



Evaluation of post total laryngectomy voice rehabilitation by Provox®2 voice prosthesis (preliminary study)

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Abstract

Introduction: Tracheo-esophageal puncture (TEP) with inserting a silicon prosthesis is the gold standard for voice rehabilitation after total laryngectomy (TL). Provox® is an indwelling voice prosthesis which is widely used nowadays.

Objective: to evaluate the outcomes of Provox®2 voice prosthesis in vocal rehabilitation after total laryngectomy.

Patients and methods: Sixteen patients who had inserted Provox®2 voice prosthesis after total laryngectomy were subjected to history taking, general ENT examination and neck examination. Patients were evaluated for voice outcome two months after the application of the Provox®2 by the maximum phonation time (MPT), Perceptual voice quality analysis by GRBAS scale, Speech intelligibility and Patient's satisfaction.

Results: We found that the production of 100% intelligible voice with a good MPT and quality of voice (assessed by GRBAS scale) using a device with an average life of 375 days would be considered as favorable.

Conclusions: The use of Provox®2 voice prosthesis is a safe and satisfactory method for post total laryngectomy voice rehabilitation.

Keywords: Total laryngectomy, Provox®2, Tracheo-esophageal puncture.

Introduction

Post laryngectomy voice rehabilitation has been a major challenge since the first laryngectomy performed by Billroth in 1873. ¹

There are three options for voice restoration in laryngectomized patients: the esophageal speech, artificial larynx and tracheo-esophageal puncture (TEP) with insertion of voice prosthesis. ²

In 1980 Singer and Bloom were the first ones to insert the silicone voice prosthesis in the tracheo-esophageal (TE) fistula. ³

In 1988, Provox® voice prosthesis (Atos Medical AB, Hörby, United Kingdom) was used at the Department of otolaryngology, Head and Neck

Surgery, cancer Institute, Amsterdam, The Netherlands. ⁴

Patients and Methods:

Patients: The study included 16 patients that had been inserting Provox®2 voice prosthesis after total laryngectomy (secondary insertion).

The study had been carried out in the department of otolaryngology at Assiut university hospital. This study was approved by the Institutional Ethics and Research Committee of the Faculty of Medicine, Assiut University, Assiut, Egypt. Dealing with the collected data of the patients and data dissemination were confidential. The study and all

interventions and surgical procedures within it were done by scientifically qualified and trained personnel.

-Inclusion criteria: Patients demanding vocal rehabilitation by the insertion of Provox®2 voice prosthesis after total laryngectomy (secondary rehabilitation).

-Exclusion criteria: Patients who refused to participate in the study, patients with pharyngolaryngectomy whose defects were reconstructed by flaps, patients with bilateral profound hearing loss, inappropriate direction of the stoma, presence of neurological problems interfering with patient's ability to occlude the stoma as Parkinsonism and patients with post-total laryngectomy dysphagia.

Each patient was subjected to:

I. Pre-operative evaluation included: -

A- History: Age, sex, special habits.

B- Examination of the neck:

1) Stoma was examined for:

- Size.

- Direction.

- Effective closure by the thumb.

- Condition of mucosa: The presence of erythema, granulation tissue, tissue necrosis, evidence of secretions and crustations.

2) Loco - regional recurrence.

3) Condition of the cervical skin.

II. Operative work up:

The voice prosthesis used in this study was Provox®2 Prosthesis (Atos Medical AB, Hörby, Sweden) and was inserted following total laryngectomy (secondary TEP). The patient was positioned supine with the neck hyperextended. After adequate level of general anesthesia, the rigid esophagoscope was introduced and moved towards the tracheostoma. When the tip of the esophagoscope reached the tracheostoma, the scope was swiveled 180°, turning the oblique open side of the esophagoscope forwards. The proper position of the scope was checked by palpation with a finger.

Atos Medical 7203 Provox® Trocar with Cannula was then placed in the midline of the tracheoesophageal wall, 5 mm below the mucocutaneous junction, and a TE fistula was created by puncturing towards the lumen of the scope. The sharp tip of the trocar was caught in the esophagoscope under visual guidance of the assistant. The trocar was removed, and the flexible guidewire was introduced through the cannula (**Figure 1**).



Figure 1: The trocar was removed, and the flexible guidewire was introduced through the cannula.



Figure 2: Provox®2 voice prosthesis attached to the connector head of the Provox® guide wire.

The esophagoscope was now removed and the Provox®2 voice prosthesis was attached to the connector head of the Provox® guide wire. (**Figure 2**)

By pulling the guide wire toward the puncture, the introduction string of the prosthesis was introduced into the TE fistula. Finally, the prosthesis was pulled and rotated into the TE fistula with the help of two curved non-toothed

hemostats. The introduction string was cut. The prosthesis was then turned in its proper position with the oval side of the flange pointing downwards in the trachea.⁵

The following data were reported:

1. Timing of insertion (relative to total laryngectomy).
2. Size of prosthesis.
3. Any intraoperative difficulty, morbidity and mortality.

Replacement of Provox ® 2 voice prosthesis:

Replacement of the Provox ® 2 voice prosthesis was carried out by anterograde insertion with disposable insertion tools (a loading tube and an inserter). Replacement procedure consisted of loading of the voice prosthesis and placing it on top of the inserter. Next the esophageal flange of the voice prosthesis was squeezed into the slit of the loading tube and the prosthesis was inserted into the loading tube with the esophageal flange folded forward. The old prosthesis was then removed from the TE fistula either by pulling out the device with a non-toothed haemostat or by cutting off the tracheal flange and pushing the remainder into the esophagus allowing passage through the intestinal tract. The loading tube can be inserted into the TE fistula until the back wall of the esophagus is reached then the inserter was pushed forward enabling the forward-folded esophageal flange to unfold itself in the lumen of the esophagus. The loading tube was removed, and the tracheal flange of the voice prosthesis was positioned properly.⁶

Postoperative care: patients stayed in the hospital one day after provox®2 application. They were not allowed to drink or eat in the first eight hours. Antibiotics were not routinely used. Analgesics were given according to needs. Vital signs were recorded every eight hours. They were discharged in the

next morning if there were no swallowing or respiratory problems.

III. Postoperative work up :

1. Patient education and training:

The first postoperative visit was done after the subsidence of edema around the prosthesis within two to three days. Under mirror guide, the patients were educated how to keep the prosthesis in its proper position, how to clean it by the Provox ® brush and use it for regular application of Mycostatine solution twice daily. They were motivated to adequately occlude the stoma in an intermittent pattern after a deep breath and exhale forcibly to phonate a prolonged sound /a /through the prosthesis .

2. Functional outcome measures: the following items were determined:

A) **Voice and speech:** patients were evaluated for voice outcome. The following data were measured two months after the application of the Provox®2:

1- The maximum phonation time (MPT) in seconds and was done by having the patient sustain the vowel /a/ for as long as possible on a single breath.⁷

2- Perceptual voice quality analysis by GRBAS scale. It is a system contains 5 well-defined items: G (overall grade of hoarseness), R (roughness), B (breathy), A (asthenic), and S (strained). A 4-point scale from 0 to 3 is used for each parameter. "0" equals normal, "1" slight, "2" moderate, and "3" severe. Results were recorded as G (0-3), R (0-3), B (0-3), A (0-3), S(0-3).⁸

3- Speech intelligibility expressed as intelligibility percentage (The mean percentage of correct words in a certain speech sample).⁹

4- Patient's satisfaction by his/her voice assessed by simply asking if he/she is satisfied or not.

B) **Recording any postoperative**

complications in the form of :

- Partial or complete extrusion of the prosthesis
- Surgical emphysema
- Formation of granulation tissue
- Stomal or pharyngoesophageal stenosis
- Periprosthetic leakage
- Leakage through the prosthesis
- Pharyngeal abscess
- Difficulty in swallowing
- Immediate versus delayed aphonia or dysphonia

C) Change of voice prosthesis (Provox®), when and why?

- 3) **Follow up:** All the patients were followed up for training and education and determining of functional outcomes and development of complications for a period that ranged from 4 months to 15 months. The follow up visits were daily for the first week, weekly for the first two months, monthly for one year and then on demand.

Statistical analysis:

Statistical analysis was performed at the end point of this research using a personal database obtained by means of statistical package for social science version 23. Quantitative variables will be expressed as Mean \pm standard deviation (SD) and qualitative variables will be expressed as number, percentage and in frequency tables.

Results:**Results of pre-operative evaluation:**

The patients included in this study were 15 males (93.8%) and one female (6.3%). The mean age was 59.88 \pm 9.26 as shown in (table 1). Their ages ranged from 45 to 82 years. Fourteen (87.5%) patients were ex-smokers. Three (18.75%) of them were Tramadol® (cyclohexanol hydrochloride) addict and only two patients (12.5%) had no special habits.

Table (1) Distribution of studied patients regarding their demographic data.

Age: (years)	Males	Females	Total number (%)
≥ 60 years	9	0	9(56.3 %)
< 60 years	6	1	7(43.8%)
Total	15(93.75%)	1(6.25%)	16(100%)
Mean \pm SD	59.88 \pm 9.26		

Neck examination:

In this study 12 patients (75%) had a favorable size of the stoma (more than 2 cm) and four patients (25%) needed stomal dilatation (size less than 2 cm). The stoma of all patients was directed forward with a good condition of the mucosa. None of the patients had a loco-regional recurrence. All of them were able to effectively occlude the stoma with the thumb. Cervical skin was normal, apart from the scar of total laryngectomy and repaired pharyngocutaneous fistula and the effect of postoperative radiotherapy.

Operative results: The voice prostheses used in all sixteen patients in this study were Provox®2 voice prosthesis. The time of voice prosthesis application after total laryngectomy ranged between 6 months and 14 months (mean= 10 months) (**table 2**).

Table (2) Timing of insertion of the prosthesis relative to total laryngectomy.

Time in months relative to total laryngectomy	No. (n= 16)	%
6-8	2	12.5%
9-11	2	12.5%
12-14	12	75%
Total	16	100%

The size of the Provox®2 used was either 8 mm (nine patients) or 10 mm (seven patients). The operative time ranged between 4 to 10 minutes without the need for endotracheal intubation. None of the prosthesis was damaged during insertion. No intraoperative

morbidity or mortality was reported. The only difficulty met during the procedure was found in insertion of esophagoscope in patients who received postoperative radiotherapy.

Postoperative results: All patients went home in the next morning after Provox®2 insertion without reported immediate surgical emphysema and respiratory distress. During the period of the first postoperative three days, all of the patients had variable degrees of local mucosal edema around the tracheal flange of the prosthesis that subsided spontaneously. At the end of the first five postoperative days all the patients managed to effectively use the Provox®2 brush to clean the prosthesis without the need of an assistant. **Functional outcome measure:** After being totally aphonic, 15 patients were able to produce voice shortly after recovery from anesthesia. Recording the MPT was done to all patients after 2 months of Provox®2 voice prosthesis application. One patient remained aphonic. Fifteen patients had a MPT that ranged from 9 to 14 seconds with mean value of 9.8 seconds (Table 3).

Table (3) Maximum phonation time.

MPT* (sec)	No. (n= 15)	%
9-11 sec	9	60
12-14 sec	6	40
Total	15	100
Mean (±SD)	9.8(±2.71)	

Apart from the patient who was unable to produce voice, the measurement of the GRBAS score after two months in the remaining 15 patients revealed a score with a mean one and two. One in R, B and A items and a mean two in G and S items (Table 4).

After two months, 15 patients were able to speak with a 100% intelligibility. They were also satisfied by their voice quality. Complications occurred in nine

patients. Four patients had leakage through the prosthesis that was reported after a period that ranged between 300 to 410 days (mean 375.5 days). It was necessary to replace the prostheses. On removal, their color turned yellow, they lost their softness and the valve lost its recoil. Another three patients swallowed the device after a period that ranged between one week to one year. They were subjected to re-application of new prosthesis. Pharyngeal abscess occurred in one patient after one year from voice prosthesis application; he was admitted to the ENT department Assiut University hospital and managed by endoscopic drainage under general anesthesia. One patient failed to produce voice after Provox® application and remained aphonic till the end of the study. He was counseled to remove the prosthesis, but he refused (Table 5).

During the period of this study (about 15 months) seven patients (43.8%) underwent voice prosthesis re-application. The main reason for re-application was due to leakage through the prosthesis (4 patients) (25%) followed by swallowing the device (3 patients) (18.8%).

Table (4) GRBAS score of the patients

Grades items	G*	R*	B*	A*	S*
0	0	4(26.7%)	8(53.3%)	9(60%)	0
1	2(13.3%)	7(46.7%)	6(40%)	5(33.3%)	3(20%)
2	10(66.6%)	4(26.7%)	1(6.7%)	1(6.7%)	9(60%)
3	3 (20%)	0	0	0	3(20%)
Total	15(100%)	15(100%)	15(100%)	15(100%)	15(100%)
Mean(range)	2(1-3)	1(0-2)	1(0-2)	1(0-2)	2(1-3)

GRBAS score was used: * G (overall grade of hoarseness), R (roughness), A (asthenic), S (strained), 0 (normal), 1 (slight alteration), 2 (moderate alteration), 3 (severe alteration).

Table (5) Complications reported after Provox®2 application.

Type of complications:	No (n= 9)	%
Leakage through the prosthesis	4	25%
Swallow the device	3	18.75%
Pharyngeal abscess	1	6.25%
Inability to produce voice	1	6.25%
Total	9	56.25%

Discussion :

Loss of voice is a major worry for patients with total laryngectomy and their inability to communicate causes a significant interference in everyday activity.¹⁰ Esophageal speech and electrolarynx were the traditional methods with many disadvantages and low success rates. Nowadays, tracheoesophageal speech with insertion of different voice prostheses has become the method of choice. There are two types of voice prostheses; the indwelling (e.g. Groningen, Provox®) and non-indwelling (e.g. Blom and Singer, Panje) devices.¹¹

In this study, it was observed that it included a single woman. This is because laryngeal carcinoma is more common in males than females as

observed by de Coul et al.,¹², Norsuhazenah et al.,¹³ and Dabholkar et al.¹⁴.

The mean age of the studied patients was 60 years and more than half of them were more than 60 years old as laryngeal carcinoma is more common in old age.¹⁵ These results were consistent with those of Dabholkar et al.,¹⁴.

This study emphasized the incrimination of smoking as a major risk factor in the development of laryngeal carcinoma as 87.5% of the patients were smokers. Nearly the same result was found by Guttman et al.,¹⁶.

Literatures reported many controversies between advantages and disadvantages of primary and secondary rehabilitation of post TL aphonia. In the current study, all the patients were subjected to secondary rehabilitation

after total laryngectomy because of the multiple advantages of secondary insertion. The latter ensures completion of healing process, stability of stoma size and freedom from loco-regional recurrence especially after postoperative radiotherapy.¹⁷ Also, secondary insertion avoids stoma related complications including fistula, leakage from the puncture site and local infection with early stomal stenosis found by some investigators after primary insertion.¹⁷ Some surgeons believe that all patients should have opportunity to try to develop esophageal speech independent of prosthesis use before puncture.¹⁷ Finally, it would be expected that after being totally aphonic for a certain time, such patients would be more satisfied by whatever quality of voice than patients with primary rehabilitation who compare the quality of their dysphonic laryngeal voice with the prosthetic alaryngeal voice.¹⁷

In contrast Karlen and Maisel¹⁸ found that there was no increased risk of complications of laryngectomy when performing a primary TEP and reinforce the value of primary TEP. Also, Guttman et al.¹⁶ found that both primary and secondary TEP are associated with high success rates, with no difference in complications.

The preoperative assessment of the patients in the current study considered the evaluation of stoma, cervical skin, the absence of neurological deficits and loco-regional recurrence. Such parameters were considered by authors to be necessary in predicting patient's suitability for secondary rehabilitation by TEP and its expected successful outcome.^{19, 20}

Numerous modifications of the technique for secondary TEP have been published over the years.²¹ The technique used for inserting the Provox® 2 in this study which is similar to that described by Hilgars et al.,⁵ was chosen because of its simplicity, short

time and immediate application of the prosthesis. It depended on the use of rigid esophagoscope and the Atos medical 7203 Provox® Trocar with Cannula. Other surgical techniques that used needles³, scalpels³ or hemostats²² for identification of puncture site seem to be complex and more time consuming. Another disadvantage is that they were followed by inserting a rubber catheter to allow fistula formation that delayed the insertion of the prosthesis for two weeks. However, the only difficulty met in the patients of this study was the difficulty of inserting the rigid esophagoscope in patients who received post TL radiotherapy. This was overcome by the use of smaller esophagoscope. Others,^{23, 24} suggested that the use of flexible transnasal esophagoscope under local anesthesia as office procedure in case of severe neck scarring. Such technique needs special instruments and a co-operative patient.

Among most of literatures, there is no international standard for measuring voice quality after surgical voice restoration and rating scales of voice quality tend to be very subjective. In general the main measures of voice quality fall under either acoustic analysis, perceptual outcomes assessed by speech pathologist and self-assessment of voice by the patients.^{10, 25} Such multidimensional assessment is useful in comparing voice quality among different methods of rehabilitation (esophageal speech, electrolarynx, and TEP) rather than the judgment of the mere success of a single method where simplified methods of evaluation are recommended. Being a preliminary report, voice quality assessment in this study depended on simple items chosen from acoustic analysis, perceptual outcomes and self-assessment of voice. They were in the form of measuring the MPT, voice quality by GRBAS score, percentage of speech intelligibility and the patients' satisfaction. It's to be noted

that the result of voice quality measuring methods was considered only in 15 patients (after the excluding of the patient who failed to produce voice).

The reported MPT among multiple reviews ranged between 0.84–23.87 seconds.²⁶ Longer MPT is indicated as being better. While Cornu et al.²⁷ considered a MPT of 10 seconds as good, a MPT of 8 seconds was defined as successful by Chone et al.²⁸ In this study the mean value of MPT was 9.8 seconds. This result is consistent with the findings in many studies.^{8,26} The shorter MPTs reported in other literatures were explained by the fact that tracheoesophageal speakers have a reduced breath support due to varying amounts of air leakage at stomal occlusion. Also, patients have to alternate constantly between conspicuously drawing air into the lungs through the stoma and stoma occlusion with a finger to produce voice naturally, resulting in slower speaking rates.²⁹

A wide variety of perceptual rating scales has been described in literatures.³⁰ They vary from a complex rating scale as that provided by Laver³¹ to a very simple rating as good, fair or poor as used by Tantawy.¹⁰ Perceptual outcomes were measured by GRBAS score in this study as it is a well-validated, widely used, simple and utilized a brief evaluation system.²⁹ The perceptual assessment of quality of voice in patients of this study using the GRBAS scale indicated a good voice quality. The mean score of the five items of such scale ranged between slight and moderate alternation of the voice quality. This result was close to the result of Kazi et al.,³² and Dabholkar et al.,¹⁴.

Again, the use of Provox®2 produced a 100% intelligible voice in patients of this study similar to what was reported by D'Alatri et al.,⁷.

The patient reported outcomes represent one of the multidimensional

assessment protocols for evaluating speech rehabilitation.³³ Within articles, they are mostly evaluated by Voice Handicap Index,³⁴ Voice Related Quality of Life,³⁵ European Organization for Research and Treatment of Cancer and Quality of Life Questionnaire.³⁶ Such questionnaires although objective, they suffer from their complex nature, dependency on geographic and socioeconomic factors. The available Arabic method is the voice problem self-assessment scale³⁷ that considers a reliable and valid measure in assessment of the impact of voice disorders in Egyptian patients. However, it seems to be more suitable for evaluation laryngeal voice rather than prosthetic voice in aphonic patients after total laryngectomy. Other reports used a more simplified satisfaction score.^{10, 38}

In this study the patients who were able to produce voice by Provox®2 (15 patients) report that they were satisfied by their voice. They used it as the main method of communication even through the phone. They discarded other methods as whispering, sign and paper and pen methods. They used their voice even in occasions like during their job.

A long list of complications has been reported in literature.³⁹ The most common of which is leakage through the prosthesis with a rate between 40% to more than 70%.⁴⁰ In this study, a comparatively lower rate was reported (25%). This could be explained by the limited number of the patients included in this study and the regular use of antifungal solution. Studies^{40,41} proved that valve failure and loss of its elastic recoil represent the main cause of leakage through prosthesis because of candida overgrowth. On the other hand, Tantawy¹⁰ considered that leakage through the prosthesis is usually due to displacement of the radio opaque ring which requires change of the prosthesis.

There is an agreement among reports

that leakage through the prosthesis does not only represent the main reason for device replacement, but also defines the device life. Literatures report great variability regarding this issue depending on many factors. In the first report by Hilgars and Schouwenberg,⁴² the average device life was 5 months. Laccourreye et al.,⁴³ reported a longer device lifetime of 10.3 months. A mean device lifetime of 10.8 months was reported by Tantawy¹⁰ and explained by regular use of topical Mycostatine solution applied by cleaning brush. In this study it is difficult to state a solid (figure) to determine the device quality of life because of the short period of follow up (the shortest being four months). However, the device life in the four patients who developed leakage through the prosthesis ranged between 300 to 410 days (mean 375.5 days). A similar long device life (303 days) was reported by Cornu et al.,²⁷.

Comparatively, the rate of prosthesis dislodgement (swallowing) in this study (18.7%) is better than that reported by Cruz et al.,⁴⁴. It is well known that such complication is mainly reported in using Provox®2 which might be due to the much thinner esophageal flange compared to that of the original prosthesis to facilitate front loading.¹¹ Lower rates of device spontaneous displacement were reported in studies using the original Provox® that had a rigid esophageal flange with sharp angles between flange and shaft.^{10,45}

Although leakage around the prostheses is considered by many authors^{40,41} to be an important, frequent and a difficult to deal complication, it was not reported among patients in this study, This is possibly because of the limited number of the patients, choosing the proper device size and the use of the Atos medical 7203 Provox® Trocar with Cannula thus creating a suitable sized fistula.

Failure to develop a successful TE

speech was demonstrated in the literatures with variable rates and causes. In this study, only one patient (6.4%) failed to produce voice. Such rate remains much lower than that reported by Cornu et al.,²⁷ and Akbas and Dursun⁴⁶ but similar to that reported by Tantawy¹⁰ (5%). Authors enumerate multiple causes to explain the inability of the patients to obtain successful voice as post-operative fistula, infection, granulations, impaired hand co-ordination, fibrosis caused by radiation and combining total laryngectomy with glossectomy.¹⁹

Hypertonicity of the PE segment remains the main cause of failure to produce a successful prosthetic voice.⁵ It seems that it was the underlying explanation in the patient of this study who was unable to produce voice particularly he was not subjected to preoperative tonic study. The presence of stricture would be an unexpected explanation since none of the patients included in this study suffer from a post total laryngectomy dysphagia. Injecting Botulinium toxin (Botox) into the pharyngeal constrictors is the preferred method to overcome such possibility.¹⁹

Being a fundamental step, performing pharyngeal constrictor myotomy during TL would seem to be sufficient to prevent development of pharyngeal spasm which is considered of paramount importance to the production of successful TE speech. The addition of pharyngeal neurectomy during total laryngectomy was suggested to reduce such complication.¹⁹

Revising the literatures concerning the issue of success of prosthetic rehabilitation revealed marked variability in its rate, criteria and factors affecting it. The lack of solid criteria of success may explain the variable reported success rates. The patient's view of success may not be the same as that of the surgeon or the speech and

language therapist. The clinician and patient may be using different standards of success; however, both should have realistic expectation. Patients should realize that there is a learning curve associated with TE speech; TE speech generally improves over time. TE voice quality is usually harsh and often loses its sexual characterization.¹⁹ Although very variable successful outcome measures include not only voice quality but also, development of complications, device life span and ability of patients to care for the fistula and the prosthesis.⁴⁷

A successful outcome of using Provox®2 in vocal rehabilitation of patients in this study was proved by analyzing the results of the previously mentioned criteria and comparing it with the successful reports among literatures. In a satisfied patient the production of 100% intelligible voice with a good MPT and quality of voice (assessed by GRBAS scale) by a prosthesis with an average life of 375 days would be considered as favorable. Its main drawback in our locality would be its cost augmented by its native nature to be expired.

Limitations in the study:

A limitation of the current study is that it included a limited number of patients. It included only one method of rehabilitation and hence did not allow comparison between other methods. All the patients had a secondary type of insertion. Methodology did not include objective measurement of PE tonicity. Short period of follow up.

Conclusion

The present study indicated that the use of Provox® is a safe and satisfactory method for post TL voice rehabilitation. Considering the patient suitability for Provox® use depends on many factors such as stoma, absence of musculoskeletal disorders, neurological defects and freedom from loco-regional recurrence. Its main disadvantages are the need for replacement and

counseling. Phoniatric co-operation is essential for obtaining a successful outcome.

Recommendations

The present study recommended that counseling the patients for total laryngectomy should include projecting patients with successful Provox® to encourage such patients in decision making. In further studies points should be considered as including large number of patients, Comparison between different methods of rehabilitations, Comparison between primary and secondary insertion, Measurement of PE tonicity in patients subjected to secondary insertion and prolonged follow up.

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