

Tracheoesophageal Prosthesis Insufflator

Computer Integrated Surgery II

(600.446)

Final Report: Group 13

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Abstract

The tracheoesophageal voice prosthesis (TEP) has seen wide success in thousands of patients who lost their ability to speak after a total laryngectomy. The device is small, sterile, and is operated by blocking the stoma to redirect air into the esophagus, allowing discernible speech. However, the physical blocking of the stoma can eventually become inconvenient for frequent speakers and perhaps even painful for those with arthritis or low respiratory capacity. The goal of this project is to develop an insufflator that will connect to the TEP and direct air into the device at the user's discretion, circumventing the need for the user to constantly raise an arm to block the stoma.

I. INTRODUCTION

A. Total laryngectomy

There are approximately 12,000 reported cases of laryngeal cancer every year. Many non-surgical procedures have arisen to eliminate the cancer, such as chemotherapy and radiotherapy, but every year, more than 3,000 patients still undergo a total laryngectomy, in which the larynx is removed^[1]. The airway leading to the mouth and nose is disconnected from the trachea, which is rerouted to an opening in the lower neck, defined as a tracheostoma or stoma. The patient must breathe through the stoma for the rest of his or her life. Often, the psychological trauma of losing one's primary ability to communicate compels patients to seek speech rehabilitation. Devices such as the electrolarynx and the practice of esophageal speech have existed for decades, but each presented their own drawbacks. The electrolarynx was notorious for its robotic and monotonic voice characteristics, while the acquisition rate of esophageal speech was very low^[2].

B. The tracheoesophageal prosthesis

In 1979 Eric Blom and Mark Singer devised another method of alaryngeal speech. Following the total laryngectomy surgical procedure, the surgeon would perform a tracheoesophageal puncture and create a fistula between the trachea and esophagus. A silicone one-way valve would then be installed in the fistula, either during or after the surgery. This valve, often referred to as a tracheoesophageal voice prosthesis (TEP), has since then become the most widely used device in alaryngeal speech. The patient breathes normally through the stoma, and when the stoma is obstructed by the patient to speak, the air coming out of the stoma is rerouted through the TEP, into the esophagus, and out of the mouth. A voice is produced by the vibration of the esophageal lining, in which the patient is trained to perform following surgery. Figuratively, the function of the vocal chords are adopted by the esophagus. Most TEP users operate the prosthesis by using their thumb to obstruct the stoma. However, a fraction of patients are unable to perform this maneuver, either due to developing arthritis or poor coordination. For other TEP users, speaking requires higher-than-adequate pulmonary strength. There are devices on the market that plug into the stoma and allow hands-free speaking, however operating these devices requires even more pulmonary reserves^[4].

C. Objective and Significance

This project's goal is to develop an insufflator that will pass air through a tube into the TEP at the user's

discretion. This will increase feasibility of speaking for patients who have difficulty obstructing their stoma or expelling enough air pressure and increase ease of speaking for other TEP patients. TEP longevity may be increased with the use of the insufflator. The primary reason for replacing the voice prosthesis is leakage of fluids through the valve such as yeast colonization, mucous, or food^[5]. Because the insufflator physically plugs into the TEP and provides an airtight seal, fluids entering the prosthesis valve could be significantly reduced, which would extend the time between TEP replacements and reduce patient expenses.

II. METHODS

The insufflator utilizes 16 gram carbon dioxide cartridges to drive pressurized air into the TEP.



Fig 1. Carbon dioxide cartridge and its receiver

The cartridges are screwed into a Genuine Innovations tire inflator, where a needle inside the receiver taps into the cartridge and the compressed carbon dioxide is able to flow out of the inflator. Expulsion of air is controlled by a trigger on the inflator and features a safety lever that blocks the trigger from releasing air out of the cartridge.



Fig. 2 Pressure Regulator Valve

A Dwyer MPR pressure regulator valve reduces air pressure from the inflator, due to the low operating pressure of the TEP. The pressure of the CO₂ coming out of the device is approximately 800 PSI, while air pressure entering the TEP in patients range from 10 to

20 cmH₂O, or 0.142 to 0.284 PSI. A knob on the regulator allows the insufflator user to adjust air pressure entering the TEP because every TEP patient will have their own preferences. Carbon dioxide flows out of the valve and through the silicone tubing into the TEP. Medical-grade silicone 1/8" tubing was chosen especially for its sterility, as well as flexibility, and durability. A quick-detach system lies in between the TEP interface and the regulator valve to serve as an interrupter of air flow should the regulator valve or pressure source fail and excess air is driven. In such an event, the patient would simply twist the system counter-clockwise and pull to break air flow into the TEP. When air regulation has been restored, the patient would join the parts together and twist it clockwise.



Figure 3. Quick-Detach system drawn in PTC Creo

The TEP connector is a 3D-printed ABS plastic tube in a right-angle shape to prevent sticking into the TEP device. A 0.5mm ridge on the TEP-end of the connector is designed to firmly remain inside the TEP chamber but can be easily removed to avoid dislodging the TEP as well as fast re-insertion. The TEP is sold in a multitude of dimensions with different bore lengths and diameters. Therefore, patients with different TEPs would require different connectors, though the simplicity of the connector schematics and the flexibility of 3D-printing solve this problem.

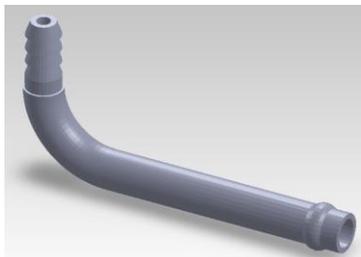


Figure 4. TEP Connector



Figure 5. Insufflator Device connected to TEP

III. RESULTS & DISCUSSION

The insufflator was successful in driving air to the TEP. The regulator was capable of limiting the air pressure to below 1 PSI, although fine tuning is necessary due to the regulator valve operating in a range of 0 to 5 PSI. 0 to 1 PSI regulator valves are not commercially available. The valve door on the TEP opens partially when air is driven, indicating the regulator valve is capable of minute adjustments.



Figure 6. TEP valve door opening via insufflator

In tests, the duration of constant TEP insufflation was remarkably short, averaging approximately three minutes before the cartridge was expended and had to be exchanged. This is due to the small volume of the CO₂ canister in which although it is highly portable, its life span is small. Larger CO₂ canisters can be used, but portability of the device will be reduced.

Several components for the insufflator design were considered but were unsuccessful. A portable air compressor was a candidate for the pressure source due to its ability to generate air pressure without using a consumable canister that would incur high long-time costs, however the smallest air compressors on the market are still very bulky. The severe reduction in portability did not justify replacing the CO₂ canisters. An alternate arrangement consisting of a dial-valve CO₂ receiver (rather than a trigger-activated receiver) and a push button valve connected downstream of the regulator valve was tested. When the push button valve

was closed, the CO₂ receiver would leak CO₂ out of its connector to the regulator valve due to air flow following the path of least resistance when the button valve blocks air flow. When the button was pressed, air correctly flowed to the TEP device. However, the constant air leakage, which would occur when the patient chooses to pause during speech, would severely affect the already-short life span of the canister as well as producing a constant hissing sound. In addition, the trigger-activated receiver serves both roles of the twist-valve receiver and the button valve, therefore reducing costs as well as opportunities for device failure.

IV. MANAGEMENT SUMMARY

Kevin Liu is the only member in Group 13, therefore he is the sole student responsible for the work in this project. The minimum deliverable of developing an working insufflator for the TEP was achieved. Testing of the device was planned for late April and early May, but setbacks in the development of the insufflator delayed testing. The optimal test to determine the insufflator's efficacy would be testing on patients who underwent a laryngectomy, a tracheoesophageal puncture, and had a TEP installed. The process would include connecting the insufflator to the TEP through the stoma with the assistance of an endoscope, having the patient pronounce vowels noting length of speech and loudness, and having the patient attempt to speak sentences. JHU IRB approval would not have been achieved in time after the development of the prototype, but post-semester testing may occur.

Dr. Richmon has a patent prepared for the insufflator device with the intentions of distributing it commercially to patients utilizing a TEP. The next step for this project would be streamlining the design of the insufflator. The current design is merely a connection of commercial parts that anyone can acquire, except for the 3D-printed components. Future designs would include a custom pressure regulator that operates within 0 to 1 PSI, a CO₂ canister that could serve for a fifteen-hour day, as well as an air release mechanism that would greatly increase the hands-free benefit of the device. Pulling a trigger requires less coordination than complete blocking of the stoma, but the user still loses social functionality of one hand. A future design that could command the insufflator to release air while the patient performs a task with both hands is ideal.

Several lessons were learned during the duration of this project. Communication with others is an essential factor in a project's progress. Even when there is nothing new to show in an update, it is still courteous to let others know that the person working on it still considers it a priority. Experience in PTC Creo as well as the 3D-Printing process was also attained during the course of this project, and will be useful in the future.

Along with the seminar article "Effect of singing training on total laryngectomees wearing a tracheoesophageal voice prosthesis" by Onofre et al. [6], this project has shed light on the societal importance of alaryngeal speech. In previous years, voice rehabilitation focused purely on restoring the physical ability to speak with others, but now more is required. When new technology is introduced, human nature compels those to improve the technology so that it can serve them in the highest imaginable capacity. In other words, patients not only want to be able to speak again, but they wish to speak as well as they could before the laryngectomy. Facts like these are rarely stated in research articles, but they are important to know nonetheless.

V. ACKNOWLEDGMENTS

Group 13 would like to thank Dr. Russell Taylor and Dr. Jeremy Richmon for their vast knowledge, patience, and steadfastness. Group 13 would also like to thank Niel Leon for his critical assistance in the 3D printing process, and Nishikant Deshmukh for his dedication to assisting the class.

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