

TEP Insufflator

CIS II Project Proposal

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ABSTRACT

The goal of this proposal is to present an alternative to the pre-existing method of treating tracheo-esophageal speech in patients who have undergone laryngectomy. This proposal outlines the background of the problem, the goal of the project, and logistical details, such as the management plan, key dates, a technical summary of the approach to treating the problem, and project deliverables.

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Introduction and Project Overview

The Tracheoesophageal Puncture (here forth referred to as TEP) insufflator is designed to replace the pre-existing solution to tracheotomy without the patient needing to cover his/her stoma with his/her thumb. The primary purpose of inventing this mechanism is to eliminate the social unattractiveness patients undergo when required to cover their stoma manually. The solution, explained in detail in the next sections, primarily encompasses a CPAP device (used in patients suffering from sleep apnea) to allow a constant flow of breathable air into the patient's stoma. By introducing a CPAP device to enable/disable the airflow into the patient's stoma, we hope to eliminate not only the social unattractiveness caused by the opening in the patient's throat, but also the unnecessary labor required to cover the stoma every time the patient is required to speak/breathe.

The prospect of this project is to allow the patient to enable/disable the airflow via a switch attached to his/her waist (such as a belt loop). This will prevent the patient from touching his/her neck and will allow him/her to simply cover/un-cover the hole in the pipe of the attachment. This attachment, along with the CPAP device and suction catheters, are shown in the coming sections. Laryngectomy is a common procedure throughout the world; by introducing an efficient way of controlling the airflow to the stoma, we not only hope to accomplish an easy, attractive, solution to this widespread problem, but also a feasible solution to underlying issues related to speaking, breathing, and swallowing.

Background/Definition of Problem

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. 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). Since the process requires the removal of the larynx, patients are unable to breathe without support from outside of their body. 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. Unlike other methods, TEP requires surgery to create a hole in the patient's stoma 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). An overview of the human anatomy before and after laryngectomy is shown in Figure 1 and Figure 2, respectively (Sievers, Walker, & Rafii).

Type	Overview	Pros	Cons
Artificial Larynx	A battery powered device that produces the vibration required to make sound	Generally easy to implement and maintain	Creates a sort of “robotic” voice pattern Takes ample practice to improve communication Battery power needs to be replaced every so often
Esophageal Speech	Utilizes the concept of manually pushing air to the back of the throat and into the esophagus	Worth the effort in many cases Does not use an electric device	Takes an ample amount of practice Not suitable for all patients, depends on their anatomy
TEP Tracheoesophageal Speech	Similar to esophageal speech; however, utilizes a tube to push air into the esophagus	One of the most preferred methods by patients Extremely easy to maintain and use once the patient has adapted to it Utilizes voice prosthesis, enabling feasibility in pushing air into esophagus	Generally takes the longest to master The voice prosthesis needs to be maintained, this is generally easy once patient is accustomed Only available to those whose anatomy supports it

Table 1: Overview of Different Speech Communication Options

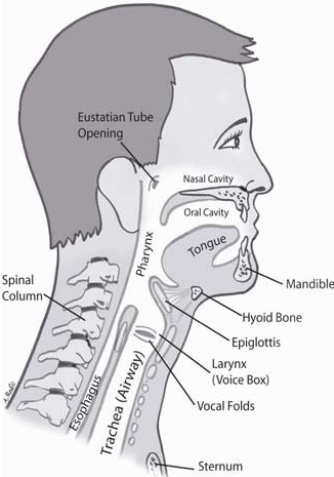


Figure 1: Normal Human Anatomy

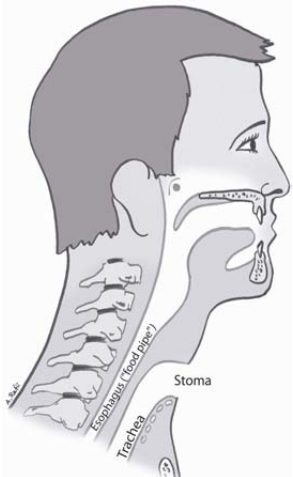


Figure 2: Human Anatomy After Laryngectomy

Detailed Project Overview and Technical Approach

The overall goal of the TEP Insufflator is to provide patients who have undergone laryngectomy with a simple, versatile, solution affiliated with speech. As explained in the background section, the current solution involves a manual closure of the patient's stoma (shown in Figure 2). In order to successfully eliminate the manual need to close the stoma, we will be connecting the voice prosthesis to a CPAP device. The CPAP device is used to provide a constant flow of air. By connecting to the voice prosthesis, the CPAP will output a constant flow of air to the voice prosthesis, which, in turn, will deliver the air into the patient. In order to allow the patient to enable/disable the flow of air, a finger-valve will be provided on the CPAP machine's connection pipe, i.e., the patient will have the option of enabling/disabling the airflow from the pipe at his/her waist level, in lieu of covering his/her stoma.

Deliverables

The deliverables of this project are as follows:

- Minimum: invention of a method that would the CPAP device to connect to the voice prosthesis. The method should enable a constant 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 the patient would not need air constantly reaching his stoma, he/she should be able to enable/disable the airflow at his/her waist level 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

Dependencies

There are numerous dependencies encompassing this project. These, along with their supplementary solutions, are shown in Figure 3. There are numerous dependencies that must be accounted for in order for this project to reach its succession. These include, and are not limited to, funding provided by Dr. Richmon (or Dr. Taylor) for the parts necessary to complete the project. Thus far, the parts have been relatively cheap and accounted for by the inventor (myself); however, as the parts necessary to complete the wireless mechanism are relatively expensive, funding must be obtained. To tackle this issue, I will speak with Dr. Richmon during our next meeting regarding funding. Should Dr. Richmon fail to provide the ample funds necessary, I will speak to Dr. Taylor immediately after so that the project is not left incomplete.

Management Plan

The TEP Insufflator project began in early-mid December of 2013. Thus, the minimum deliverable has been achieved and the expected deliverable is en route to completion. A completely plan is shown in the Gantt chart in Figure 4. At its current standing, we have been successful in connecting the CPAP device (Figure 8) to the voice prosthesis. To

accomplish this, we created a custom-made attachment that connects the CPAP pipe to the suction catheter (Figure 6), which in turn, connects to the voice prosthesis.

Assessment and Misc. Details

This project is of high important as it enables patients' to eliminate awkwardness and the social stigma related to their tracheostomy. By inventing a method where patients can speak without needing to cover their stoma, we not only eliminate the social issues, but also the discomfort caused. Additionally, by introducing a mechanism where the stoma will be covered by the CPAP's pipe, we eliminate the possibility of debris reaching the voice prosthesis. While the voice prosthesis is designed to prevent food and other items from reaching the trachea of the patient, the pipe eliminates any possibility of this happening. As this project requires a knowledgeable understanding of tracheostomy, laryngectomy, and tracheo-esophageal speech, majority of the reading list conducted will cover these topics. Thus far, I have been successful in finding a plethora of articles published by reputable sources such as Mayo Clinic (Staff, 2012), Steady Health (Steady Health, 2011), University of California's medical resources (Sievers, Walker, & Rafii), and other empirical studies found on Google Scholar. Therefore, while the reading list for this project isn't set in stone of specific articles, there is a plethora of articles available on the Internet that will enable me to successfully deliver this project.

This project is of great relevance as it not only incorporates the invention and its trial and error process, but also the business aspect related to the project. More specifically, the project is great for students studying management (like myself) as it encompasses the IRB application, the invention, and the overall project management scope related to finishing the device. Likewise, the project has some great points affiliated with it. For one, the logic of the project is absolutely intelligent as it enables patients to speak without any present issues. At the same time, the project makes use of existing technology (like the CPAP device) to tackle a widespread problem. On the other hand, it can be argued that the device isn't universal to all patients, as it requires a change of the suction catheter. Specifically, since the suction catheter depends on the patient's anatomy, the tube must be changed for every patient. While this is not major issue, it leads to inconvenience.

Wrap-Up

The TEP Insufflator project is of great use to those who have undergone laryngectomy and/or tracheostomy. By introducing a simple, yet versatile, solution to this problem, we hope to tackle a widespread issue through the use of existing technology. The current estimate of project completion is aimed to be at the end of April, although I aim to accomplish it much before to allow ample time for testing on patients. I would like to thank Dr. Taylor and Dr. Richmon for their guidance and support on this project.

Works Cited

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Appendix

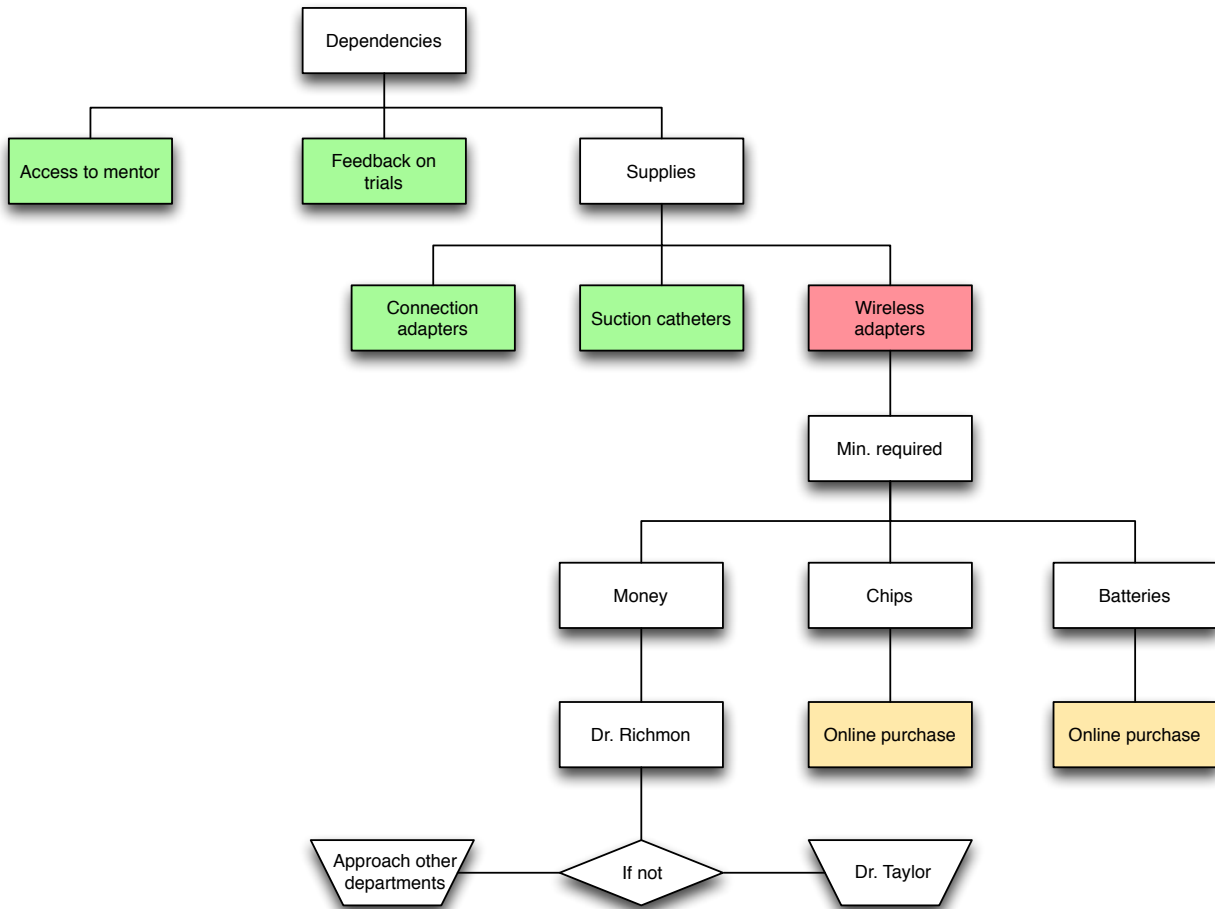


Figure 3: Dependencies Block Diagram

Task	Start	Finish	Duration	% Comp	2013					2014		
					DEC	JAN	FEB	MAR	APR			
1 Meet Dr. Richmon	12/2/2013	12/2/2013	1	1	100%							
2 Obtain CPAP and voice prosthesis	12/2/2013	12/19/2013	18	14	100%	Obtain CPA...						
3 Develop connection between CPAP and voice prosthesis	12/2/2013	12/19/2013	18	14	100%	Develop co...						
4 Meet Dr. Richmon	1/9/2014	1/23/2014	15	11	100%		Meet Dr...					
5 Develop method to install suction catheter to attachment	1/24/2014	2/5/2014	13	9	100%		Develo...					
6 Give Dr. Richmon CPAP for clinical trial	2/6/2014	2/14/2014	9	7	100%			Give...				
7 Develop finger valve and method of occluding suction catheter	2/15/2014	2/24/2014	10	6	90%			Deve...				
8 Meet Dr. Richmon	2/25/2014	2/25/2014	1	1	0%							
9 Figure out money source	2/26/2014	3/3/2014	6	4	0%							
10 Purchase components for wireless mechanism	3/4/2014	3/17/2014	14	10	0%							
11 Connect finger valve to wireless method	3/18/2014	4/14/2014	28	20	0%							
12 Test device on patients	4/15/2014	4/18/2014	4	4	0%							
13 Begin poster presentation	4/19/2014	4/30/2014	12	8	0%							
14 Meet Dr. Richmon	4/30/2014	4/30/2014	1	1	0%							

Figure 4: Management Plan



Figure 5: Voice Prosthesis



Figure 6: Suction catheter and attachment



Figure 7: Opening for finger-valve placement



Figure 8: CPAP device and connection pipe