Original Article

Silicon Airflow Prosthetic Device after Laryngectomy: A Clinical Trial

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Abstract

Context: Tracheostoma stenosis is a common problem after laryngectomy. Stenosis of trachea stoma leads to respiratory complications. Preservation of stoma patency by implanting a silicon prosthetic device in tracheal stoma could affect the outcome in these situations. **Aims:** To evaluate tracheal stoma patency in postlarngectomy patients with the silicon prosthetic device. **Settings and Design:** This is a case series of seven patients who received the device. **Materials and Methods:** Seven adult patients American Society of Anesthesiologists Grade IV who had undergone laryngectomy for carcinoma larynx received a silicon airflow prosthetic device which was devised for each patient in the prosthodontic laboratory. All the patients were followed at 3 and 6 months to observe the efficiency and potency of device. **Results:** The average stoma size and average peak expiratory flow 25-75% in litres/sec at first patient visit, 3 and 6 months after receiving the device was 13.42 ± 0.71, 12.55 ± 0.82, 12.7 ± 0.92 mm and 3.08 ± 0.19, 3.10 ± 0.13, 2.89 ± 0.15 mm, respectively. **Conclusions:** The silicon airflow prosthetic device continued to maintain uninterrupted airflow and prevented tracheal stoma stenosis which encouraged us to place it for longer time after laryngectomy without any eventuality.

Key words: Postlaryngectomy, silicon airflow prosthetic device (SAPD), tracheastoma stenosis

Introduction

Larynx is instrumental to speech and airflow. Total laryngectomy is a complex operative procedure where larynx is separated from oropharynx, oesophagus, and trachea and resected *en bloc*. Due to anatomic distortion of the airway, it is not practical to maintain airflow through the natural passage which is surgically obliterated. Under this circumstance, the distal end of the transected trachea is brought to the surface on the anterior neck and sutured [Figure 1].[1] Adapting one of the several methods for supraglottic closure avoids soiling of the trachea while the deficit in skin on the anterior neck after laryngectomy gets healed by granulation tissue formed around the stoma, thereby delaying process of epithelization. The stoma may be narrowed (tracheal stoma stenosis) due to formation of excess fibrous tissue. This may progress to clinically significant respiratory distress. Stoma stenosis is a grievous complication after laryngectomy. Various contributing factors for stoma stenosis have been documented. These include infection, fistula formation, and improper mucocutaneous approximation.[2] This situation can be dealt with frequent tracheostomy tube change and use of silver nitrate. Preserving patency of the stoma is essential in postlaryngectomy cases. Stoma size of < 10 mm is considered to be critical. According to literature, the incidence of stoma stenosis has been quoted to vary from 4% to 13%.[3]

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Materials and Methods

This clinical trial was conducted on seven patients aged between 59 and 70 years who had undergone laryngectomy for carcinoma larynx. All patients received customized airflow device.

Procedure to construct silicon airflow prosthetic device (SAPD)

Before carrying out the procedure, we ensured the availability of all resuscitative equipment. The airway of the patient was anesthetized by 10% lignocaine spray, and an appropriate, and an

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appropriate size-cuffed endotracheal tube was inserted into the trachea. Cuffed tube was preferred to avoid soiling the trachea with the material used. A preliminary impression of the stoma was obtained using irreversible hydrocolloid impression material that is alginate. Once the impression was set, it was removed from the patient by backing it with plaster of Paris so that it does not tear off. Thereafter, the impression was poured on dental stone to obtain the primary cast. A special tray with wax spacer was made on the primary cast using autopolymerized acrylic resin. The tray had a hole to maintain airway during the final impression procedure. The special customized tray was checked on the patient so that it did not hamper any neck movement. Once the fit was reasonably acceptable, final impression was made with polyvinyl siloxane impression material of light body consistency with fine details. The final prosthetic device was obtained on the master cast. The wax try-in was obtained on the patient. The shade matching with the skin color was achieved at the time of try-in. The silicon device was finally complete to be implanted on the patient [Figure 2]. In case of any discomfort or patient being unsatisfied, the whole process was repeated until it was acceptable to the patient.

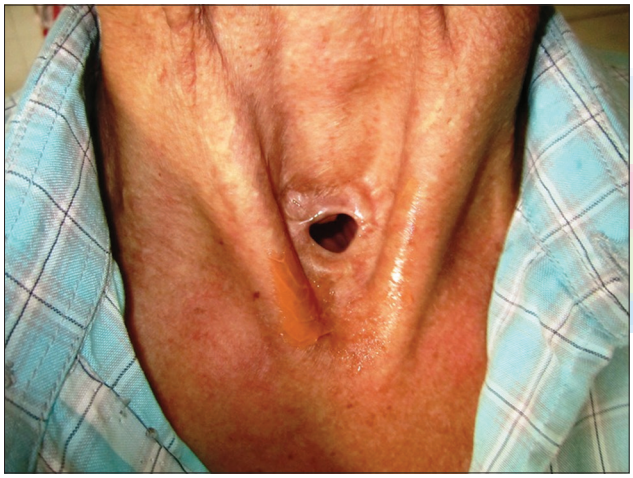

Figure 1: Tracheostoma after laryngectomy

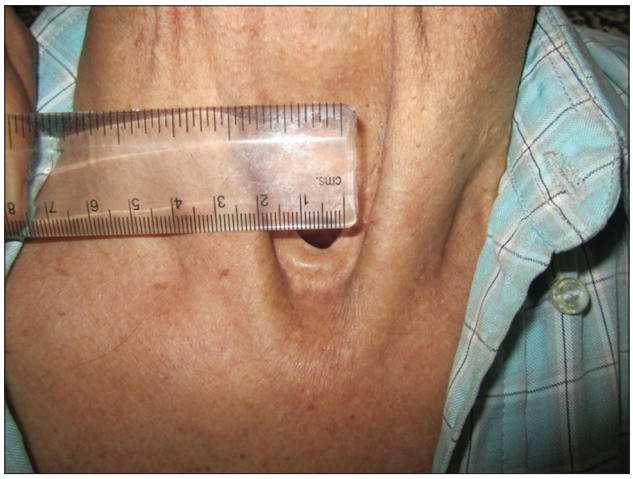

Figure 3: Measurement of stoma size

Stoma size was measured with scale in both vertical and horizontal dimensions [Figure 3]. Average of the two was considered in the measurement of stoma diameter, and average of three forced expiratory airflow (25–75%) attempts for each patient on RMS Medspirer was recorded at the time of presentation before fixing the device, then at 3 months and 6 months after planting device. The results were expressed as mean ± standard deviation.

Results

The average dimension of stoma and forced expiratory flow (25–75%) was observed for the two groups immediately, 3 and 6 months after receiving the device [Table 1].

Table 1: Average age, stoma size and peak flow rate

Parameter	Values (mean±SD)
Age (years)	58.15±5.65
Male/female	7/0
SS at first fitting (mm)	13.42±0.71
SS at 3 months	12.55±0.82
SS at 6 months	12.7±0.92
PEFR (l/s) at first	3.08±0.19
PEFR at 3 months	3.1±0.13
PEFR at 6 months	2.89±0.15

SS: Stoma size, PEFR: Peak expiratory flow rate

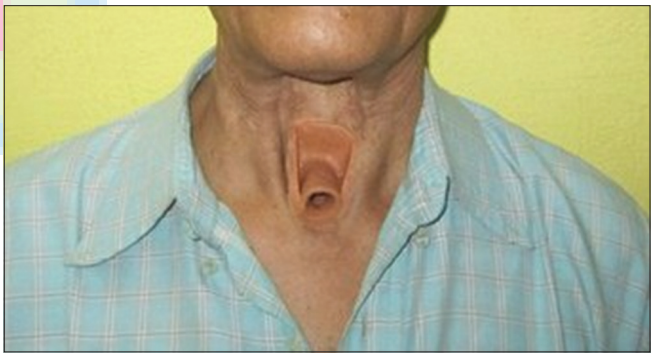

Figure 2: SAPD fitted on stoma

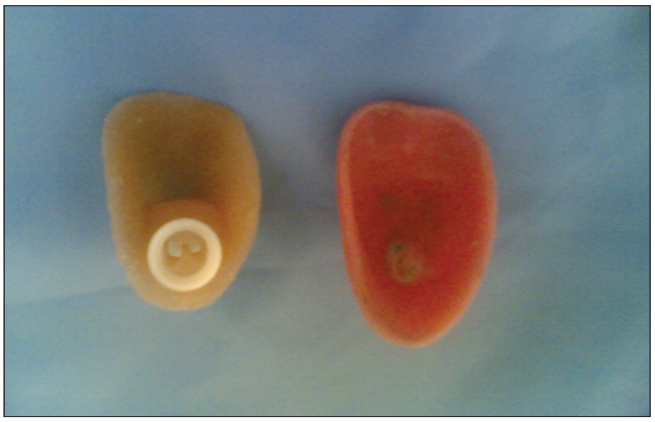

Figure 4: SAPD with attached filter

Discussion

Laryngectomy appends not only functional challenges but also psychological stress due to cosmetic implications.[4] One of the essential requisites of laryngectomy is to construct adequate size stoma. It is imperative that the stoma should be of an appropriate size to clear the trachea-bronchial secretions. Inadequate clearing predisposes to retention of mucous with recurrent pulmonary infection.[5] None the less, it should allow proper approximation of the silicon device in the tracheal stoma.[6] Montgomery classified stoma in accordance with its shape: Concentric, vertical slit, and inferior shelf.[7] Tracheal stoma stenosis is most commonly encountered in the concentric type of stoma. Excess fibrous tissue formation around the stoma may predispose to constriction and inadequate flow of air to the trachea-bronchial tree. Different options have been tried in the past to manage stoma stenosis. This may scope from repeated dilatation of the track and use of stent as described by Soo and Tong to diverse range of surgical techniques including stomaplasty.[8,9] Outcome have been variably reported with these techniques. Undesirable bleeding and crusting are associated with repeated dilatation and stents. Various stomaplasty techniques have been advocated. Circumferential dissection and excision of scar tissue, modified advancement and slaying of trachea where posterior part is left untouched but anterior 2/3 with top two tracheal rings are freed, straight transection of trachea, beveling the trachea, plastic or flap construction technique, V-Y flaps, Z plasty, and interposition flaps are some of the procedures that have been described in these cases.[10-12] The outcome are inconsistent with no clear benefit of one technique over the other.

The silicon airflow prosthetic device has been designed to maintain the caliber of tracheal stoma. The device can maintain unabated flow of air to lungs and by providing easy clearing of the tracheal secretions offers to maintain pulmonary hygiene. It can prove to be invaluable in patients with reduced pulmonary compliance where any degree of tracheal stoma stenosis can be distressing and unwelcome. The silicon device a well-tolerated since it evokes minimal tissue reaction. There were no incidence of bronchospasm encountered even when the material was poured around the endotracheal tube. Since silicon maintains its shape at body temperature, it allows for proper approximation of the device to the posterior tracheal wall contour. The device is lightweight to ensure patient comfort and safety. It is reusable with bare minimal requirement for maintenance. It can be cleaned with soap and water and allowed to dry up before next application. A light brush can be used to remove any dust particle from its surface. This would make it more durable with less possibility of developing cracks.

However, certain safety measures should be warranted while using this device. During sleep, any foreign object such as bug, hair, and dirt particle may get access to trachea and cause respiratory distress and fatal consequences. A filter can be adjusted to address this issue [Figure 4]. In addition, there is possibility that opening in the device can get incidentally covered by blanket or sheet. Shower cover can be placed over the device to protect the airway and stoma cover can be used outdoor if the individual prefers so.

Conclusions

To maintain airflow and protect trachea, bronchial tree is an utmost important aspect in the rehabilitation of postlaryngectomy patients. In our opinion, silicon airflow prosthetic device can be an important armamentarium in this regard. Its discreet appearance could add many benefits to its user.

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Conflicts of interest

There are no conflicts of interest.

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