Proof of Concept of a Tracheoesophageal Voice Prosthesis Insufflator for Speech Production After Total Laryngectomy

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Summary: Importance. There may have a variety of reasons why patients are unable to produce tracheoesophageal speech after total laryngectomy (TL) including poor pulmonary reserve or other comorbidities that prevent adequate stoma occlusion and intratracheal pressure to voice. Other patients find it difficult, uncomfortable, or socially awkward to manually occlude the stoma with the finger or thumb.

Objective. The study aimed to assess the feasibility of achieving TE speech with a prototype TE voice prosthesis insufflator (TEVPI).

Design, Setting, and Participants. We prospectively assessed the feasibility of achieving TE speech with a commercially available continuous positive airway pressure device in six TL patients.

Intervention. The intervention is the use of a prototype TEVPI.

Main Outcomes and Measures. A battery of acoustic and perceptual metrics were obtained and compared between TEVPI speech and standard tracheoesophageal voice prosthesis (TEVP) speech.

Results. Voicing was accomplished with the TEVPI in five of six participants. On average, the duration of phonation with TEVPI was shorter, not as loud, and perceived to be more difficult to produce compared to TEVP speech. **Conclusions and Relevance.** The TEVPI is a feasible, hands-free solution for restoring speech after TL. Although the current model produced inferior acoustic metrics compared with standard TEVP speech, further modification

and refinement of the device has the potential to produce much improved speech.

Key Words: Tracheoesophageal speech–Tracheoesophageal prosthesis–Total laryngectomy–Speech rehabilitation– Aphonia.

INTRODUCTION

Despite major strides in conservation laryngeal surgery and the increasing use of concurrent chemoradiation modalities, total laryngectomy (TL) remains the primary procedure for advanced-stage and recurrent laryngeal carcinoma.¹ Although this procedure can be curative, it is associated with significant morbidity, such as loss of voice, and olfactory and gustatory changes, in addition to psychosocial alterations affecting patients' overall quality of life. Postlaryngectomy rehabilitation focuses on optimizing speech and swallow function. The goal of treatment is not only to eradicate cancer but also to return patients to a life fulfilled with the greatest function and social integration possible.

Although there are numerous methods that enable communication after TL (eg, writing, mouthing, esophageal speech, electrovibratory devices, text-to-speak devices), one of the most effective methods is the creation of a small tracheoesophageal (TE) tract that is maintained by a silicon one-way TE voice prosthesis (TEVP).² The TEVP allows for the transfer of pulmonary

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air into the neopharynx when the tracheostoma is occluded. The sound generated by the mucosal vibrations in the neopharynx is then articulated into intelligible speech in the oral cavity.^{1,3} The last two decades have seen tremendous technical improvements in valve design and method of insertion, and with the introduction of hands-free, low-pressure, indwelling, and fungal resistant valves.³ These endeavors aim to provide TL patients with an effortless voice that is easy to maintain over a long period of time.^{4,5}

Despite the many advantages of TE speech, there remain significant challenges to achieving fluent, intelligible speech for all TL patients. The process of acquiring TE speech requires focused efforts and commitment both from the patient as well as the clinician. Multiple appointments with a speech language pathologist for therapy are not possible for some patients, especially those who live in rural locations and in less developed countries. Additionally, patients may have cognitive or physical impairments (eg, arthritis, unfavorable stomal anatomy) that prevent them from successfully occluding their stoma and insufflating the neopharynx. As pulmonary air drives tracheoesophageal voice production, patients with pulmonary conditions may have decreased ability to produce TEVP speech. In patients who receive a TEVP, intelligible speech is obtained in 40–90%,⁶⁻⁹ with the higher rates reported following recent refinements in TEVP valve design. Furthermore, for those patients who do have successful TE speech, many speak less frequently than before laryngectomy or choose to avoid speaking in public or social situations as they may find it socially awkward and embarrassing to manually occlude their stoma with their finger or thumb.

One potential solution to the drawbacks of TE speech would be a device that insufflates air through the TEVP, essentially recreating the pulmonary drive that is produced when a patient occludes

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the stoma manually. The air flow would be controlled by the push of a button or even remotely avoiding conspicuous movements currently required for TE speech. Herein we perform a proof of concept study to evaluate if TE speech could be produced by a mechanical air insufflator. This study will determine the value of developing a novel air insufflator specifically for TE speech.

METHODS

Under institutional review board approval, we performed a prospective study to assess the feasibility of achieving TE speech with a commercially available continuous positive airway pressure (CPAP) device in TL patients. A convenience sample of six proficient TEVP users who had no evidence of persistent or recurrent disease were invited to participate in this feasibility study. All participants had a minimum of 1 year of experience using the TEVP. There were no restrictions on specific prosthesis brand, style, or size used. Patients who had signs or symptoms of recurrence, difficulty with TEVP speech, and evidence of prosthesis problems (ie, fistula, infection, leakage, and granulation tissue) were not eligible to participate in this study.

A standard Respironics CPAP device (Philips Healthcare, Vantaa, Finland) was used as the TE voice prosthesis insufflator (TEVPI). The pressure was turned to maximum and fluctuated between 20 and 30 cm H₂O. TEVP speech is approximately 30 cm H₂O, but can reach over 100 cm H₂O.^{10–12} Our CPAP device was not capable of producing pressures beyond this level, which minimized potential barotrauma. No technical modifications of the CPAP device were performed. The CPAP tubing was connected to the patient's TEVP device via a small diameter tracheal suction catheter that was inserted into the prosthesis. The size of the catheter chosen was such that it fit snugly directly within the TEVP lumen. When the CPAP device was activated, it provided continuous airflow into the tube. The test subject would manually cover the suction control port of the tracheal suction tube to direct all the air through the TEVP into the neopharynx to phonate (Figure 1). Starting and stopping phonation was therefore done under the control of the test subject occluding the control port rather than the stoma to speak.

The participants completed a series of voice tasks while using their standard TEVP speech and then while using the TEVPI. They were asked to sustain the vowel /a/ for as long as possible. During this task, the maximum duration, average intensity, and fundamental frequency were extracted using the KayPENTAX Computerized Speech Lab (CSL). The participants were asked to serially count as high as they could on a single breath. Again, the mean intensity and frequency were extracted. Following completion of speech tasks with standard TEVP speech and TEVPI, each participant completed a 100 mm visual analog scale, where 0 indicated greatest ease and 100 indicated greatest difficulty producing voice.

RESULTS

All six participants completed the evaluation of the TEVPI. The average age of the participants was 65 (range, 56–76) and all were men. The average time since the TEVP placement was 6.4 years (range, 3–11). The type of surgical procedure and the prostheses are summarized in Table 1. In all but one patient, the pressure generated by the CPAP device was capable of producing audible





FIGURE 1. Photo of the prototype design showing the continuous positive airway pressure (CPAP) device attached to the tracheoesophageal voice prosthesis (TEVP) through a tracheal suction catheter. TEP: tracheoesophageal prosthesis.

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