

TRACHEOESOPHAGEAL PROSTHESIS INSUFFLATOR (TEPI) COMPUTER INTEGRATED SURGERY II (600:446)

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ABSTRACT

Every year, over 3,000 patients undergo laryngectomy in the United States (Steady Health, 2011). Patients who undergo total laryngectomy, a process where the patient's voice box is removed, require a method to be able to speak post-surgery. The tracheo-esophageal prosthesis' (TEP) purpose is to restore a person's ability to speak after his/her vocal cords are removed. As the nose and mouth are permanently separated from the patient's trachea and lungs, he/she is required to undergo tracheostomy, a process where a permanent breathing hole is created in the patient's neck, called the stoma (University of Pittsburg Medical Center, 2014). To restore speech, surgeons place a one-way valve into the patient's TEP, which keeps food out of the trachea, but allows air into the patient's esophagus. When the patient occludes the stoma, exhaled air is blocked from leaving the body through the stoma and passes through the valve. This process requires the patient to manually cover his/her stoma every time he/she wishes to speak, and can quickly become very tiring, challenging, and socially awkward. The goal of this project is to develop an insufflator that, through the use of a CPAP device, will obviate these challenges.

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Introduction and Project Overview

The Tracheo-Esophageal Prosthesis (here forth referred to as TEP) insufflator is designed to help laryngectomy patients by obviating the need to cover their stoma with their thumbs/fingers. The primary purpose of inventing this mechanism is to eliminate the issues related to manually occluding the stoma. Manually covering the stoma is tiring, socially isolating, non-hygienic, and not suitable for every patient, as his/her anatomy may not support the seal. Likewise, patients suffering from arthritis or other anatomic restrictions will find it hard to cover their stoma every time they wish to speak. The solution, explained in detail in the next section, primarily consists of a CPAP device (used in patients suffering from sleep apnea) to allow a patient to control the flow of air into his/her TEP. As the CPAP device must connect to the patient's voice prosthesis, a valve-attachment was designed to allow flow of air from the CPAP device to the patient's prosthesis. Total laryngectomy is a common procedure throughout the world; by introducing an efficient way of controlling the airflow to the stoma, we hope to eliminate the need to manually occlude the stoma, allowing for more socially acceptable interactions.

Solution

We propose a modified CPAP device to insufflate a patient's TEP, via a small caliber tube, to allow fluent tracheo-esophageal speech without the need to manually occlude the stoma. When the CPAP device is turned on, it produces a constant flow of air to the patient's TEP. This airflow blows through the insufflator into the patient's TEP and allows him/her to generate sound in a way similar to that of occluding the stoma manually. As CPAP devices take time to turn on and off, a finger-valve was developed to allow the patient to quickly enable and disable airflow. With a simple turn, the patient is able to turn airflow on to occlude the TEP and generate voice. A detailed explanation of how this voice is generated is found in the Background section.

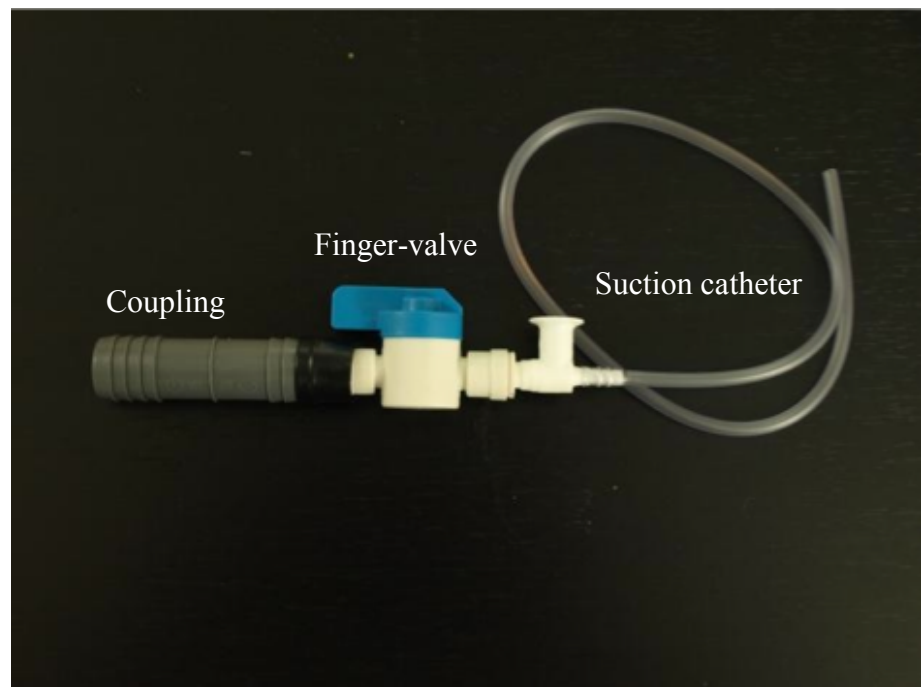


Figure 1: Finger-Valve Attachment

Background

In the United States, there are approximately 3,000 patients who undergo laryngectomy annually (Steady Health, 2011). Laryngectomy is a process where a patient's larynx is removed due to oral cancer or other throat related issues. Common issues that result in laryngectomy include laryngeal cancer, certain types of head and neck cancer, and severe swallowing problems (Brook, 2009). While smokers and tobacco users make up vast majority of the population of laryngectomy patients, people who suffer from specific types of head and neck cancer are also known to undergo this type of surgery (Steady Health, 2011). Additionally, since the larynx, also called the voice box, allows humans to make sound, which is then converted into speech through the use of the tongue and lips, its removal prevents a patient from speaking (Sievers, Walker, & Rafii).

In order to supplement the removal of the voice box, surgeons refer patients to speech pathologists, who then work with the patient on numerous methods of communication. While there are numerous methods that enable speech after laryngectomy (outlined in Table 1), one of the most effective methods found of transferring sound into the patient's throat is TEP. First described by Singer and Blom in 1980, TEP with prosthesis placement is a simple technique that involves the surgical placement of a one-way valve between the tracheostoma and neopharynx. The one-way valve works by allowing air to be shunted on demand through the neopharynx and produces speech similar to esophageal speech (Goyal, Baker, & McGinn, 2013).

Unlike other methods, TEP requires surgery to create a hole in the patient's neck to allow connection to the trachea and the esophagus. In order for the patient to speak using this method, he/she must cover up the stoma using his/her thumb, "which when you breathe out, allows air into the [patient's] esophagus producing vibration" (Sievers, Walker, & Rafii). Specifically, when the patient covers his/her stoma, exhaled air gets rerouted to pass through the voice prosthesis. The air enters the patient's esophagus and exits through the mouth. In order for this to happen, air must pass through the upper tissues of the esophagus and lower throat, resulting in vibration in the neoglottis. This vibration produces sound, which is then turned into understandable speech through the use of the tongue and lips. An overview of the human anatomy before and after laryngectomy is shown in Figure 2 and Figure 3, respectively (Sievers, Walker, & Rafii).

Advantages of TEP

Studies have shown that speech produced by TEP is superior to that of electrolarynx and esophageal speech. TEP is rated closest to laryngeal speech and as many as 50-90% of patients are able to learn and use the prosthesis successfully. On the other hand, only 23% of patients are able to learn esophageal speech (Goyal, Baker, & McGinn, 2013). Likewise, the air supply for speech in TEP is pulmonary and phonation sounds natural. A comparison of common methods can be found in Table 1.

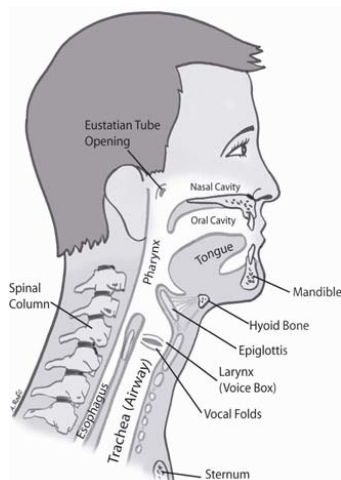


Figure 2: Human Anatomy Prior to Total Laryngectomy

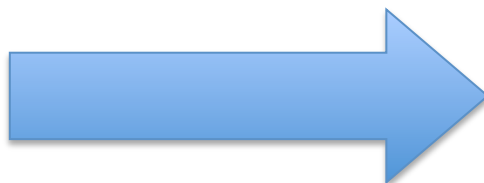


Figure 3: Human Anatomy After Total Laryngectomy

Type	Overview	Pros	Cons
Artificial Larynx	A battery powered device that produces the vibration required to make sound. Placed on the side of the neck or under the chin, sound is conducted into the oropharynx and articulated normally	After surgery, voice restoration is immediate Minimum maintenance	Creates a sort of “robotic” voice pattern Battery power needs to be replaced every so often
Esophageal Speech	Speech produced by insufflation of the esophagus and controlled release of air causing vibration of the PE-segment	No machinery is required Does not require further surgery	Large learning curve Patients are known to have difficulty phrasing certain words and controlling loudness
TEP Tracheoesophageal Speech	Similar to esophageal speech; however, utilizes a one-way valve to guide air from lungs into the esophagus without food or liquid passing through into the trachea	Most effective Pulmonary air supply Quick voice restoration – occurs within 2 weeks after surgery	See Disadvantages and Contraindications

Table 1: Overview of Different Speech Communication Options

Disadvantages and Contraindications

There are numerous disadvantages to TEP. For one, the one-way valve needs to be replaced every now and then, resulting in high expense for the patient. Similarly, the valve is prone to becoming colonized with yeast, which can leak from the esophagus into the trachea. The biggest disadvantage, however, is that current methodology requires hands to occlude the stoma when the patient wishes to speak. While hands-free valves do exist, they are not suitable for everyone (Cancer Research UK, 2013).

Most contraindications to TEP are relative. “Absolute contraindications include a subtotal laryngectomy, such as a cordectomy, hemilaryngectomy, supraglottic laryngectomy, or near-total laryngectomy” (Goyal, Baker, & McGinn, 2013). Also, separation of space between the esophagus and tracheostoma are contraindications as they create a space for infection or abscess. Relative contraindications include poor pulmonary function and prevent the use of prosthesis, as they require higher positive pressures in the trachea. Likewise, a strong alcohol drinking habit increases the possibility of aspiration and inability to maintain the prosthesis. As the prosthesis require regular maintenance and cleaning, a strong drinking habit that causes manual dexterity or impaired mental status can result in lack of maintenance of the prosthesis (Goyal, Baker, & McGinn, 2013).

Proposal

Use of Modified CPAP for TEP Insufflator

The primary goal of using a CPAP device poses numerous advantages. For one, the use of a portable CPAP device will enable a patient to be completely hands-free. An example of a portable CPAP can be seen in Figure 4. The patient here has the ability to attach the CPAP to his/her belt loop and go about his/her day. Likewise, there are few disadvantages to this method. A portable CPAP must be used, and according to our research, there isn't much availability of portable, battery-operated, CPAP devices on the market. Moreover, portable devices that are battery-operated have a maximum pressure of 20cmH₂O. In our clinical trials, it was determined that a pressure of 20cmH₂O was too less to generate a sound. We are currently awaiting IRB approval on a new CPAP device that is capable of delivering pressures of up to 30cmH₂O. However, this device is neither portable nor battery-operated, and requires a direct power-source at all times. An image of this machine can be seen in Figure 5. It should be noted that this device is for the purposes of testing and delivering a proof of concept.

Necessary Modifications

The current solution to attaching a CPAP device to the voice prosthesis consists of a rotating valve that connects to the pipe of the CPAP device. In practicality, a device that is integrated into the CPAP machine would be more efficient. Specifically, a similar valve mechanism would be integrated inside the CPAP device and would be controlled via a remote controller. This setup would eliminate the need for the patient to carry an extra attachment and manually turn the valve to speak. Moreover, by integrating a wireless controller, i.e. a ring on the patient's finger, the patient will be able to turn on/off the device with a simple push of a button.



Figure 4: High-pressure CPAP device (Sleep Review Magazine)



Figure 5: Z1 portable CPAP device (Mistatic.com)

Deliverables and Methodology

The deliverables of this project were as follows:

- Minimum: invention of a method that would allow the CPAP device to connect to the voice prosthesis. The method should enable airflow to travel through the pipes and reach the voice prosthesis
- Expected: the minimum deliverable plus a method of constraining the airflow into the voice prosthesis. More specifically, as patients would only need air to travel to their TEP when they wish to speak, they should be able to enable/disable the airflow without reaching for the stoma. For the purposes of this paper, this is known as the finger-valve system
- Maximum: the expected deliverable plus a method of wirelessly enabling/disabling the finger-valve system wirelessly as to enable the patient to use a ring (or any other object that is wireless) to enable/disable the airflow to the stoma

The minimum and expected deliverables were accomplished. The maximum deliverable was not accomplished for numerous reasons. For one, the concept of creating the insufflator is to allow patients to go hands-free without compromising on portability. In order to successfully turn the valve via a motor, the motor would need to be strong enough to handle the load. Currently, the closest motor that can do this is over one and a half inch long and an inch in diameter. Moreover, in addition to the motor, a microcontroller is required to guide the motor. Additionally, as the maximum deliverable calls for a wireless method, a wireless shield is required to receive signal from a remote control. Combined together, this would not only make the insufflator extremely bulky, but also impractical, as portability would become infeasible. The ideal way to go about doing this would be to implement the attachments with wireless components inside the CPAP device (see Necessary Modifications); however, as these machines have proprietary software that is controlled by the manufacturer, it must be done at the time of manufacture.

Methodology

The current solution involves a finger-valve that connects to the pipe of a CPAP device on one end, via a PVC coupling. On the other end, the finger-valve connects to a suction catheter, which then connects directly to the voice prosthesis. As the suction catheter features an opening, small corks were used to occlude the air from escaping. An image of the finger-valve attachment can be seen in Figure 1. The transparent tube coming out of the suction catheter fits into the voice prosthesis; which in turn, connects to the TEP. An image of the voice prosthesis can be seen in Figure 6.



Figure 6: Voice Prosthesis (Atos Medical AB, Sweden)

The finger-valve used in the insufflator is an easy to use, rotating valve that features a circular wall within the valve. Specifically, when the cap of the valve is rotated 90°, the valve opens, allowing the air to go through. Likewise, when the cap is turned back to its original position, the valve closes, preventing all air from passing. This allows the patient to quickly and easily enable/disable airflow. This works under the assumption that the CPAP device is turned on and left at this position. Turning the CPAP on and off every time is unpractical and time consuming. Moreover, if the patient tries to speak while the device is powering on/off, he/she will belch.

Current Status and Future Direction

The project is currently on hold awaiting IRB approval on the high-pressured CPAP device. Once the approval is granted, Dr. Richmon will conduct clinical trials. These trials, if successful, will enable Dr. Richmon to submit a proof of concept. Once the patent has been filed and proof of concept acquired, Dr. Richmon will have the ability to market the concept to medical device manufacturers and/or patients requiring TEP.

Wrap-Up

The TEP Insufflator project is of great use to those who have undergone total laryngectomy. By introducing a simple, yet versatile, solution to this problem, we hope to tackle a widespread issue through the use of existing technology. TEP is one of the most effective methods to restoring speech after total laryngectomy and by introducing a hands-free solution, we hope to not only prevent the unnecessary labor required in closing the stoma, but also the social stigma that patients undergo.

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