

Tracheal Anti-suction Safety Device used During Implanting/Replacement of Phonatory Prosthesis

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Vocal rehabilitation in patients with total laryngectomy can be done by using a phonatory prosthesis. The functioning principle of a speaking prosthesis is based on the existence of one-way valve from the trachea to the esophagus that allows the exhaled air to enter the residual pharynx and produce the voice. One of the possible complications that can occur during this process is represented by the aspiration of the prosthesis into the trachea. The aim of this paper is to present the design of a safety device, made of polydimethylsiloxane, which should prevent the tracheal aspiration of the phonatory prosthesis during primary or secondary insertion or during the replacement procedures.

Keywords: phonatory prosthesis, laryngectomy, polydimethylsiloxane

The phonatory prosthesis represents the most common method of vocal rehabilitation in patients with laryngo-pharyngeal cancer who underwent total laryngectomy.

Phonatory prosthesis implantation can be done primarily, during the total laryngectomy or as a second step, after the surgery was performed and the radiotherapy treatment was finalized.

The functioning principle of a speaking prosthesis is based on the existence of one-way valve from the trachea to the esophagus. After implanting it, when the patient wants to speak, he inhales air into the lungs and when he exhales, the tracheal stoma is covered and the air is directed through the prosthesis into the esophagus. The esophageal mucosa vibrates and the sound is produced; the sound is then modulated at the level of the oropharynx and the oral cavity.

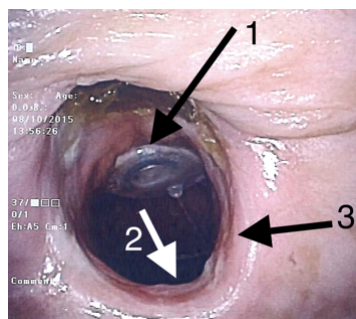


Fig. 1. Voice prosthesis in total laryngectomy patient with permanent tracheostoma
(1) Voice prosthesis;
(2) trachea; (3) tracheostoma

During the feeding process, the one-way valve of the phonatory prosthesis is maintained closed and does not allow food aspiration in the trachea. The valve is also protected by a silicon structure situated on the superior esophageal part of the prosthesis.

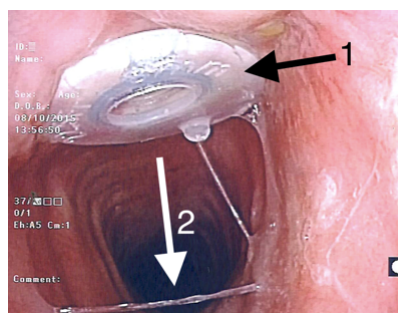


Fig. 2. Fiberoptic exam in tracheostoma orifice
(1) voice prosthesis;
(2) trachea

Experimental part

The implantation of the phonatory prosthesis has the following steps: a tracheoesophageal fistula is performed with a special instrument that produces a small hole in the tracheoesophageal wall, then a guiding wire is introduced through this instrument in the surgically created fistula. This guiding wire is pushed with slow moves until it is exteriorized in the esophagus, at the distal part of a rigid esophagoscope, then it is directed towards the oral cavity [1,2].



Fig. 3. Syringe type inserter for the phonatory prosthesis



Fig. 4. Cable guided device for inserting/replacing the phonatory prosthesis

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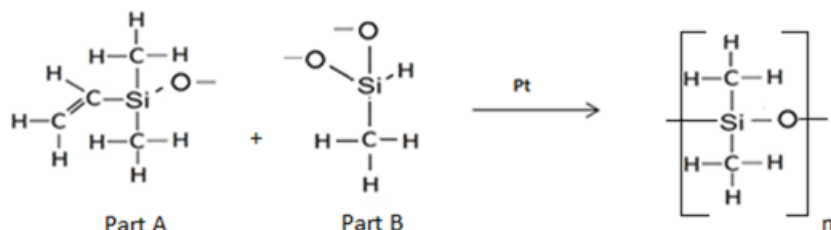


Fig. 5. Chemical reaction for obtaining polydimethylsiloxane

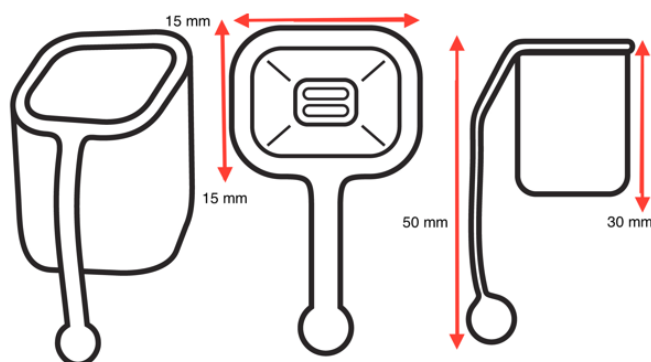


Fig. 6. Tracheal anti-suction safety device used during implanting/ replacement of a phonatory prosthesis

The esophagoscope is withdrawn. Then the phonatory prosthesis is attached at the distal part of the guiding wire. This wire is pulled by the proximal part until the distal part of it is situated at the level of tracheoesophageal fistula. The speaking prosthesis is fixated with a Pean forceps and through rotatory movements it is correctly placed. The guiding wire can be used for primary insertion, for secondary insertion or for replacement of the prosthesis [3].

Another modality of replacement of the speaking prosthesis, especially used in the ENT ambulatory, is represented by the usage of the syringe device. This instrument allows the possibility to replace the prosthesis under local anesthesia. The performing time is minimum and the patients do not require any general anesthesia or hospitalization [4].

The possible complications that can occur during this process are represented by bleeding, infection, mediastinitis, edema, food or saliva drainage through the prosthesis or periprosthetic leakage. The distant complications include: granulation tissue formed at this level, saliva drainage, infections and the ingestion of the prosthesis.

Despite the safety systems designed by the producers, the ingestion or suction of the prosthesis in the trachea is described. The suction of the tracheal prosthesis is a complication described in 3.9-6% of the cases and is mainly produced during the replacement procedures, when patients cough and the prosthesis is suctioned. The alcohol abuse leads to a lack of coordination of the patient and increases the risk of prosthesis suction. There are others factors that can produce this effect, such as neurologic diseases or radiotherapy.

The suction of the speaking prosthesis represents a medical emergency and the prosthesis should be extracted immediately by performing a rigid or flexible bronchoscopy [5]. The lack of this procedures, can lead to aspiration pneumonia, which in turn can cause significant morbidity or death.

In order to localize the prosthesis in the airways, a cardio-pulmonary radiography should be performed. Mainly, the phonatory prosthesis is aspirated in the main right bronchia, but there are cases when this process involves the main left bronchia.

Results and discussions

All the procedures involved in phonatory prosthesis implanting or during its replacement are located at the level of tracheal stoma. This tracheal stoma has different shapes, dimensions or angulation. The ideal safety device should be placed at the level of the tracheal stoma, without occluding it. This device should prevent the tracheal suction of the prosthesis, but it should not impede in any way with the breathing process during the implanting/replacing procedures.

Also, the device should be easily introduced and extracted. In case the prosthesis would be suctioned into the trachea, this device should allow its safe extraction together with phonatory prosthesis.

The material used in the composition of this device should be easily tolerated by the patient, and must be soft but resistant enough to the movements and pressures exerted during the implanting process.

We selected polydimethylsiloxane as a safe material for manufacturing this device because it is cheap, transparent, has good mechanical properties and it is non-toxic.

Concerning the design of the safety device, we imagined a basket shaped device which has multiple holes at the base that allow the breathing process to take place normally. The dimensions of the holes should be smaller than those of a phonatory prosthesis. In case of prosthesis suction, this device does not permit the speaking prosthesis to be aspirated into the trachea.

The safety device will have an extension that allows the prosthesis to be extracted after the implanting/ replacement steps are finished or when this prosthesis is suctioned.

Because of the different tracheal diameters, we will have different dimensions of this safety device, similar to those of the tracheal cannulas (8,10,12 mm).

The functioning principle of this device is as follows: before we initiate the steps of implanting the phonatory prosthesis, the patient undergoes local anesthesia (tracheal stoma and mouth).

The safety device is fixed at the level of the tracheal stoma and by using a Pean forceps, this device is placed almost 2 cm in the trachea. It should be taken into account that the device walls should be fixed correctly on the trachea. Through the small holes, situated at the base of the device, the patient can easily breathe.

After the safety device is placed, we can start the implanting/replacing steps of the phonatory prosthesis as recommended by the producers. After these procedures are fulfilled, the safety device is gently removed by acting on its exterior component.

If the prosthesis falls into the trachea, we can easily pull the exterior part of the device, using a Pean forceps, and simply extract it, thus removing the prosthesis as well. In this way we can successfully prevent the slip of the phonatory prosthesis into the trachea or further.

Conclusions

The process of tracheal suction of the prosthesis during implanting/removing of the phonatory prosthesis is a well known complication and represents a surgical emergency. There are cases when it can be removed by flexible bronchoscopy, but there are cases when a rigid bronchoscope is used. These procedures used for recovery of the prosthesis from the trachea involve some costs (surgical procedures, hospitalization, antibiotherapy) and significant discomfort to the patient.

The safety device imagined has the advantage of preventing the suction of the phonatory prosthesis in the trachea and allows its safe implanting/replacement. It is a very simple and cheap device and can be used by the patient as well, during the maintenance procedures of the prosthesis

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