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Conversion from a non-indwelling to a Provox®2 indwelling voice prosthesis for speech rehabilitation: comparison of voice quality and patient preference

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Abstract

This prospective study assessed the advantages and problems associated with converting a patient using an older generation non-indwelling voice prosthesis to a newer generation indwelling voice prosthesis, in this case the Provox®2. The voice characteristics of each patient were measured using the old and then the new voice prosthesis. Technical aspects of the insertion of the indwelling prosthesis were noted. Each patient completed a questionnaire after a period of use with the indwelling prosthesis.

Changing the prosthesis was simple and uncomplicated in 15 of 17 patients. Acoustic analysis showed improved parameters with the indwelling prosthesis, but no perceptual difference between the two prostheses. The questionnaire revealed that most patients preferred the indwelling prosthesis.

Replacing a non-indwelling with an indwelling prosthesis is technically simple, leading to improvement in voice quality and patient satisfaction. It may be reasonable to offer this choice to patients currently using an older generation non-indwelling voice prosthesis.

Key words: Laryngectomy; Speech, Alaryngeal; Larynx, Artificial

Introduction

The loss of laryngeal speech is the most obvious consequence of a total laryngectomy since Billroth first performed the procedure in 1873.[1] Vocal rehabilitation is now achieved by a variety of means, of these the best voice quality is obtained by a prosthesis placed into the tracheo-oesophageal fistula.[2] This form of voice rehabilitation has been popular since 1979 when Singer and Blom introduced their prosthesis,[3] with other prostheses following soon after.[4] Initially these prostheses were non-indwelling and had certain disadvantages, such as the need to remove them to clean them.[5] Patients often experienced difficulties in reinserting the prosthesis into the fistula.[6] To eliminate these problems most of the prostheses have been redesigned, leading to the development of a newer generation of indwelling voice prostheses, such as the Groningen prosthesis introduced in 1981,[7] the Provox® prosthesis introduced in 1990[8] and the Blom-Singer indwelling prosthesis introduced in 1994.[9] The indwelling prostheses are removed and replaced by the health-care provider when indicated.[10]

A population of patients exist who currently use non-indwelling voice prostheses for voice rehabilitation following a laryngectomy. With the improved design of indwelling voice prostheses, their availability and the education of surgeons and speech therapists in their use, indwelling prostheses have become popular. It has generally been accepted that indwelling prostheses have definite advantages such as lower opening pressures and less care needed to clean them. Most do not have a tag and so tape does not have to be stuck around the stoma. This prospective study was undertaken to determine whether there are any benefits to patients currently using the older generation non-indwelling voice prostheses in converting to the newer generation indwelling voice prostheses.

Patients and methods

Patients

Patients who had previously undergone a total laryngectomy and were currently using tracheo-oesophageal speech as their primary mode of communication were contacted by the department

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of Otolaryngology at Tygerberg Academic Hospital. Patients using a non-indwelling voice prosthesis were informed that an indwelling prosthesis, a newer alternative to a non-indwelling prosthesis, may offer them certain benefits and that to determine whether such benefits existed or not, they were invited to participate in this prospective clinical study. Some of those patients who were totally satisfied with their non-indwelling prosthesis declined participation. After counselling and having given their informed consent, 17 patients voluntarily entered the study. All the patients had previously received speech rehabilitation from the same speech pathologist.

Voice analysis

The voice characteristics of each patient were measured twice. Initial measurements were taken with the patient using their usual non-indwelling voice prosthesis. The non-indwelling voice prosthesis was then removed and an indwelling voice prosthesis of the appropriate size was fitted.

Once the patient had become comfortable using their new indwelling prosthesis the voice characteristics of the patient were measured again. This was done within a week of the exchange.

A qualified speech pathologist performed a real time objective analysis of each patient's voice using a Kay Elemetics CSL 4300 computerized speech laboratory. On each occasion the patient was seated comfortably in a sound proof booth and under similar circumstances. The microphone was at a standard distance and angle from the mouth. On each occasion the following acoustic variables were determined: (1) length of utterance, (2) maximum phonation time, (3) dynamic range, (4) frequency range, (5) average pitch, (6) average intensity, (7) jitter and (8) shimmer. At each session a recording was made of the patient reading a standard paragraph for future perceptual analysis by two independent speech pathologists. When that was done the listeners perceptually rated three items, availability (of voice), fluency and intelligibility (of speech). These were scored as either poor, moderate or good.

Prosthesis exchange

All patients had been using non-indwelling prostheses with a shaft diameter of 5.4 mm (16 French gauge) but with varying shaft lengths. These were either a Blom-Singer low pressure or Duckbill voice prosthesis (Inhealth Technologies) or a Bivona® voice prosthesis (Bivona Medical Technologies). Topical anaesthesia was usually used (10 per cent lidocaine spray). The non-indwelling prosthesis was removed and a silicon tracheo-oesophageal puncture dilator (22 French gauge) was inserted into the fistula and pushed in down to the hilt of the dilator. The fistula tract had to be dilated up from 5.4 mm, the shaft diameter of the non-indwelling prostheses, to 7.5 mm, the shaft diameter of the Provox®2 (Atos Medical) prosthesis. If resistance was experienced then the tract was dilated slowly over a number of minutes. Once the tract was dilated the length of the tract was measured with a Provox® measure. The Provox®2 prosthesis was chosen as the indwelling prosthesis for this study from the six or more indwelling prostheses available because both surgeons and one of the speech therapists had acquired considerable experience with the Provox® prosthesis while working in The Netherlands where the Provox® prosthesis was developed, is popular and widely used. Further local experience with the Provox® prosthesis follows routine primary placement of this prosthesis at the time of surgery in those patients undergoing total laryngectomy at Tygerberg hospital. A Provox®2 voice prosthesis of the appropriate shaft length was selected and inserted into the fistula in the prescribed anterograde method. The correct position of the voice prosthesis was confirmed by rotating the device and applying moderate traction. The size of the old and new prosthesis, fistula length, local appearance of the fistula, ease of insertion, difficulties and complications were noted. Once any local swelling had settled, and the patient become familiar with the new prosthesis, the voice characteristics were re-measured.

Patient questionnaire

At least two weeks after receiving their new prosthesis the patients were asked to complete a structured questionnaire detailing their assessment of the indwelling prosthesis. They were asked to comment on whether the following parameters had either improved or increased, stayed the same with no change, or decreased and become worse: intensity of voice, fluency of voice, intonation of voice, availability of voice, swallowing ability, increase in voice use, mucus production, effort needed to produce speech, time to maintain the prosthesis, benefit of not needing to remove and re-insert the prosthesis daily, family reaction and the patient's prosthesis preference (Appendix). The question on swallowing ability was used to indicate bias in this regard as it was felt that there should be no difference between the two prostheses.

Results

Fifteen men and two women participated in this study (age range 50 years to 78 years, mean age 62.6 years).

Voice analysis

The mean value and standard deviation was calculated for each voice parameter of each patient using the old prosthesis and using the new prosthesis (Table I). Increases in mean values were observed with the new prosthesis for length of utterance, phonation time and frequency range. There was a decrease in the mean value of shimmer with the new prosthesis. When a paired samples test was applied to these values, there was a significant difference between the old and the new prosthesis for the length of utterance ($p = 0.027$)

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TABLE I
PAIRED SAMPLES STATISTICS OF ACOUSTIC ANALYSIS OF THE NON-INDWELLING AND THE INDWELLING VOICE PROSTHESES (N = 17)

	Non-indwelling prosthesis		Indwelling prosthesis		
	Mean	SD	Mean	SD	*p*
Length of utterance (n)	19.235	10.26	22.647	12.47	0.027
Phonation time (s)	9.177	7.50	10.412	6.81	0.160
Dynamic range (dB)	55.030	7.48	53.971	9.31	0.600
Frequency range (Hz)	153.941	38.09	157.530	44.61	0.784
Pitch (Hz)	143.765	53.35	143.353	44.58	0.967
Intensity (dB)	57.235	7.39	54.941	7.73	0.294
Jitter (%)	3.632	3.86	3.917	3.18	0.815
Shimmer (dB)	3.645	2.93	3.139	1.87	0.518

Voice availability, fluency and intelligibility were scored on a three-point scale as either poor, moderate or good. This was done for each patient while using the old prosthesis and then again with the new prosthesis. The assessment was done independently by two speech pathologists (Table II). The kappa coefficient was used to test similarity between assessors. Although there was reasonable agreement between the two raters, kappa 0.6 to 1 (Table III), no significant difference was demonstrated between the old and new prostheses for these parameters.

Prosthesis exchange

The normal method for placing the Provox®2 voice prosthesis is in an anterograde direction, and this was achieved in 15 patients.

In two patients a tight fibrous ring at the oesophageal end of the tract prevented sufficient dilation to occur in order to allow the Provox®2 introducer through, and so the prosthesis was introduced in a retrograde direction. The problem with anterograde placement was due to a long and angulated fistula, something that seems to occur with non-indwelling prostheses and which we have not encountered when an indwelling prosthesis is placed primarily.

The change was performed under local anaesthetic in 15 patients and under general anaesthetic in two. The non-indwelling prostheses used by the patients in this study were supplied in shaft lengths of 6 mm to 28 mm. This resulted in fistula tracts that were often longer than 10 mm in length. This made insertion sometimes difficult as the introducer had to dilate the entire tract while the prosthesis was being advanced through it. The longest shaft length prostheses were used in these cases.

TABLE III
KAPPA VALUES FOR THE TWO RATERS OF VOICE CHARACTERISTICS

	Kappa	
	Non-indwelling prosthesis	Indwelling prosthesis
Voice availability	0.7538	1
Fluency	0.7385	0.6566
Intelligibility	1	1

We encountered two fibrous strictures at the oesophageal end of the fistula which needed division in theatre under general anaesthetic.

With longer-term follow-up outside the parameters of this study, one patient whose tract went superiorly at an acute angle struggled to produce voice and so abandoned the system. In one patient the device extruded over time and a secondary puncture and insertion of a prosthesis was performed. One patient subsequently needed a stomaplasty, excision of the fistula and repuncture.

Patient questionnaire

Thirteen patients completed the questionnaire. Table IV reports the patients' ratings of the quality of their speech using the indwelling prosthesis compared to the non-indwelling prosthesis. The majority thought that the intensity of their voice was better (77 per cent), the fluency of their voice was better (62 per cent), the intonation of their voice was better (62 per cent) and that their voice was more available (85 per cent). They found no difference in their swallowing ability (85 per cent) or in the amount of mucus produced (62 per cent). Fewer than half the patients (46 per cent) used their voice more, and more than half the patients (62 per cent) felt that the effort required to produce voice was less. Most patients (92 per cent) found the maintenance time less and more than half the patients (69 per cent) felt that not having to remove and re-insert the prosthesis was beneficial. More than half (62 per cent) of the family members and most (92 per cent) of the patients preferred the indwelling prosthesis.

Discussion

This study was conducted to establish whether there were any benefits to a patient currently using a non-

TABLE II
PERCEPTUAL EVALUATION OF THE VOICE BY TWO RATERS (N = 17)

		Non-indwelling prosthesis			Indwelling prosthesis		
	Rater	Poor	Moderate	Good	Poor	Moderate	Good
Availability	A	6	31	63	6	12	83
	B	6	29	65	6	12	83
Fluency	A	6	18	76	6	12	82
	B	6	29	65	0	24	76
Intelligibility	A	6	35	59	6	29	65
	B	6	35	59	6	29	65

% of patients

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TABLE IV
PATIENT RATINGS OF THE INDWELLING PROSTHESIS COMPARED TO THE NON-INDWELLING PROSTHESIS (N = 13)

	Better	Same	Worse
Intensity	76.9	15.4	7.7
Fluency	61.5	23.1	15.4
Intonation	61.5	30.8	7.7
Availability	84.6	7.7	7.7
Effort to swallow	15.4	84.6	0.0
Family preference	61.5	38.5	0.0
Patient preference	92.3	7.7	0.0
	More	Same	Less
Voice use	46.2	46.2	7.7
Mucus production	15.4	61.5	23.1
Effort to speak	15.4	23.1	61.5
Maintenance time	7.7	0.0	92.3
Benefit of non removal	69.2	23.1	7.7

% of Patients

indwelling voice prosthesis in changing to an indwelling prosthesis. Objective voice tests showed no difference between the two types of prostheses, which may not be surprising since both prostheses allow low pressure pulmonary driven air flow to produce vibrations from the same pharyngo-oesophageal segment. It has previously been shown that tracheo-oesophageal speech is the best form of vocal rehabilitation after laryngectomy, being superior to other forms of vocal rehabilitation including oesophageal speech.[2]

There are two categories of prostheses used to maintain the tracheo-oesophageal fistula, a non-indwelling type and an indwelling type. The non-indwelling types have some disadvantages. The prostheses have to be fixed to the skin with tape and need to be removed, cleaned and replaced, often daily, by the patient.[5] The inability of the patient to manage the tracheo-oesophageal fistula is one of the major causes of failure.[6] Improper replacement or spontaneous dislocation of the prosthesis can lead to a false passage or eventual closure of the fistula.

There are various reasons why a group of patients currently use a non-indwelling prosthesis for voice rehabilitation. Many patients were initially fitted with a non-indwelling prosthesis prior to the availability of the newer indwelling prostheses, and have continued to use them. The traditional experience of some surgeons and speech therapists may be limited to the older non-indwelling voice prostheses. Cost constraints require some institutions to make available to patients the less expensive non-indwelling prosthesis instead of the more expensive indwelling prosthesis. Tygerberg hospital is in the fortunate position of carrying both non-indwelling and indwelling prostheses as standard stock items. Although the unit price of an indwelling prosthesis ranges from 100 to 200 per cent greater than a non-indwelling prosthesis, it is not a foregone conclusion that the expense is greater because of the differing device lives of the two types of prostheses. While this study did not address financial factors, we acknowledge the importance of health economics.

The indwelling voice prosthesis represents an improvement over the non-indwelling prosthesis. These have the advantage of requiring less dexterity from the patient since daily maintenance is limited to *in situ* cleaning of the prosthesis and the replacement is performed by the health-care provider when indicated.[10] The indwelling prosthesis eliminates the need for a tag which is taped to the skin, and so there is a better seal of the stoma during phonation. Some studies have suggested a slightly lower complication rate with the indwelling voice prosthesis.[11]

In this study the Provox®2 prosthesis was chosen as the indwelling prosthesis with which to replace the non-indwelling prosthesis. In two studies comparing indwelling prostheses to each other, no difference was found in the survival time between the Provox®2 prosthesis and the Blom-Singer prosthesis,[12] and no difference was found in voice quality and patient satisfaction between the Provox®2 prosthesis and the Blom-Singer prosthesis.[13] The Provox®2 is a front-loading, or anterograde insertion and removal, indwelling prosthesis. The concept of the study was easy for patients to accept because they were familiar with the removal and replacement of a prosthesis in this manner. The method of anterograde placement has been shown to be less time consuming than the retrograde method.[10] The anterograde method diminishes and produces less uncomfortable side-effects such as coughing, gagging, pain and anxiety.[14] The placement of the new prosthesis in the anterograde direction eliminates potential problems associated with pharyngeal strictures that may be present in 15 per cent of patients.[10] Fistulae tracts longer than 8 mm in length should be dilated first, before attempting to insert the Provox®2 prosthesis in the anterograde direction.[10]

Thirteen patients completed the questionnaire. The majority thought that the intensity, fluency, intonation and availability of their voice was better and that speaking required less effort. No difference was noted in their swallowing ability or mucus production. Approximately half used their voice more. Most found the maintenance time less and more than half felt that not having to remove and re-insert the prosthesis daily was beneficial. Family members preferred the indwelling prosthesis in over 50 per cent of the cases while most of the patients preferred the indwelling prosthesis. This difference may be a surrogate outcome measure, the patients reporting greater satisfaction to please their surgeon, which is inherent in this type of study. However, the difference may also be due to the patient being the person who actually wears the prosthesis, and not the family.

The patients in this study indicated a general preference for an indwelling prosthesis. The reduced effort required to phonate resulted subjectively in a louder voice and better intelligibility of speech. This is in agreement with other published studies where patients almost uniformly preferred the indwelling to a non-indwelling voice prosthesis for both care and maintenance.[9]

Conclusions

There are advantages for patients who currently use a non-indwelling voice prosthesis in converting to an indwelling voice prosthesis.

- **This is a prospective study of patients who had had a non-indwelling voice prosthesis previously and who were subsequently fitted with a Provox value**
- **Most patients and their families preferred the indwelling prosthesis**
- **Subjectively the indwelling prosthesis also provided a louder voice with greater speech intelligibility**
- **No significant improvement in objective voice parameters was noted**

The conversion was uncomplicated in 15 of 17 patients. However, when the existing fistula was longer than 8 mm, dilatation or even division of fibrous strictures may be necessary.

Although significant improvement in objective voice parameters could not be demonstrated in this study, most patients preferred the indwelling prosthesis. Half of the patients spoke more, requiring less effort to produce a better voice, and for most of the patients, the time spent maintaining the prosthesis was less.

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Appendix

Patient questionnaire – Indwelling *vs* non-indwelling voice prosthesis

We are interested in your opinion of your new indwelling voice prosthesis compared to your old non-indwelling voice prosthesis. Please answer all of the questions yourself by circling the answer that best applies to you. There are no 'right' or 'wrong' answers.

1 How do you rate the loudness of your voice with the new prosthesis?

Softer *The same* *Louder*

2 How do you rate the fluency of your speech with the new prosthesis?

Less fluent *The same* *More fluent*

3 How do you rate the intonation of your voice with the new prosthesis?

Worse *The same* *Better*

4 How would you rate your ability to begin speaking with the new prosthesis?

Easier *The same* *Harder*

5 How would you rate your ability to swallow with the new prosthesis?

Easier *The same* *Harder*

6 How does your family rate the new prosthesis?

It is worse *It is the same* *It is better*

7 Overall, which prosthesis do you prefer?

Old prosthesis *No difference* *The new prosthesis*

8 How would you rate your use of your voice with the new prosthesis?

Use it less *Use it the same* *Use it more*

9 How would you rate the amount of mucus that you produce with the new prosthesis?

Less *Same* *More*

10 How would you rate the effort that it takes to speak with the new prosthesis?

Less *Same* *More*

11 How much time do you need to spend maintaining/cleaning the new prosthesis?

Less *Same* *More*

12 How would you rate the benefit or not removing and replacing the new prosthesis?

Less *Same* *More*