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A Novel Voice Prosthesis after Total Laryngectomy with Laryngoplasty Reconstruction

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ABSTRACT

BACKGROUND: Although many patients achieve serviceable speech after total laryngectomy (TL), many are limited by un-naturally low pitch. We describe a cadaveric study to provide proof of concept for of a novel voice prosthesis after TL with free tissue laryngoplasty.

METHODS: Devices were implanted into fresh frozen cadavers after TL and free tissue laryngoplasty. Phonation pressures were measured using a custom Blom-Singer Manometer (InHealth Technologies, Carpinteria, CA) and acoustic files were analyzed using Praat, a speech analysis software.

RESULTS: Two fresh frozen cadavers were implanted with the voice prosthesis. Both prostheses demonstrated appropriate stenting of the laryngoplasty. Successful sound production was achieved after airflow generation at the proximal trachea. An average phonation pressure of 3.5cmH_2O (SD 1.7cmH_2O) was necessary to generate a sound intensity of 80.6dB (SD 0.2dB) at an average fundamental frequency of 299.5Hz (SD 112.6Hz).

CONCLUSIONS: The novel voice prosthesis described herein offers a feasible speech generation mechanism.

INTRODUCTION

Total laryngectomy (TL), the surgical removal of a patient's larynx, was first performed by Billroth in 1873.[1,2] However, this surgery carries significant functional and psychological morbidity associated with losing one's voice. Many techniques have been developed in an attempt to address these issues and provide post-laryngectomy voice restoration. The primary methods of voice restoration include esophageal speech, use of an electrolarynx, or tracheo-esophageal speech.[3,4] The current gold-standard, tracheo-esophageal speech, was initially introduced over half a century ago, but gained popularity after durable results were achieved through the use of a reliable tracheo-esophageal prosthesis (TEP).[5-8]

Despite the potential for alaryngeal patients to achieve adequate speech, the quality of this speech is highly variable and many patients do not become effective TEP users.[4,9] Reasons for poor voice outcomes after TEP placement are multifactorial, but include high phonation pressures, poor compliance with voice rehabilitation, and anatomic issues at the neo-pharyngeal conduit (ex. stricture, tone, mucosal quality, etc.). Phonation times, sound intensity, and fundamental frequency (F_0) are also all significantly lower in TEP speech compared to laryngeal speech.[9-11] A lack of universally accepted outcome metrics (patient reported or otherwise) for alaryngeal speech also makes direct comparison difficult. These patients generally suffer from un-naturally low fundamental frequency when compared to normal laryngeal speech,[12] which can lead to significant psychological distress, especially in female patients.[13,14] These results also vary significantly based on the extent of ablative and reconstructive surgeries as well as the prosthesis' reliance on the neo-pharyngeal mucosa vibrations for sound generation.[15] The quality of sound production from this mucosa is further affected by radiation treatment and pharyngeal reconstruction in this area that typically accompanies TLs. Previous attempts have been made at

introducing sound generating devices to address many of these issues.[14,16,17] Various systems including metal reeds, silicone lips, and membrane based devices have been described.[18-21] However, many of these recent attempts have been limited by their use of the tracheo-esophageal puncture site as a conduit for the sound generating mechanism. This small area limits the airflow across the sound generation source, heightens the impact of secretions on the prosthesis, and creates a close proximity to the neo-pharyngeal mucosa – vibrations of which can result in interference.[14,22]

Herein we propose an alternative voice restoration method for patients with TL. The Feng-Zenga-Varvares (FZV) prosthesis is a 3D printed device that acts as a conduit, resting within a laryngoplasty reconstruction after total laryngectomy.[23,24] This conduit can then serve as a housing system for a more robust sound generation source, circumventing issues that arise with placement of these devices in a tracheo-esophageal puncture site. This study aims to characterize the sound production, phonation pressure, and acoustic characteristics of the FZV that houses a single polycarbonate reed through a cadaveric study.

METHODS

Cadaveric Model and Ablation

This cadaveric study was given exempt status after review by the Massachusetts Eye and Ear Institutional Review Board. Two fresh frozen cadaver heads (with distal tracheas) and forearms were used for this study. TL and bilateral neck dissections were performed in each cadaver head with preservation of surrounding pharyngeal mucosa to allow for primary closure. The pharynx was entered in an infra-hyoid fashion to preserve the hyoid bone during the dissection (Figure 1A). This technique allows for suspension of a free-tissue laryngoplasty

reconstruction, as previously described by Hagen and Hackenberg.[23,24] The neo-pharynx is closed up to the inferior aspect of the hyoid. A fishmouth opening was left at the superior aspect of the neo-pharynx to allow for subsequent inset of the laryngoplasty reconstruction (Figure 1B).

Laryngoplasty Reconstruction

Free tissue laryngoplasties were created from cadaveric radial forearm free flaps. A modified design based on the description created by Hagen[23] was used. The distal aspect of the free flap was an 8cm long by 6cm rectangle. This base was made wider than the original laryngoplasty described by Hagen to accommodate the FZV prosthesis. A rectangular extension (5cm long by 4cm wide) was incorporated at the proximal end of the free flap to create a neo-epiglottic tab for the reconstruction (Figure 2A and 2B). The distal aspect of the flap was sewn circumferentially, while the proximal tab was sewn onto itself (Figure 2C). The proximal end of the flap was inset to the fishmouth opening of the ablative defect. The distal aspect of the flap is sewn over the laryngostoma opening, creating a conduit between the laryngoplasty and trachea, leaving an anterior opening for the horizontal limb of the prosthesis (Figure 2D).

Total Laryngectomy Voice Prosthesis

Initial prototypes were created using a Form 3 3D printer (Formlabs, Somerville, MA, USA). Injection molds were built using a photopolymer resin and injected with medical grade silicone rubber (QP1-240, Dow Corning, Midland, MI, USA) to create the final model (Figure 3A). The superior aspect of the implant has a beveled edge and a posterior turn to help prevent aspiration. The horizontal limb of the implant comes out of the laryngostoma to maintain the airway and allow placement of a speaking valve. A small portion of the vertical limb extends

into the tracheostoma to help prevent displacement of the prosthesis and create an appropriate seal for sound generation. The internal component of the design includes a vibrating polycarbonate single reed system that serves as the sound generation source, although this is easily replaceable. The reed vibrates once sufficient airflow is generated, creating a pressure differential over its surface. The pitch is governed by the length, thickness, and material properties of the reed. The reed also achieves dynamic changes in pitch (pitch bending) through alterations in airflow. This vibration system sits above the horizontal limb of the prosthesis in order to maintain airway patency. The prosthesis also stents the laryngoplasty flap open to prevent collapse or stenosis (Figure 3B). The design was created so that simple placement of the prosthesis that could be done in the clinic or at home, similar to a laryngectomy tube, allowing the patient to easily clean and maintain the device. This is made possible by a thinned posterior wall that allows the device to be easily bent in a Y-configuration during placement and removal. An in-vivo cross-sectional representation of the FZV prosthesis and reed system is shown in Figure 4.

Experimental Design

After the ablation and reconstruction of each cadaveric head, the FZV prosthesis was placed in the laryngoplasty. A Blom-Singer Manometer (InHealth Technologies, Carpinteria, CA, USA) was attached to the horizontal limb of the prosthesis to measure phonation pressures. A bag-valve was attached to an endotracheal tube (ETT). The ETT was placed in the distal trachea from below the cadaver. The cuff of the ETT was inflated and the bag-valve was squeezed to simulate patient breaths and phonation (Figure 3C and 3D). Tape was placed over the distal end of the prosthesis horizontal limb to simulate finger occlusion. An iPhone 10 was

placed 10cm above the oral cavity to record phonation attempts. Six trials were done for each cadaver. Each trial was done by squeezing the total volume of the bag-valve in a single attempt. One set of trials was done for two different cadaver positions: one with the jaw in repose and one with anterior jaw thrust. Each set of trials consisted of a bag-valve attempt with light exertion (the minimum effort required to create sound), medium exertion (subjectively between light and full exertion), and full exertion (forceful squeezing of the bag-valve). These trials were chosen to assess the full range of required phonation pressures and the pitch bending range for a given reed.

Spectral Analysis

Spectral analysis of individual voice recordings was done using Praat,[25,26] a free speech analysis software. The audio recording of each trial was analyzed to determine its intensity (dB) and F_0. The first (F_1) and second (F_2) formants of each trial were also recorded to ensure internal consistency and determine whether audio recordings resembled American English vowel sounds. All audio recordings were taken from a fixed distance (10 cm) directly above to the cadaveric oral cavity. Formant plots were used to demonstrate similarity to known historical values of F_1 and F_2 for various American English vowels.[27]

RESULTS

TL and free tissue laryngoplasty procedures were successfully performed in two fresh frozen cadaver heads. The FZV device was easily placed into and removed from the laryngoplasty conduit via the laryngostoma. With the prosthesis seated in the laryngoplasty conduit, normal saline was irrigated through the oral cavity with the cadaver in an upright

position. The fluid passed through the end of the distal esophagus without evidence of gross fluid leaking from the FZV prosthesis to the distal trachea or through the laryngostoma. The manometer was attached to the horizontal limb of the prosthesis during each cadaver trial. The bag valve system was successfully attached to each distal trachea to simulate the positive pressure generated during vocalization. This setup is shown in Figure 3.

During light exertion trials, an average phonation pressure of 3.5 cmH_2O (SD 1.7 cmH_2O) was recorded to generate an average sound intensity of 80.6 dB (SD 0.2 dB). There was slight variation based on cadaver position, with phonation pressures being lower with jaw thrust (mean, 2.0 Hz) compared to repose position (mean, 5.0 Hz). During medium exertion, an average phonation pressure of 14.8 cmH_2O (SD 4.1 cmH_2O) was recorded to generate an average sound intensity of 81.0 dB (SD 0.4 dB). During full exertion, an average phonation pressure of 35.0 cmH_2O (SD 4.8 cmH_2O) was necessary to generate an average sound intensity of 81.6 dB (SD 0.5 dB). These results are summarized in Table 1.

Notable differences were also seen for the F_0 during each trial. Lower values were shown for light exertion (mean 299.5 Hz; SD 112.6 Hz) compared to medium exertion (mean 339.7 Hz; 64.1 Hz) and full exertion (mean 405.9 Hz; SD 39.6 Hz). F_0 continued to increase as the exertion placed on the bag valve system (and therefore volumetric flow rate) increased. These results are summarized in Figure 5. There was also evidence of F_0 variation between cadaveric specimens despite a constant sound generation source. This was most notable at levels of low exertion, where the F_0 in cadaver 1 was 130.5 Hz while in repose compared to 356.1 Hz for cadaver 2 while in the same position. These variations were also seen – to a lesser degree – for medium exertion, where the F_0 was higher for cadaver 1 (mean, 392.9 Hz) compared to cadaver 2 (mean, 286.6 Hz).

The F_1 and F_2 values for every trial were also recorded in Table 1. By using historical data from Hillenbrand et al., F_1 and F_2 values for each trial were plotted against the formant chart for American English vowel sounds.[27] Despite the variance in F_0 and subsequent pitch generated by each cadaver, 4/4 (100%) of light exertion trials and ¾ (75%) of medium exertion trials fell within the α ("ah") vowel sound. The majority of full exertion trials (3/4, 75%) were out of the range of any vowel formant plots. These results are graphically depicted in Figure 6.

DISCUSSION

Despite its utility as a curative oncologic procedure and a rehabilitative strategy to regain swallowing in some patients, TLs carry significant associated morbidity. Reliance on alaryngeal speaking methods for communication (esophageal speech, electrolarynx, TEP) becomes a major functional hurdle for patients to overcome as poor voice outcomes result in significantly worse quality of life.[28,29] TEP use remains the current gold standard for post-laryngectomy voice, however it has several inherent shortcomings that prevent patients from achieving sound quality similar to their pre-morbid voice. Our study presents an alternative method of alaryngeal speech production. Here, we introduce a novel prosthesis as a conduit for independent sound generation. We believe that housing this device within a laryngoplasty reconstruction may offer advantages over other devices that place sound generation mechanisms within a controlled tracheo-esophageal fistula.

Free tissue laryngoplasty was described by Hagen as an alternative for voice restoration in the alaryngeal patient.[23] He used a free flap composed of superimposed rectangular skin paddles to create a conduit connecting the TL stoma to the neo-pharynx. One tab is tubed to create a conduit between the neo-pharynx and the laryngostoma, while the other is used to create

a neo-epiglottic tab. By leaving the hyoid bone in during the resection, this tab can articulate during deglutition to help prevent aspiration. Initial results demonstrated voice restoration at lower pressures and improved subjective voice quality. More recently, data for 39 patients in their series has shown voice restoration in 77% of patients.[24] Lower initiation pressures were present, resulting in a more natural voice with 61% voice intelligibility via telephone test compared to 44% for TEP users. 62% of patients were also able to phonate hands-free. However, 5% of patients did experience aspiration and voice restoration was more successful for patients not receiving adjuvant radiation (91%) compared to those who were irradiated (41%). In irradiated patients, failure occurred due to resulting stenosis of the laryngoplasty lumen and neo-epiglottic tab.

These drawbacks have limited the more widespread adoption of free flap laryngoplasty after TL. However, methods to further augment post-laryngoplasty voice, prevent post-radiation stenosis, or prevent aspiration have not been investigated or described. The FZV device is designed specifically for use in patients who have received a free flap laryngoplasty after TL. It houses a separate vibration mechanism that generates sound, as opposed to the vibration of the mucosa found in the neo-pharynx. This allows for lower phonation pressures and improved sound intensity. While various sound generating mechanisms (metal reeds, silicone lips, membrane based devices) have been described for alaryngeal speech, these have been limited to placement within a modified TEP. The size of this conduit creates many inherent limitations, including reduced airflow across the sound generation source, increased sensitivity to the impact of secretions on the prosthesis, and a close proximity to the neo-pharyngeal mucosa – vibrations of which can result in interference.[14,16,17,22] The size of the FZV allows for the implementation of a more robust sound generation source. Both the caliber of the sound generating source and

resulting separation from the neo-pharyngeal mucosa may help circumvent some of the issues associated with previously described sound generating TEPs. When tested with normal saline, fluid passed through the distal esophagus of the cadaver without evidence of a gross leak through the FZV prosthesis or distal trachea. While dynamic movement of the tongue and pharynx may affect potential aspiration, this suggests that the introduction of the FZV would not worsen the aspiration risk in a free tissue laryngoplasty reconstruction.

Previous studies have investigated phonation pressures for esophageal and tracheoesophageal speech in alaryngeal patients.[9,11] Takeshita et al.[9] analyzed twenty TL patients who primarily used TEP speech. Individuals categorized as good speakers had an average pressure amplitude of 34.67 cmH_2O, while individuals categorized as moderate speakers had an average amplitude of 49.50 cmH_2O and those categorized as poor speakers had an average amplitude of 55.01 cmH_2O. Furthermore, the majority of patients in this series were moderate (65%) or poor speakers (25%) while only two patients were categorized as being good TEP speakers (10%). These values are significantly higher than those obtained through a laryngoplasty reconstruction alone or with the FZV prosthesis adjunct. In an initial series of seven patients, Hagen[23] demonstrated phonation pressures varying between 10.20 – 20.39 cmH_2O for TL patients having undergone free tissue laryngoplasty. When the prosthesis is used in conjunction with the laryngoplasty reconstruction, we demonstrated an average phonation pressure of 3.5 cmH_2O with light exertion.

The FZV device also demonstrates an increase in sound intensity at lower phonation pressures. In our trials, the mean sound intensity for light exertion was 80.6 dB (range, 80.3 – 80.9 dB). Historical data suggests consistently lower sound intensity values for alaryngeal patients who use TEP speech. Multiple studies have investigated sound intensity levels for both

soft and loud voice attempts in these patients. Deschler et al.[30] demonstrated an average intensity of 57.7 dB for soft voice and 64.6 dB for loud voice across eleven patients. More recent studies have verified these values, with Schindler et al.[31] demonstrating an average sound intensity of 50.4 dB for soft voice and 67.9 dB for loud voice across twelve patients. In all of these instances, the sound intensity is lower than the intensity produced through the FZV prosthesis.

Pitch in these TEP patients is also consistently lower than those of typical human voice. With soft voice, F_0 for TEP speech was 82.0 Hz and 106.4 Hz in these respective studies. For loud voice it was 116.4 Hz and 124.2 Hz.[30,31] The typical F_0 for normal laryngeal speech varies by gender, but is higher in both males (range, 110 – 130 Hz) and females (range, 210 – 230 Hz).[32,33] While laryngeal male voices are somewhat similar to the pitch produced through TEP speech,[34] laryngeal female voices have a much higher F_0. This dissonance presents a significant issue for many patients and may disproportionately affect females. Our trials demonstrated an average F_0 of 243.0 Hz with light effort while in repose. There was also significant variation across light and medium exertion trials (mean, 319.6 Hz; SD, 87.5 Hz), whereas full exertion trials appeared to reach a plateau (mean, 405.9 Hz; SD, 39.6 Hz). This suggests that the acoustic chambers of the head and neck and their surrounding soft tissues may play an important role in the modification of sound. However, once a certain level of exertion (air flow) is reached, a plateau that mirrors the fundamental frequency of the vibrating reed will be heard. This also shows that the FZV is capable of achieving a higher F_0 that is required to approximate the female voice. However, the F_0 of the current reed mechanism is abnormally high and would have to be adjusted to prevent a harsh and un-natural neo-voice.

For light and medium levels of exertion, these sounds also closely resemble the acoustic characteristics of typical American English vowel sounds.[27] 100% of the trials at light exertion

and 75% of the trials at medium exertion created voice that closely resembles α vowel sounds ("ah"). Since the FZV device does not solely rely on the vibration of neo-pharyngeal mucosa to produce sound and instead houses a mechanical sound generator (single reed), tuning of the reed system will allow for variable acoustic characteristics tailored to individual needs.

Despite these potential advantages, several limitations exist with our current study. We demonstrated the initial feasibility of the FZV prosthesis in a human cadaveric model. Future animal models and in vivo testing will be needed to fully assess the FZV's impact on alaryngeal speech. Articulation of the lips, tongue, palate, and pharynx will all have a significant impact on sound production and perceived voice. Further characterization and tuning of the reed system will also be required to produce patient specific sound that can mimic pre-morbid voice. Both objective measures (ex. acoustic characteristics) and subjective measures (ex. patient reported outcomes) will be required to compare the utility of the FZV to the current standard of care for alaryngeal speech. Although variation in fundamental frequency across cadaver heads may have been from variation in the acoustic chamber and mucosal properties of the cadavers, interference through significant neo-pharyngeal vibrations may have occurred. This possibility along with the sequelae of a double F_0 requires further investigation. The F_0 achieved during our trials is also higher than the average female, producing a harsh neo-voice. Tailoring of the internal reed and incorporation of other sound generation mechanisms are necessary and will be done in future studies.

Furthermore, studies from Hagen and Hackenberg demonstrated safe use of the free tissue laryngoplasty reconstruction, however 5% of patients experienced some level of aspiration.[23,24] The contracture of the free tissue laryngoplasty due to radiation changes will also affect the fit and performance of the FZV device. The added bulk of the FZV device may result

in unintended issues with pooling of debris, granulation tissue development, or device irritation. The beveled edge at the superior limb of the device is intended to help divert some debris away from the conduit and the small aperture of the sound generation source may prevent larger debris from falling past the horizontal limb of the device. However, we do expect at least low levels of aspiration through the FZV device that may only be tolerated by select patients. Debris in this area would also impact the vibrating mechanism, which may require frequently cleaning and maintenance. The bulk of the FZV device may also create un-intended swallowing issues or serve as an irritant to some patients. Continued long-term follow-up of free tissue laryngoplasty patients is also required to assess any changes in aspiration risk over time. The addition of the FZV device will undoubtedly add another variable that may affect this risk. Testing with in vivo models will be required to fully assess the extent of these potential complications.

The combination of lowered phonation pressure and increased sound intensity may allow the FZV to provide a speech alternative in select alaryngeal patients. These factors could allow patients to better regulate their speech duration while enhancing sound intensity. Utilization of an internal reed mechanism provides proof of concept for the FZV as conduit to sound generation sources, however other mechanisms should could also be used in conjunction with the FZV (silicone lips, membrane based devices, electronic devices). Introduction of these mechanisms might allow patients to achieve fundamental frequencies that more closely approximate typical laryngeal speech. Further clinical studies are required to validate these assertions. The ease of placement of the FZV would allow patients who currently have laryngoplasty reconstructions to test the device safely in clinic settings.

CONCLUSION

The FZV prosthesis represents a feasible speech generation mechanism. Through augmentation of previously described free tissue laryngoplasty procedures, the FZV is capable of achieving lower phonation pressures and higher sound intensities when compared to typical TEP speech in a cadaveric model. Further investigation is required to determine the utility of this device in alaryngeal patients.

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LIST OF FIGURES AND TABLES

Measurement		Cadaver 1			Cadaver 2		
		Light Exertion	Medium Exertion	Full Exertion	Light Exertion	Medium Exertion	Full Exertion
Repose	Pressure (cmH_20)	6.0	20.0	42.0	4.0	16.0	34.0
	Intensity (dB)	80.4	81.5	81.8	80.9	80.6	80.9
	Frequencies (Hz)						
	Fundamental (F_0)	130.5	370.6	429.8	356.1	283.0	422.7
	First Formant (F_1)	906.4	856.1	1421.3	1037.4	940.9	1271.2
	Second Formant (F_2)	1528.0	1554.3	1859.3	1472.1	1466.3	1395.0
Jaw Thrust	Pressure (cmH_20)	2.0	11.0	32.0	2.0	12.0	32.0
	Intensity (dB)	80.7	80.9	81.7	80.3	80.9	81.9
	Frequencies (Hz)						
	Fundamental (F_0)	355.5	415.1	424.3	355.7	290.1	346.7
	First Formant (F_1)	971.6	920.8	1272.1	941.1	1032.5	1026.5
	Second Formant (F_2)	1399.2	1670.1	1927.6	1415.2	1347.4	1779.0

Table 1. Summary of phonation pressure, intensity and frequencies generated by cadaver specimens after total laryngectomy, free tissue laryngoplasty, and implantation of total laryngectomy voice prosthesis. Measurements are given for varying levels of exertion (light, medium, full) and cadaver positions (repose, jaw thrust).