

A new and simple method of fabrication of tracheostomal prosthesis

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Abstract

Patients with a tracheostomy stoma experience compromised speech and function due to the associated changes in airflow patterns. Rehabilitation of a patient with tracheal stoma is a highly challenging task. The main objective is to design an inexpensive, easily fabricated stomal prosthesis for postlaryngectomy patients who require prolonged tracheotomy. This clinical case report describes a 29-year-old male patient who underwent for tracheotomy 3 months before for respiratory distress following a suicidal attempt. Hence tracheotomy was done, and the patient has been with the tracheostomal tube since surgery for the past 3 months. Laryngoscopy examination reported as restricted bilateral vocal cord movements, and the cords were in the adducted position with minimal glottic chink. No history of difficulty in swallowing. On examination, no scar or ulceration is seen around the stoma. The skin around the stoma is healthy. The patient was referred to the oral and maxillofacial Prosthodontics Department from the Department of ENT. The patient's old tracheostomal tube was used as the dimensions of the custom made tracheal prosthesis without making a functional impression of the mature stoma. A tracheal button was made with 2 mm polyethylene urethane sheet to maintain the airway patency of the mature stoma. Width and length of the old tracheostomal tube were measured and customized with polyurethane sheet by directly flaming over heat. The finished product was thin, flexible, maintains enhanced tear strength, require no tapes or adhesives and less technique sensitive. These properties of the prosthesis make more advantageous than the commercially available tracheal buttons. The result in this patient was excellent with no postoperative complications. An innovative approach for fabrication of tracheostomal prosthesis was discussed to increase its successful use in tracheostomal patients. The patient's old tracheostomal tube was used as the dimensions of the custom made tracheal prosthesis without making a functional impression of the mature stoma. The finished product was thin, flexible, maintains enhanced tear strength, require no tapes or adhesives and less technique sensitive. These properties of the prosthesis makes more advantageous than the commercially available tracheal buttons. The result in this patient was excellent with no postoperative complications.

Key Words: Poly ethylene urethane sheet, tracheal button, tracheal stoma, tracheotomy

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INTRODUCTION

Tracheostomy is a surgical procedure of creating a direct opening into the windpipe for breathing purposes. Patients with a tracheostomy stoma experience compromised breathing and speech due to the associated changes in airflow patterns. Prosthetic rehabilitation of the stoma restores the normal airflow patterns required for proper breathing. Standard

stent tubes may not adequately restore the defect and may be uncomfortable to wear. The tracheostomal button has the advantage of permitting easy breathing and eliminating the inconvenience, unwanted attention and lack of hygiene associated with manual occlusion.^[1] Tracheostomies are usually performed during emergency situations or on very ill patients. Tracheostomies are of temporary, semi-permanent or permanent, depending on the indications.^[2,3] Temporary tracheostomy are indicated for any airway obstruction at or above the level of the larynx, life-threatening pneumonia, respiratory failure requiring prolonged ventilation due to spinal cord lesions in the neck, prolonged endotracheal intubation, sleep apnea disorders and angioneurotic edema where the patient comes back to normal breathing when the cause for tracheostomy is revoked. Whereas the permanent tracheostomy are indicated for patients with bilateral paralysis of recurrent laryngeal nerve, cricoarytenoid arthritis, laryngomalacia, laryngeal spasm or tetany, and corrosive drug poisoning.

Head and neck rehabilitation surgeons and speech pathologists agree as a general guideline that a stoma size of 10mm or less is considered problematic. When evaluating the problem the team should consider the patient's body size, stoma and tracheal appearance (crusting, poor healing, mucous plugs, etc., are problematic), ability to clean the stoma, clear mucous from the airway and the ability to breathe comfortably at all times.

A tracheal prosthesis is a rigid cannula that can be placed into the tracheostomy stoma after removal of a tracheotomy tube. Standard stent tubes may not adequately obdurate the defect and may be uncomfortable to wear. The prosthesis does not extend into the tracheal lumen. It requires a mature stomal tract and is generally used as a long-term solution for people after tracheotomy. Fabrication of tracheostomal prosthesis requires the clinician to select the material for fabrication. Various materials have been described in the literature for use as tracheostomy aids and include silver alloy, acrylic resin, glass, and silicone.^[4] These materials may be resilient or nonresilient. Swerdlow *et al.*^[5] discussed complications associated with nonresilient material such as tissue irritation, tracheobronchial secretions and crusting. This article presents the procedures used to fabricate custom tracheostomal prosthesis without making the functional impression of stoma. However, commercially available postlaryngectomy products such as silicone laryngectomy tubes, stoma buttons or tracheostomy vents are alternatives to repeat surgery are not readily available in the local market and quite expensive. It is observed that the long-term usage of tracheostomy tubes causes persistent cough due to chronic irritation of the tracheal wall.

The main objective of this article is to design an inexpensive, easily fabricated stoma buttons using the measurement of

old tracheostomal tube for patients with stomal stenosis without making the functional impression of stoma. This article proposes an improvised stoma button fabricated from polyethylene urethane sheets as inexpensive alternative material to currently available commercial products without making a functional impression. The coordinated effort of the ENT specialist and the prosthodontist in the fabrication of this prosthesis enhances the quality of life for the permanent tracheostomy patient.

CASE REPORT

A 29-year-old male patient was presented with the chief complaint of pain in and around the neck since 3 months with a metallic tracheostomy tube *in situ*. Furthermore, the patient is apprehensive of the rope tied around the neck for the retention of the metallic tracheostomal tube. No history of difficulty in swallowing was noted. On clinical examination, no scar or ulceration is seen around the stoma. The skin around the stoma is healthy. The patient had undergone for suicidal attempt 3 months before. Following a suicidal attempt with the patient complaining of breathing difficulty he underwent immediate video laryngoscopy examination, which reported as bilateral vocal cord movements were restricted, and the cords were in adducted position with minimal glottic chink. The recurrent laryngeal nerve was severely damaged, and the patient have undergone for gasping with the difficulty in breathing. Emergency tracheostomy was done, and the patient was with the metallic tracheostomy tube for the last 3 months. The patient was apprehended with the metallic tube and had a frequent history of pain and irritation around the tracheostomy site for the past 3 months. The patient was referred to the oral and maxillofacial Prosthodontics Department from Department of ENT to customize tracheal prosthesis for the stoma site instead of the metallic tracheostomy tube.

On physical examination, the patient was with a metal tracheostomy tube tied by a rope around his neck. Mild hoarseness of voice noted, and there was no difficulty in swallowing. There were no secretions, ulcerations and granulation around the stoma. The skin around the stomal tissue was healthy with a stomal diameter of 6–7 mm. Routine blood and relevant investigation reports were within the normal limits. The patient consent was obtained. A custom made tracheal button made of polyethylene urethane sheet was fabricated for the patient to maintain the airway patency of the mature stoma.

Procedure armamentarium

- Poly ethylene urethane sheet – 2 mm commonly used for bleaching the tray
- Patient's old tracheostomal tube

- Ruler scale for measurement
- Bunsen burner
- Sharp scissors or bard parker blade no 15
- Cotton tip applicator
- Silicone burs
- Glutaraldehyde (1%) solution (Sporicidin Sterilizing Solution).

Technique

- A poly ethylene urethane sheet of 2 mm was selected [Figure 1]
- The snug fit of the old metal tube was tested in all head movements. As custom impression was not done the width and length measurement of the old tube was taken as the guide and noted [Figures 2 and 3]. It was approximately of 6 mm × 10 mm dimensions
- With the informed consent of the patient, the tracheostomal diameter of 6.5mm was measured with a vernier caliper. The distance of 15mm from the anterior edge of the stoma to the posterior tracheal wall was determined with a cotton tip applicator. This measurement was done to

cross verify whether the determined measurement of the old tube approximates the original measurements of the stoma. A difference of 5 mm from the original length of the stoma to the metal tube was noted. This 5 mm of difference in length compensates the posterior tracheal wall from the contact of the prosthesis to avoid irritation of the posterior tracheal wall

- The polyethylene sheet was cut for the above measurements (6 mm width × 10 mm length) with sharp scissors or BP blade. As the sheet is thermoplastic, it is easily flamed over the burner, rolled and fused, which forms the body or shaft [Figures 4 and 5]. This urethane tube was lukewarm and soft at this stage and inserted into the stoma with fingers to customize for stomal patency and check for fit
- Anterior retention was achieved by a 2 mm flange [Figure 6]. A 2 mm width × 10 mm length polyethylene sheet was cut, flamed and fused to the anterior region of the shaft to produce the flange. Now the body and flange were cooled to room temperature to make it semi-rigid



Figure 1: Armamentarium



Figure 2: Width of old metal tube



Figure 3: Length of old metal tube



Figure 4: Polyethylene urethane sheet flamed

- Again, only the flange area was softened to the temperature that could be withstood by the patient and inserted into the patient's stoma. Now the flange would contact the anterior tissue surfaces, and the flange was kneaded over the peristomal skin surface to achieve better adaptation of the prosthesis
 - Lipping was done by heating the posterior region of the shaft and rolled backward by finger manipulation. This lipping would aid in posterior retention of the prosthesis [Figure 7]
 - The finished product was thin, flexible with enhanced tear strength. The edges of the prosthesis were trimmed with silicone burs to allow for better accommodation to the tissue surface without distortion
 - An ideal tracheostomal button with the body or shaft, anterior flange and posterior lip [Figure 8] was ready for insertion
 - After an acceptable prosthesis was obtained, it was cleaned, and cold sterilized in glutaraldehyde (2%) solution [Sporicidin Sterilizing Solution] for overnight.
- The prosthesis was checked and verified for the fit and inserted into the patient [Figures 9-11]
 - The insertion was done by flattening and folding the prosthesis with the fingers and then inserting the prosthesis at a 45° angle to the patient's stoma. After insertion, the fingers were released. Now the prosthesis would open and conform itself into the stoma. To remove the prosthesis simply grasp it on one side and gently pull toward the opposite side. When the prosthesis was in place inside the stoma, the prosthesis would fit snugly and require no tapes or adhesives
 - The patient recalled the next day for initial follow-up and was instructed about the placement, removal and homecare of the button. The tubal patency was checked for every 2 weeks, and the initial gradual improvement of speech with reduction in hoarseness of voice was also noted. The intake of food and regular activity were noted and found to be normal
 - The patient has been on regular follow-up in ENT OPD since 7 months after the placement of this prosthesis, and an excellent cure of his symptoms was noted [Figure 12].



Figure 5: Rolled and fused



Figure 6: Anterior flange



Figure 7: Posterior lip



Figure 8: Final prosthesis



Figure 9: Insertion of the prosthesis



Figure 10: Preoperative photograph-patient with old prosthesis



Figure 11: Postoperative photograph – patient with new prosthesis



Figure 12: Review photograph after 6 months

DISCUSSION

Stomal stenosis is one of the complex and serious problem causing anxiety and distress to the patient and creates a clinical challenge to the medical team.^[6-8] The reported incidence varies, ranging from 4% to 42% and is typically found more frequently in women than men.^[9,10] The patient treated here was diagnosed as bilateral vocal cord paralysis in the adducted position with stomal stenosis, which creates the discomfort as stated in the chief complaint. As would be expected, this complication creates a great deal of concern and anxiety for the tracheostomy patient and the rehabilitation team. It may be a short-term problem that can be managed using much dilation or stretching methods to widen the stoma depending upon the severity.^[11,12] The main goal was to allow the patient to breathe and function comfortably. In the more recent papers, various types of laryngectomy products, such as silicone laryngectomy tubes, stoma buttons or tracheostomy vents are advocated. These products are often very helpful in keeping the stoma from narrowing.

Custom silicone speech valve prosthesis was made for patients undergone for Tracheoesophageal Puncture where an airway block and loss of speech present due to the damage of both superior and recurrent laryngeal nerve. Here the reported case had only recurrent laryngeal nerve damage with airway block and bilateral vocal cord paralysis leading to mild hoarseness in the voice. Though some author states that the stoma can be left open without any prosthesis, this could not be allowed without surgical intervention as there maybe granulation formation with the closure of the stoma.^[13] To avoid such complications, the stomal prosthesis should be placed. The fabrication of a custom silicone tracheostomal prosthesis by Andres *et al.*,^[14] Görür, *et al.*,^[15] Ochiai, *et al.*,^[4] Lemon, *et al.*,^[3] Meyer and Knudson^[16] incorporating a speaking valve housing within the prosthesis were reported. Retention of the speech valve within the housing is the major problem identified in these cases. Despite numerous attempts made to modify the housing attachment, the success of these devices is limited due to the inability to maintain the adhesive seal attaching the housing to the peristomal skin. The weight of the prosthesis

also increases; thereby dislodgement from the stoma is quite common. To avoid these inconveniences most, patients prefer using hand closure method to improve their speech. In these conditions also, the presented tracheostomal can be used without speech valve.

The procedure presented in this article used a thermoplastic non-rigid material, and its selection was based on the resiliency, comfort, durability, ease of manipulation and availability. Usage of the measurements of the old tracheostomal tube which the patient was wearing since surgery avoids impression making of the stomal defect. Impression making of the stoma has a life-threatening risk of aspiration of the impression material into the tracheal bronchi leading to suffocation and cardiac arrest. Though custom impression making during the initial stage is not done, but during the fabrication procedure, when the polyethylene urethane sheet is in lukewarm and soft consistency, is inserted into the stoma and customized for stomal patency. McKinstry^[17] reported the success using of Molloplast B material as a resilient lining along acrylic resin tracheostomal prosthesis. The use of acrylics is not advisable because of its rigidity and weight. A heavy prosthesis may transfer excessive forces to the supporting soft tissues and compromise patient comfort.

In 1988, Barton *et al.*^[18] introduced a modification of the Helper stoma button, which was originally designed as a stomal dilator that could be used as an intra-luminal attachment for the tracheostomal prosthesis. The Barton button virtually eliminated the need for adhesives and tapes required with peristomal attachments and became the preferred method of attachment for most of the tracheostomal patients. Currently, the Barton button is not widely used for several reasons. As the Barton button is rigid, it irritates and prevents the patients from wearing the device. Furthermore, due to the lack of contiguous “Stomal lip”, the button does not provide adequate seating and retention of the prosthesis within the trachea while the patient speaks.

The prosthetic restoration of tracheostomal defects is complicated by variations in the size and shape of the stomal opening and by the contours and mobility of the peristomal soft tissues. The choice of materials to fabricate tracheostomal prosthesis is based on the needs of the individual defect. Biocompatibility, adaptation, durability, comfort, cost and esthetics are the factors that must be considered. Despite the commercial availability of various stent designs and sizes, patients may complain of persistent peristomal soft tissue irritations and excessive mucosal secretions when this prosthesis does not have adequate fit in their defects.^[19]

Stenosis results in laminar flow becoming turbulent, with an increase in speed and resistance of air transit, leading to

dehydration of the mucosa and the accumulation of crustiform tracheostomal secretions. In some cases, this gives rise to severe super infection related tracheal inflammation, known as a crust-like tracheitis, causing hemoptysis and occasionally very severe dyspnea. De Virgilio *et al.*^[20] stated that diabetes mellitus and local infection were the only factors to be considered as risk factors for tracheostomal stenosis. Increased secretions, crusting, mucosal infection and granulation formation around the stoma due to irritation are potential and relatively benign complications of a permanent tracheostomy tube. Case reports of patient with an unusual and near fatal complications of the tracheostomy tube after long-term use under poor hygienic condition were reported.^[21] Hence, to reduce these risk factors, a tracheostomy button made of silicone was fabricated for this patient.

Vencio and Cruz,^[22] made tracheostomal prosthesis for a patient with bilateral vocal cord paralysis who require prolonged tracheostomy. They used plastic syringe which is readily available in the hospital setting to fabricate the prosthesis and are inexpensive. Though their improvised stoma button had the advantages of versatility for different sizes, lighter weight and easy accessibility of cleaning the secretions, it is not flexible and has to be tightened around the neck by strings which were irritant and unesthetic for the patient.

Large or small stomal diameters can be a problem for patients who wear standard buttons. A snug fit is often difficult to achieve, and as a result air can leak and the button may dislodge during speech. Though Barton button is a simpler, more efficient alternative, that provides intraluminal attachment within the trachea, constraints in standard designs and dimensions have limited its success. The above described prosthesis can be custom enlarged and the anterior flange, and posterior lip expanded to improve the fit and seal to avoid these problems. This tracheostomal prosthesis is inexpensive, relatively easy to fabricate, easy to insert and well tolerated by the patient compared with previously used commercially available tracheotomy tubes. Different sizes of this prosthesis could be fabricated which makes it a versatile appliance to fit varying sizes of stoma, and the procedure is easy to follow and can be duplicated. The translucency of the polyethylene material reflects the natural underlying skin color of the neck, which is well appreciated by the patient. Furthermore, the best fit is often achieved with the prosthesis that does not require a strap, tapes, adhesives or glues.

Among the advantages of this improvised prosthesis against the tracheotomy tube is that where the length of the prosthesis is shorter resulting in less tracheal irritation, its lighter weight, and smaller size, making it more comfortable and acceptable to the patient and its accessibility to clean easier when there

are secretions. Complications from long-term use of the stoma prosthesis include biofilm formation, stomal edge abrasions and granulation tissues which were the limitations for tracheostomal prosthesis. Periodic monitoring, daily cleaning and early intervention may prevent these complications. The cleaning of the prosthesis with a brush and detergent is more effective and safe to facilitate the daily maintenance of the prosthesis.

CONCLUSION

The ideal result for individuals who have undergone a tracheostomy is a nonrigid, soft, strapless and colorless tracheostomal prosthesis which prevents crusting. This case report generates a critical thinking to fabricate a tracheostomal prosthesis using a new material and customizing the prosthesis without impression making as a take home message. Clinical trials on more subjects should be conducted to assess parameters for long-term efficacy and frequency of replacement. Recommendations are made for future improvements in design and fixation techniques.

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