgitation of swallowed air to produce vibration of the pharyngo-oesophageal (PE) segment and hence sound, which is modified by the mouth, lips and tongue to produce the spoken word. Because of the limited capacity of the air reservoir the spoken phrases are of short duration and not in the normal phase with respiration.

The method which results in more versatile vocalization and is in phase with respiration uses the natural air reservoir of the lungs, redirected through the PE segment via a surgically created tracheo-oesophageal fistula while the tracheostome is covered.

Such a fistula alone is prone to leakage and aspiration of saliva or to closure by unwanted healing (Staffieri, 1980). However, use of a prosthetic valve in the fistula has helped to solve these problems since it was first described by Blom and Singer (1979), and such valves are now inserted as a primary procedure at laryngectomy (Singer *et al.*, 1989) or shortly afterwards in some centres.

The standard Groningen valve, first described by Nijdam *et al.* (1982) has two advantages over the Blom–Singer valve in that it is self-retaining and requires minimal patient maintenance. Reported series (Manni and Van den Broek, 1990; Rosingh *et al.*, 1991) have shown that it is highly acceptable, even being used tracheogastrically in a patient after a stomach pull-up (Izdebski *et al.*, 1988), and it has been used regularly in Sheffield since 1986 (Parker *et al.*, 1992a). Our series to date is the largest and longest documented in the UK. A modification of the Groningen valve was described by Zijlstra *et al.* (1991), designed to provide a lower resistance to air flow (GLR). They reported that airflow resistance of the GHR was relatively high compared with the figures from other workers reports on Blom–Singer low pressure and other low pressure valves. This work is difficult to translate between studies because comparison of results of *in vitro* measurements of various types of prosthesis in their respective studies is not reliable owing to the different set-up of the experiments (Nieboer and Schutte, 1986). Hilgers and Schouwenberg (1990) listed the priorities for an improved voice prosthesis, first among which was low airflow resistance leading to effortless, fluent speech. They described a new low-resistance, self-retaining prosthesis called Provox. *In vitro* direct comparison of opening pressure for the Provox with Blom–Singer low-resistance and Panje low-resistance valves (both of which need to be changed frequently) showed them to be similar.

The aim of this study was to compare the *in vitro*

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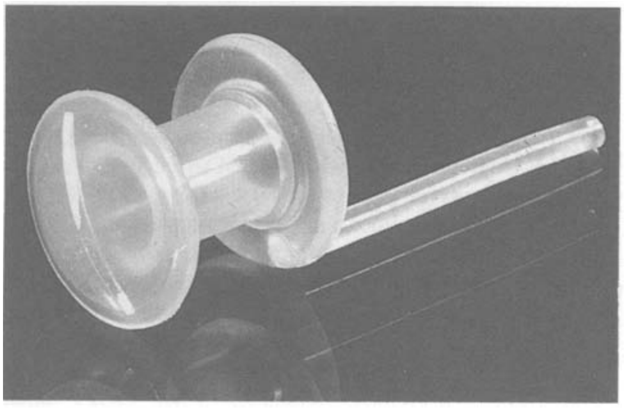

FIG. 1
Original or standard Groningen valve (GHR).

characteristics of GHR with GLR and Provox directly under the same experimental conditions, using previously validated equipment and methods (Parker *et al.*, 1992b).

Methods

Samples of new GHR, GLR and Provox valves were obtained. These were matched for size with a median of 7.0 mm (range 5.0–9.0 mm). Valves were taken straight out of the packet and tested prior to insertion (Figures 1, 2 and 3). *In vitro* valve pressure/flow dynamics were determined using apparatus which has been described in detail elsewhere (Parker *et al.*, 1992b). This consists of a compressed air supply, a graduated flow meter so that air flow through the valve can be varied, a calibrated transducer to determine the pressure acting on the valve and a receptacle into which the valve is placed so that air can be passed through it (Figure 4).

The following two parameters were studied since they were considered relevant to valve action, i.e. phonatory function and the prevention of aspiration. For each valve tested, three estimations were made of the parameter and the arithmetic mean taken.

(1) Forward opening pressure

This was that a pressure, acting on the tracheal surface of the valve, which was just sufficient to produce valve opening (Parker *et al.*, 1992b). This was judged by suspending the valve in water and increasing the air pressure

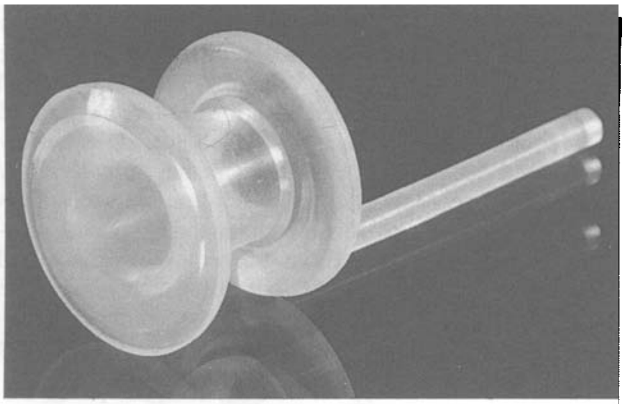

FIG. 2
Modified Groningen 'low resistance' valve (GLR).

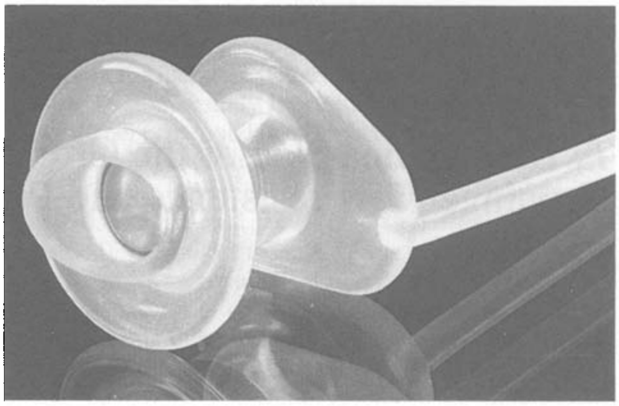

FIG. 3
Provox valve.

at the tracheal surface at a set rate until bubbles appeared on the oesophageal surface. Previous preliminary studies confirmed repeatability and reproducibility, both intra- and inter-observer.

(2) Forward resistance

This was the change in pressure across the valve from tracheal to oesophageal surfaces in response to an air flow change of 1600 ml/min (Parker *et al.*, 1992b):

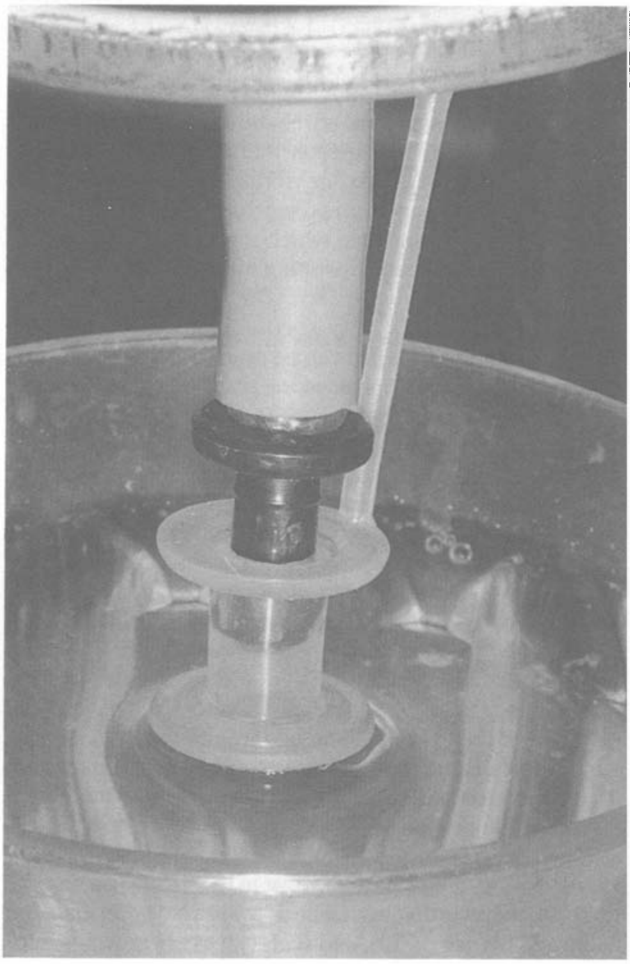

FIG. 4
Apparatus arranged for *in vitro* measurement of valve forward opening pressure.

TABLE I

	GHR		GLR		Provox	
	Median	Range	Median	Range	Median	Range
Forward opening pressure (mmHg)	6.3	1.7–18.0	3.3	1.7–9.1	2.1	0.5–8.9
Forward resistance (mmHg min/ml)	4.3	2.9–11.3	2.0	0.8–3.4	0.7	0.1–1.3

Forward resistance (mmHg min/ml) =

$$\frac{\begin{pmatrix}\text{pressure across valve}\\ \text{at flow of 1800 ml/min}\end{pmatrix} - \begin{pmatrix}\text{pressure across valve}\\ \text{at flow of 200 ml/min}\end{pmatrix}}{\text{1600 ml/min}}$$

Results

Forty-four new GHR, 37 GLR and 19 Provox tracheo-oesophageal prostheses were studied. The results of testing them for the two parameters are displayed in Table I and graphically in Figures 5 and 6.

Statistical analysis was accomplished on the MINITAB statistics package using the Mann-Whitney U-test, as normality of distribution of the data was not assumed. The forward opening pressure results showed both the GLR and Provox being lower than GHR (GHR *versus* GLR, $p<0.0001$: CI 1.4–3.9; GHR *versus* Provox, $p<0.0001$: CI 2.5–5.5) and the Provox lower than the GLR ($p<0.01$: CI 0.4–2.1). The mean forward resistance of GHR was significantly higher than that of both the more recently developed valves (GHR *versus* Provox, $p<0.0001$: CI 3.3–4.0; GHR *versus* GLR, $p<0.0001$: CI 2.0–2.5), while that of the Provox was significantly lower than that of GLR ($p<0.0001$: CI 1.2–1.7).

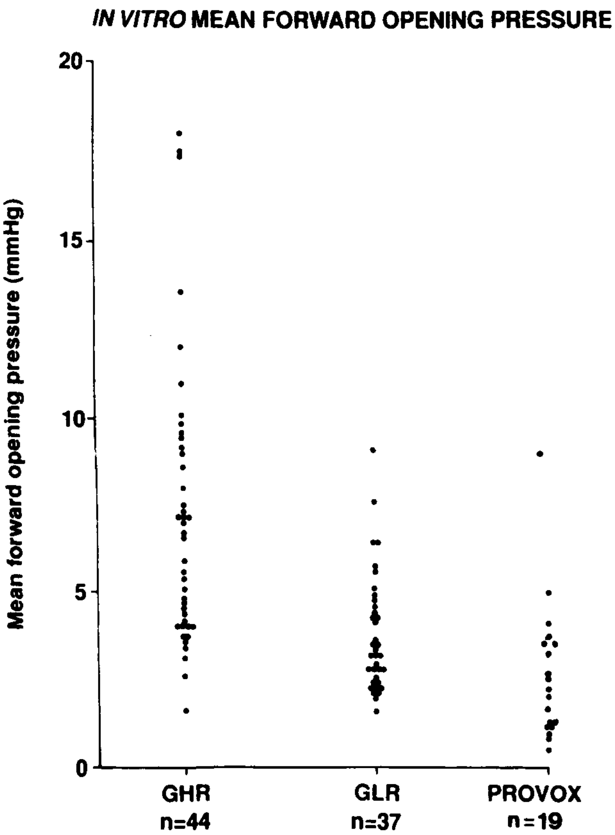

FIG. 5

In vitro mean forward opening pressure for the three types of valves.

The possibility of a type I error occurring has been considered in the light of the number of statistical tests performed. This is unlikely however since significance is still apparent if the accepted p value of $p<0.05$ is decreased to $p<0.01$.

Discussion

In patients using tracheo-oesophageal valves following laryngectomy, durability of prosthesis, as well as quality of speech, is of paramount importance. Patients generally prefer lower pressure devices (Zijlstra *et al.*, 1991) and valves with lower preinsertion opening pressures and resistances may last longer before requiring to be changed (Parker *et al.*, 1992c). The introduction of more recent valves with similar biflanged fittings has prompted comparison. It is interesting to speculate about the relationship, if any, between the *in vitro* preinsertion parameters measured here and the subsequent speech quality and duration of action in an established user. Detailed examination of the data, especially for the GHR prosthesis, reveals an appreciable difference in the various parameters across the sample of new valves. Knowledge of these prior to insertion may be of relevance in selecting a satisfactory prosthesis, although *in vivo* factors such as PE segment tone may be more important.

In vivo studies are required to compare these valves in more detail before the clinical usefulness of the findings in the present study can be established. It would seem

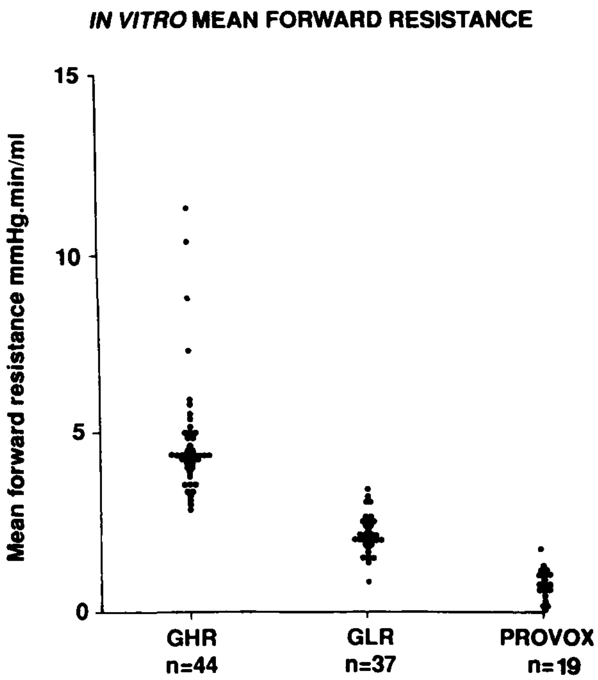

FIG. 6

In vitro mean forward resistance for the three types of valves.

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reasonable to suppose that the opening pressure of a device is only of relevance to the patient if it exceeds that of the opening pressure of the PE segment. Similarly the actual resistance of the device may only be of concern once it becomes an appreciable constituent of the total opposing the flow of air up through the respiratory tract, pharynx, oral and nasal cavities.

The data suggests that both the GLR and particularly the Provox valves have significantly improved characteristics compared to the GHR, with the consequent expectation of easier fluent speech, longer duration of action and improved patient acceptability. Further clinical studies are indicated to confirm these in relation to *in vivo* valve function.

Acknowledgement

'Provox' is the registered trade mark of ATOS Medical, A.B. Horby, Sweden, and Entermed, Woerden, The Netherlands.

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