Tracheoesophageal Prosthesis Insufflator

Computer Integrated Surgery II
(600.446)

Project Proposal: Group 13

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Abstract

The tracheoesophageal voice prosthesis (TEP) developed by Blom and Singer in 1978 has seen wide success in thousands of patients who lose their ability to speak after a total laryngectomy. The device is small, sterile, and is operated by simply blocking the stoma to redirect air into the esophagus, allowing relatively low-effort, 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 poor coordination. 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

Every year, 3,000 patients undergo a laryngectomy, in which the larynx is removed, often due to laryngeal cancer. The airway leading to the mouth and nose is disconnected and the patient must then on breathe through an opening in his or her neck, referred to as a stoma. The most common method of restoring speech to total laryngectomees is to install the Blom Singer tracheoesophageal prosthesis, a one-way valve that connects the trachea to the esophagus. The laryngectomee breathes through the stoma, and when the stoma is obstructed so the patient can 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 vibrating the esophageal lining, similar to speaking while belching. 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 arthritis, poor training, or poor coordination. For other TEP users, some view the maneuver as an inconvenience because preparing to speak requires more effort than a healthy person. There are devices on the market that plug into the stoma and allow hands-free speaking, however patients have to apply more force through their lungs to operate the device, which may be tiring. This project's goal is to develop an insufflator that will pass air through a tube into the TEP with the push of a button. This will increase feasibility of speaking for patients who have difficulty obstructing their stoma and increase ease of use for other laryngectomees. In addition, because the air is provided by the insufflator and not the lungs, the patient theoretically will use less effort to speak than a normal person.

II. TECHNICAL APPROACH

Means of propelling air through the insufflator must be considered. The two most current practical methods of generating pressure in the insufflator are the self-contained gas canisters and portable air compressors. Air canisters are very portable and if designed correctly, are easy to replace. In addition, air canisters are inexpensive and some can be refilled. There are only a few drawbacks, including the possibility of constantly purchasing expendable canisters that may not be refillable and also the potential, though unlikely, danger of rupturing the canister. A portable air compressor circumvents the main shortcoming of the air canister. It can generate its own source of pressure, therefore the patient only needs to make a one-time purchase, assuming the patient maintains the device. However, portable air compressors are bulky and noisy, which reduces portability. For the sake of mobility, this project will utilize air canisters.

The pressure in a 12 gram CO2 canister is approximately 850 PSI while the pressure exerted from the mouth is approximately 2 PSI. To reduce the air pressure from the canister going into the esophagus, several components are required in the name of safety. The most important will be a pressure regulator valve connected between the TEP and the pressure source. This device directly reduces air pressure between two devices and because it can vary how much pressure passes, it allows for the user to change the pressure flowing into the TEP to his or her needs. A quick-detach component will also be implemented. Should the regulator valve fail, the patient can disconnect the tubing to the pressure source in one quick motion and reduce injury.

The medium being exhaled from the esophagus does not necessarily have to be air or carbon dioxide. It is common knowledge that inhaling helium and exhaling while speaking raises the pitch of the speaker's voice. If there is a way to infuse helium into a pressure canister, then the insufflator will not only provide convenience for the patient, but also make the patient's voice more attractive, especially for female patients.

III. PROJECT LOGISTICS

A. DELIVERABLES

Minimum Deliverable (Mid-April)
A working CAD and pad sketch of insufflator
Initial prototype with 3D-printed parts

Expected Deliverable (Late April)
Revision of insufflator prototype
Develop and perform means of testing device on non-humans

Maximum Deliverable (May)
Insufflator prototype in an end-user form
Insufflator could meet IRB standards should testing be a future possibility

B. DEPENDENCIES

Dependency: Acquiring TEP Device
Without the TEP device, designing the interface between the insufflator and the prosthesis would be difficult. There is no alternative.
Resolution: Acquire from Dr. Richmon

Dependency: 3D Printing/Rapid Prototyping
The interface with the TEP and the quick-detach system, which are not common parts in most markets, can only be realized as a custom part. There are possibilities of not being able to use the 3D printer, such as lack of training or high costs. The alternative would be to somehow connect the insufflator tube to the TEP with more common hardware parts, though exact fitting is unlikely.
Resolution: Collaborate with colleagues in the Mechanical Engineering Dept. at Wyman Park

Dependency: Testing
The most direct way to test the efficacy of the insufflator would be to gain feedback from patients utilizing a TEP. However, IRB approval is required and the application process is lengthy. An alternative is to create a simple model of the esophagus and using physiological data, simulate the air going into and out of the esophagus.
Resolution: Seek volunteers or discuss alternative

C. MANAGEMENT PLAN

- Regular updates with mentors on project status
- Updated Dokuwiki page on project progress or hindrances
- Demonstration of device to Dr. Richmon (TBD)

D. SCHEDULE/GANTT CHART

Due to formatting of document, see Dokuwiki page at (Must have a login ID and password): https://ciis.lcsr.jhu.edu/dokuwiki/doku.php?id=courses:446:2013:446-2013-13:446-2013-13

IV. RELEVANT READINGS

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