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Voice rehabilitation after laryngectomy with the Provox® voice prosthesis in South Africa

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Abstract

A study was undertaken to determine whether the Provox® voice prosthesis provides good voice rehabilitation following a total laryngectomy in the urban, suburban and rural populations served by a tertiary referral hospital in South Africa.

Between 1995 and 1999, a cohort of 128 patients at Tygerberg Hospital was rehabilitated with the Provox™ voice prosthesis after laryngectomy. In 104 patients primary placement of the prosthesis was done at the time of the laryngectomy. Mean device life and adverse events were determined. Voice quality was assessed subjectively in 104 patients and objectively in 26 patients.

The mean device life was 303 days and adverse events occurred in 16 patients. Subjectively, 77 of 104 patients had a good voice, and objectively 22 of 26 patients had good voice intelligibility. The Provox® voice prosthesis provides good voice rehabilitation following total laryngectomy, with minimal complications, in the population served by Tygerberg Hospital.

Key words: Laryngectomy; Prostheses and Implants; Treatment Outcome

Introduction

A total laryngectomy is mainly performed on patients who have advanced malignant disease of the larynx. The operation involves removing the larynx and closing the resulting pharyngeal defect. The tracheal stump is brought out anteriorly and sutured end-to-side to the suprasternal skin as a tracheostoma. This separation of the air and food passages prevents aspiration, the prevention of which is the primary function of the larynx. Voice production, the other main function of the larynx, is however lost.

Voice rehabilitation following a total laryngectomy has continued to be a challenge since the procedure was first performed by Billroth in 1873. His patient was rehabilitated with a device described in the publication by his assistant Gussenbauer.[1] Pulmonary-driven air from the lungs was directed into the pharynx by the device in order to produce sound.

The problems of aspiration and spontaneous closure of surgically created fistulae were largely solved by the introduction of a device by Singer and Blom in 1980, that resulted in excellent tracheo-oesophageal speech.[2] The basic principle is that when the patient exhales and closes the stoma with a finger there is a one-way flow of air through a device placed in the tracheo-oesophageal fistula. While allowing the flow of air into the pharynx the device prevents aspiration of oesophageal contents into the trachea. The flow of air sets up vibrations in the pharyngeal mucosa, which are modified by the tongue and lips in the usual way to produce speech. Initially the valves were non-indwelling, in that the patients had to remove them periodically to clean them. More recently they have been re-designed, and a newer generation of indwelling devices have been developed, of which the Provox® voice prosthesis is one.[3–5] A tracheo-oesophageal voice prosthesis is the standard method of voice rehabilitation in patients undergoing a laryngectomy at Tygerberg Hospital. This study was done to assess whether these newer devices would be appropriate for these patients.

Patients and methods

Between January 1995 and September 1999, all patients undergoing a total laryngectomy at Tygerberg Hospital were entered into a prospective study. The main outcome measures were device-life, adverse events relating to the prosthesis and fistula, and subjective and objective voice quality.

A total of 128 patients undergoing total laryngectomy at Tygerberg Hospital between January 1995 and September 1999 were rehabilitated with a Provox™ voice prosthesis. Of these, 113 (88 per cent) were male and 15 (12 per cent) were female.

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TABLE I
TYGERBERG PROVOX® PROJECT

Gender	No. of cases	Placement	No. of cases
Male	113 (88%)	Primary puncture	104 (81%)
Female	15 (12%)	Secondary puncture	24 (19%)
Total number of patients	128 (100%)	Total number of patients	128 (100%)

Their ages ranged from 41 to 88 years with a mean age of 57 years. In 104 (81 per cent) patients, primary puncture of the tracheo-oesophageal segment and placement of a Provox® voice prosthesis was done at the time of the total laryngectomy. In 24 (19 per cent) patients the placement was delayed and placed as a secondary procedure (Table I). The technique for primary and secondary placement of the Provox® voice prosthesis was similar to that used by Hilgers and Schouwenburg.[3,4] When replacement of the prosthesis was indicated, it was usually done by the retrograde method utilizing a guide-wire and pulling the device into the fistula from the pharynx. In three cases, the replacement prosthesis was introduced into the fistula in an anterograde direction using the Provox®-2 introducer.[6,7]

The mean device-life was calculated from the total follow-up time (from initial placement to time of analysis), and the number of prostheses used for each patient in that time.

A note was made in the patient's file of all procedures performed which related to the Provox® prosthesis. The technique of primary and secondary placement was recorded as were any difficulties or complications. When the device needed replacement, the reason for replacement, condition of the stoma and fistula and difficulties encountered during replacement were recorded.

The voice quality was rated subjectively by a speech therapist or by the surgeon using a simple three-point scale rating as being either 'good', 'poor' or 'no speech'. 'Good' means an acceptable voice used as the primary method of communication and 'poor' means an unacceptable voice, not useful as the primary communication method. If there was no speech, it was noted whether the prosthesis was used at all or not.[4] The voice was rated after primary placement, and when the patient returned for follow-up or for replacement of a prosthesis.

Some patients were evaluated objectively with a computerized speech laboratory (Speechlab® CSL 4300 Kay Elemetrics, Philadelphia, USA). The objective evaluation included maximum phonation time, dynamic range, frequency range, mean pitch and intensity, jitter and shimmer. These patients were further evaluated while speaking spontaneously on a chosen subject, counting from one forwards with one breath, and sustaining the vowel /a/ for as long as possible. This was to determine the length of utterance, speech rate, maximum phonation time, availability, tonicity, fluency and intelligibility.

TABLE II
ADVERSE EVENTS (16 PATIENTS)

Type of adverse event	No. of events
Posterior displacement of prosthesis	5
Anterior displacement of prosthesis	9
Granuloma formation	2
Enlarged fistula	3
Leakage adjacent to the fistula	3

Results

Twenty-four (19 per cent) patients were lost to follow-up. The mean device-life was 303 days. The minimum device-life was 10 days while the maximum exceeded 1191 days. Sixty-three Provox® valves were replaced during the period of the study. The reason for replacement was either leakage of fluids through, or around, the prosthesis or loss of the prosthesis. The fistula closed following displacement or removal of the prosthesis in six patients.

Some patients experienced one or more adverse events during their follow up. These included displacement of the prosthesis, granulation tissue formation around the prosthesis, leakage around the prosthesis and aspiration pneumonia.

There were 22 adverse events, and these were mainly fistula-related problems. There were five posterior displacements of the prosthesis, nine anterior displacements of the prosthesis, granuloma formation around the fistula occurred in two patients and an oversized fistula required hospitalization for shrinkage of the fistula in two cases. One patient returned with the loss of the prosthesis from a large fistula with a thin and weak wall. He had been chronically aspirating and was in a cachexic state. Despite a cuffed tracheostomy tube being placed into the trachea and nasogastric tube feeding, he continued to aspirate tracheo-oesophageal secretions. To definitively prevent further aspiration of secretions he underwent a surgical closure of the fistula but developed a severe aspiration pneumonia in the post-operative period. He was admitted to the intensive care unit where he eventually died of a multiple organ failure. In three patients a leak next to the prosthesis was controlled by a submucosal purse-string suture around the tracheo-oesophageal fistula. Overall, 16 patients (15 per cent) had adverse events, four of them had more than one event (Table II).

Quality of voice assessments were performed for 104 patients. Subjective rating of the patients' voice using the Provox® voice prosthesis following total

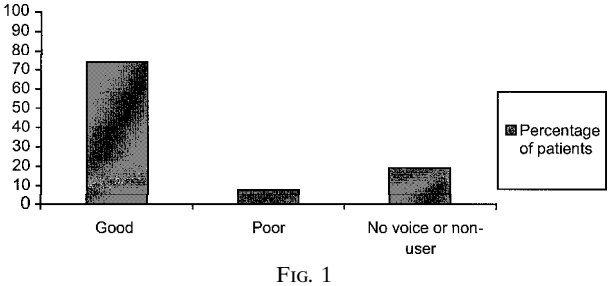

FIG. 1
Subjective voice rating with the Provox™ voice prosthesis (n = 104)

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TABLE III

OBJECTIVE VOICE ANALYSIS (N = 26). IDEAL VALUES FOR TRACHEO-OESOPHAGEAL SPEECH (TES) ACCORDING TO CRITERIA ADOPTED DURING THE THIRD INTERNATIONAL CONGRESS ON THE VOICE PROSTHESIS IN GRONINGEN (1988),[12] AND NORMAL SPEECH VALUES

		Ideal values for TES			
	Results	Good	Moderate	Poor	Normal speech
Maximum phonation time(s)	8.5	>9	4–9	4	21
Dynamic range (dB)	42.5–56.9	>24	16–24	<16	96
Frequency range (Hz)	132–208				500–2000
Intensity (dB); mean	50				78
Frequency (Hz): mean	181				
Jitter (%): mean	4.2				<0.8
Shimmer (dB): mean	2.9				<0.5

laryngectomy revealed that 77 (74 per cent) patients had a good voice, seven (seven per cent) patients had a poor voice, 18 (17 per cent) patients had no voice and two (two per cent) of patients did not use the prosthesis (Figure 1).

Of the 77 patients who had a good voice, an unselected sample of 26 of them, 21 men and five women, underwent objective voice analysis using the Kay CSL 4300 Speechlab. The results are tabulated in Table III.

The tracheo-oesophageal speech of this group of patients was evaluated while speaking spontaneously on a chosen subject. The length of utterance was good (>19 syllables) in 83 per cent of the patients, and moderate (10–18 syllables) in 17 per cent of the patients. The speech rate was good (>140 syllables/min) in 58 per cent of patients, moderate (100–139 syllables/min) in 38 per cent, and poor (<99 syllables/min) in four per cent of patients. The maximum phonation time was good (>10 seconds) in 31 per cent of patients, moderate (4–9 seconds) in 65 per cent, and poor (<3 seconds) in four per cent of patients (Figure 2).

Subjective speech evaluation of this sample was performed. The availability was assessed as good (delay <3 seconds) in 100 per cent of patients. The voice quality was eutonic (good) in 69 per cent of patients, hypertonic (moderate) in 23 per cent of the patients and hypotonic (moderate) in eight per cent. The fluency was good in 100 per cent of patients. The intelligibility was good in 86 per cent of patients and moderate in 12 per cent (Figure 3).

Discussion

Voice rehabilitation is essential for every patient who undergoes a laryngectomy. Options include oesophageal speech, where no device is needed, or methods requiring some sort of device. These range from an electrolarynx, a reed and tube device or a valve placed into a tracheo-oesophageal fistula. Tracheo-oesophageal speech is considered the best form of voice rehabilitation at present because phonation is immediate, the training is simple, phonation time is longer and there is greater volume and better intelligiblity.[8] Tracheo-oesophageal speech requires the placement of a one-way valve between the trachea and the oesophagus, which allows the passage of air in one direction while preventing aspiration of pharyngeal contents. Numerous such valves are now commercially available. They can be divided into non-indwelling prostheses, those that the patient removes daily to clean, and indwelling prostheses, that the physician changes periodically when indicated. The indwelling devices have the advantage in that the patient's dexterity and visual acuity is not a pre-requisite to their use. No special skills are needed by the patient to use and care for them. The Provox® voice prosthesis is an indwelling device and the only maintenance required is for the patient to clean it daily with a small specially designed brush. The devices are made of silicon and may become colonized with *Candida* over time. This can cause the valve within the device to fail, leading to leakage through the valve, requiring the prosthesis to be replaced periodically. The fistula into which the prosthesis is placed is dynamic and so fistula-related problems may cause the prosthesis to become ill-fitting or to be extruded, giving rise to leakage around the valve.

The mean device-life has been reported as being approximately 163 days with a range of 148 to 311 days.[9] At Tygerberg Hospital the mean device-life in this study was 303 days, which is long in comparison to other results published in the literature.[3,4,10–16] The reason for this is probably the more conservative

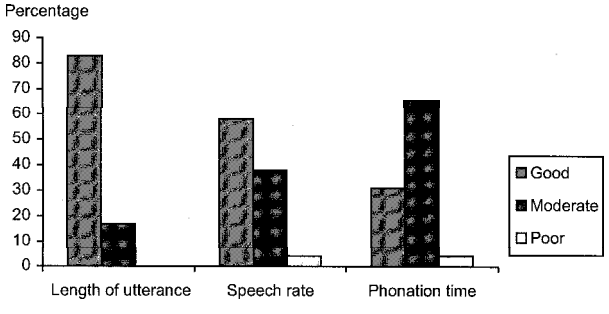

FIG. 2

Subjective speech evaluation with the Provox® voice prosthesis (n = 26).

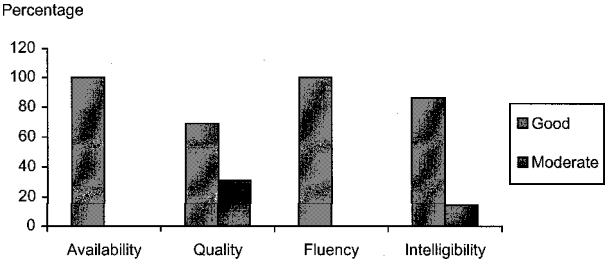

FIG. 3

Subjective speech evaluation with the Provox® voice prosthesis (n = 26).

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approach adopted by our patients when intermittent leakage occurs through the prosthesis. This was the main reason for replacement in 73 per cent of cases in a large study in the Netherlands.[9] Our patients adopted a similarly conservative approach to intermittent leakage around the prosthesis, that accounted for 13 per cent of replacements in the large Netherlands study. This conservative approach is compounded by problems that patients encounter in being regularly followed-up, including transport and financial difficulties. The hospital serves an urban, suburban and rural population including patients from a poor socio-economic background, for whom transport to the hospital is expensive and irregular.

Leakage through the prosthesis, most likely due to *Candida* deposits on the valve edges, has been reported to be the main reason for replacement in three quarters of cases.[9] Antifungal preparations have been advocated by many authors to prevent the colonization of the silicon prosthesis by *Candida*,[4,17,18] but these are rarely used at our hospital. Ideally a walk-in service should be available to patients who need their prostheses changed when they leak or when the pressure needed to initiate speech becomes high.

We encountered adverse events in 15 per cent of the patients. The tracheo-oesophageal fistula was closed in six patients because of: local infection or excessive granulation tissue (two cases); an inability of the patient to care for the fistula (two cases); an oversized fistula (one case) and displacement of the prosthesis by tumour recurrence (one case). One patient who required a long-term admission for shrinkage of the fistula subsequently developed aspiration pneumonia. Although his fistula was eventually closed surgically, he died of multiple organ failure in the ICU.

Tracheo-oesophageal speech is considered the best method of communication in patients who have undergone laryngectomy, and far superior to other methods of voice rehabilitation. Placement of a prosthesis at the time of laryngectomy usually allows the patient to commence tracheo-oesophageal speech before discharge from hospital.

These results compare favourably with 84 per cent fair-to-excellent voice quality in one study and 88 per cent fair-to-good voice quality in another study, both from The Netherlands.[9]

Conclusion

Primary tracheo-oesophageal puncture and insertion of a voice prosthesis at the time of laryngectomy is our preferred method of voice rehabilitation. The Provox® voice prosthesis provides good voice rehabilitation following a total laryngectomy with minimal complications in the population served by Tygerberg Hospital. Of the 84 patients who use the valve and were followed up, 77 had a good voice.

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