

Voice Prosthesis Use in the First Two Years of Recovery  
Status Post Total Laryngectomy

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By

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## **Dedication**

This thesis is dedicated to my parents, Michael and Peggy Stroh, and my sister, Stephanie Stroh, for all of their support and unconditional love.

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## **Abstract**

Advanced laryngeal cancer requires laryngeal amputation (laryngectomy) (Graham, 1997). As a sequelae to laryngectomy, the surgeon redirects the trachea to the external neck, creating a tracheostoma. This serves as the path for respiration as there is no longer a connection between the trachea and the upper airway (Plante & Beeson, 1999). The laryngectomy deprives the patient of the power source (exhaled air) for speech and the vibrating source (vocal folds) for speech.

There are three forms of voice restoration following total laryngectomy: esophageal speech, speech with an artificial larynx, and tracheoesophageal (TE) speech, requiring use of a voice prosthesis (v.p.). TE speech is the focus of the present study.

Voice prostheses have evolved immensely since their introduction in 1980; therefore, clinicians face a multitude of decisions in managing speech rehabilitation. Questions arise regarding which v.p. design is “best” and what criteria should be considered when selecting v.p.s.

This study is a chart review of 11 patients with total laryngectomy and primary TEP who have been in recovery for two years (time frame, 2003-2005). The goal was to identify changes in selected v.p.s and reasons for such changes in the first and second years post-surgery.

The primary trend was that patients required progressively shorter v.p.s in the first year vs. negligible change in the second year. A second trend was that clinician-inserted v.p.s tended toward a relatively short useful life. A third trend was that more female laryngectomees were retained in the second year of recovery than males. A fourth trend

was the pervasive presence of candida colonization of v.p.s (a condition producing breakdown of the v.p. valve.

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## **Introduction**

The larynx is the part of the respiratory tract between the pharynx and the trachea, having walls of cartilage and muscle and containing the vocal cords enveloped in folds of mucous membrane (Blom, Singer, & Hamaker, 1998). It is important in phonation and protection of the airway, but due to its mucous membrane lining the larynx is susceptible to cancer. The exact site, extent, and type of primary tumor have a direct effect on the physician's treatment recommendation. When laryngeal cancer is advanced, the surgical procedure of choice is total laryngectomy (Graham, 1997). The first successful laryngectomy for cancer was done in 1873 and the process has immensely evolved and improved since then (Keith & Darley, 1986). With laryngeal amputation an incision is made in the neck and the entire laryngeal mechanism is removed, from the hyoid bone to the upper two to three rings of the trachea (See Appendix A). Structures that are removed include the hyoid bone; epiglottis; thyroid, cricoid, and arytenoids cartilages; upper two to three rings of the trachea; and surrounding musculature, including the strap muscles (Graham, 1997). The surgeon then redirects the trachea and sutures it to the area of the external neck that lies just above the notch of the sternum. This opening in the neck is called a stoma and it serves as the point of air exchange with the atmosphere as there is no longer a connection between the trachea and the pharynx, nose, and mouth (See Appendix B). The surgeon also sews the hypopharynx to the upper esophagus so that the passage of liquids and foods remains the same as before the surgery (See Appendix C).

Removal of the larynx by laryngectomy causes alterations in many important functions including respiratory, circulatory, fixative, protective, phonatory, olfactory, and

coughing (Salmon, 1999). The source of voice (or phonation) is produced by the vibration of the two vocal folds from within the larynx which are removed during a total laryngectomy. Due to the loss of the vocal mechanism an alternate form of communication must be learned by the laryngectomee. The three forms of voice restoration include esophageal speech, speech with an artificial larynx, and tracheoesophageal speech (See Appendix D). It is a hard decision to make as each method has its advantages and disadvantages and also there is no guarantee that one specific method will suit a patient's communication needs over time and across all speech contexts. Speech-language pathologists and otolaryngologists are responsible for providing patients information about their various communication options and allowing the laryngectomee to make choices based on personal desires and capabilities (Graham, 1997).

Historically, esophageal speech has been the voice restoration method of choice (Blom, Singer, & Hamaker, 1998). For esophageal speech the laryngectomee must learn to trap air in their mouth and project it into the esophagus. Once air is trapped in the esophagus, it is released, creating sound by vibration of the upper esophageal tissues. The sound then resonates within the oral and nasal cavities and is transformed into words by the articulatory movements of the teeth, tongue, and lips, as with normal speech (Plante & Beeson, 1999). Teaching patients to over-articulate slightly will help to open the vocal tract and improve the resonance of sound (Stemple, Glaze, & Klaben, 2000). The major advantage of esophageal speech is the cost aspect. This type of alaryneal speech does not require expensive devices and prostheses, yet does require months of voice therapy. Disappointingly, only a small percentage of laryngectomee patients are



able to acquire a level of esophageal speech that resembles pre-surgical communication parameters, despite months of therapy and practice (Blom, Singer, & Hamaker, 1998).

Historically, the development of artificial larynges dates back to 1859, but over the years two basic types have emerged, pneumatic and electronic (Salmon, 1999).

Although seldom used in the United States, the Memacon and Tokyo pneumatic artificial larynges are still available for purchase (Stemple, Glaze, & Klaben, 2000). Pneumatic artificial larynges contain a cuff that fits over the stoma with a flexible rubber or plastic tube attached. As the patient expels air for speech, the tube placed in the patient's mouth transmits the vibration from the cuff. The patient articulates as the sound is produced. Loudness variations occur as the air pressure levels change during breathing for speech. Length of the tube and its placement within the mouth will influence both ease of articulation and resonance (Keith & Darly, 1994). The main advantages of this device are that sound quality may be more pleasing than that of electronic devices, there is no electronic noise or buzzing sound with the pneumatic device, and that they are inexpensive, requiring no batteries or battery chargers. The major disadvantages of the pneumatic device are that the presence of the tube in the mouth may interfere with articulation and eventually collect moisture condensation or saliva within the tube, and it does require the use of one hand for the placement of the cuff over the stoma (Stemple, Glaze, & Klaben, 2000).

There are three types of electronic artificial larynges, neck-type devices, oral devices, and intraoral devices (Stemple, Glaze, & Klaben, 2000). The neck-type artificial larynges are hand-held vibrators that make a buzzing sound that substitute for vocal fold vibration. The device is placed on the neck so that sound travels through the tissues of

the neck into the vocal tract, producing a voice that is modified into speech by mouthing words (Plante & Beeson, 1999). Speech via a neck-type device has its advantages and disadvantages as well. The main advantages are that it is useful in advanced age, useful in poor physical or mental health, permits prompt and immediate speech, is easily learned, and does not interfere with other forms of alaryngeal speech the patient is trying to learn (Salmon, 1999). Some disadvantages include that it produces a mechanical sound, maintenance can be expensive, mechanical breakdown leaves the patient helpless, and it requires the use of one hand (Salmon, 1999). Also, the neck or cheek tissue must be malleable enough to allow transmission of the electronically induced vibrations into the hypopharynx and oral cavity. Following surgery, often the surface of the neck is too irregular to make a good seal with the head of the device (Graham, 1997).

Oral artificial larynges generate sound in a small battery operated transducer and then transfer it into the speaker's mouth via a tube placed 1 to 1 1/2 inches in the speaker's mouth on top of the tongue (Stemple, Glaze, & Klaben, 2000). The speaker must learn how to coordinate activation of the sound generator and speech simultaneously, while practicing the use of natural pauses and reducing the rate of speech to increase intelligibility. Controls within the vibrating mechanism allow variations in frequency and intensity. Disadvantages of this device (similar to pneumatic devices) are the oral tube's interference with articulation, the collection of saliva within the tube, and that it is dependent on batteries. Advantages of the oral device are that it can be used immediately following surgery to communicate, and that it can be used in patients with extreme scar tissue or edema, unlike the neck-type electrolarynx (Stemple, Glaze, & Klaben, 2000).

The last type of electronic artificial larynges is intraoral devices. The UltraVoice is an intraoral remote-control-device that can be custom-built into the top of an upper denture or orthodontic retainer. The basic unit (denture/retainer), worn in the mouth, is comprised of three components. The first of these is a loudspeaker covered by a silicone membrane to protect it from saliva, foods, and liquids. According to the manufacturer, the speech tone can be adjusted to that of a typical male or female voice, there by simulating a sound produced by a normal larynx (Keith & Darley, 1994). The second component is a miniature electronic circuit that allows the user to adjust the pitch and volume. The final component is two small batteries that are a power source for the loudspeaker and a control circuit for an average day of talk time. The remote-control operates from batteries, has a slide button that turns the UltraVoice on or off, and adjusts both pitch and volume. In addition, the UltraVoice includes a charging unit that simultaneously recharges batteries for both the basic unit and the remote-control. While this product is devoid of large external units, it is very expensive, costing approximately \$2,750 (Keith & Darley, 1994).

The third form of voice restoration is tracheoesophageal (TE) speech. In order for a patient to obtain TE speech, the surgeon must create a fistula or puncture for the placement of a small tube, voice prosthesis (v.p), into the tissue (often termed common wall) that divides the trachea from the esophagus. This tracheo-esophageal puncture (TEP) is created either at the time of the total laryngectomy (primary puncture) or at some subsequent time (secondary puncture). The voice prosthesis is a one-way air valve that shunts air from the trachea into the esophagus when the speaker occludes the tracheostoma. The shunted air vibrates the esophageal tissue in the same way as the

forced vibration in esophageal speech, resulting in voice (Plante & Beeson, 1999). Voice prostheses are not only important in the process of voice production, but as well they aid in maintaining the TEP and preventing food and liquid from passing from the esophagus into the trachea during swallowing (Salmon, 1999). Swallowing becomes a much greater risk given that inhalation of foods and liquids can contribute to the development of aspiration pneumonia, reduced lung volume, and a potential for a myriad of additional pulmonary problems (UNC, 2006).

Voice prosthesis development has immensely evolved over the past seventy-five years. The first tracheal shunt established in 1931, was not done by a doctor, but rather by a post-laryngectomy patient who pierced his own neck with a red hot ice pick and then used a goose quill to maintain the puncture. While this gentleman developed the “best” alaryngeal voice heard to date, problems of stenosis and infection overshadowed the benefit of this method (Singer, 1983). In the decades to follow many others proposed reconstructive methods to establish voice following total laryngectomy. These methods usually incorporated shunts or planned fistulae with which pulmonary airflow could be directed to the cervical esophagus or pharynx. Essentially all these methods failed over time because the reconstructive communication either became too patent, leading to aspiration, or the opposite, stenotic, resulting in excessive air-flow resistance and effortful phonation. Finally, in 1972 Taub devised a method that avoided these problems by introducing a valved prosthesis to support and protect a shunt. He developed the first commercially available v.p., the Voice Bak (Blom, Singer, & Hamaker, 1998). The device was not a huge success as it was expensive, awkward, and required regular maintenance (Singer, 1983). Not long after, in 1978, Blom and Singer pioneered the

method of tracheoesophageal puncture and valved silicone voice prosthesis that has become the international standard for voice restoration over the past 26 years, enabling thousands of patients worldwide to regain their ability to speak (InHealth Technologies ENT Product Catalog, 2005).

Following Blom and Singer's lead, numerous voice prostheses have been developed in the past two decades; therefore, speech-language pathologists and otolaryngologists face a multitude of decisions when assisting the laryngectomee. In order to maximize alaryngeal phonatory and speech efficiency, correct fitting of and appropriate training with the most well suited v.p. is critical. As well, choosing the appropriate v.p. can prevent isolation and depression for the post-laryngectomy patient (Lee, 2005). There are numerous factors that speech-language pathologists and otolaryngologists must consider when establishing TE speech in a patient: length of v.p, expense, diameter, type of retention collar, method of insertion, need for follow up care, risk of v.p. aspiration, and the patient's ability to care for the prosthesis. The wrong decision may lead to the laryngectomee not being able to communicate vocally. Choosing a prosthesis that is too short may result in closure, while one that is too long will result in leakage and aspiration. The wrong prosthesis may also pose more serious complications including pneumonia (due to chronic aspiration of fluids into the airway via the prosthesis), and airway compromise associated with the prosthesis occupying space in the tracheostoma or actually dislodging and falling into the trachea (Laccourreye, et al.,1997).

One very important factor speech-language pathologists and otolaryngologists must consider when choosing the appropriate v.p. for their patient, is who is responsible

for removing and replacing improperly functioning devices. Clinician-inserted and patient-inserted prostheses fulfill the same purposes: to keep the fistula open, to prevent food and liquid from passing from the esophagus into the trachea, and to act as a shunt through which exhaled air enters the esophagus and activates the sound-generating mechanism, usually the pharyngoesophageal (PE) junction (Salmon, 1999). Both types of voice prostheses are hollow silicone tubes, and are available in various lengths and diameters to securely fit into the TEP. Clinician and patient-inserted prostheses are both comprised of a retention collar, and a one-way valve. In addition, some include a neck strap which is located on the tracheal end of the v.p. and is used to secure the v.p. onto the neck. The retention collar snaps into place on the esophageal end of the fistula to prevent v.p. dislodgement and leakage (Graham, 1997). The one-way valve opens under positive tracheal pressure, diverting the air into the esophagus, and closes by elastic recoil (Stemple, Glaze, & Klaben, 2000).

Until 1995 all v.p.s required the patient or caregiver to insert, remove, and clean the device (Stemple, Glaze, & Klaben, 2000). However, the more recent development of clinician-inserted devices has greatly decreased the v.p. responsibility demands placed upon the patients. The clinician-inserted device was created for use by patients who do not want the responsibility of taking care of their own v.p. or those who are physically unable to do so. Clinician-inserted v.p.s have larger tracheal and esophageal retention collars; hence they require greater effort to remove or replace. The user is responsible for cleansing the device, which is done in situ (Blom, Singer, & Hamaker, 1998). Despite the fact that the clinician-inserted v.p.s are intended to last longer (6-12 months), they are also substantially more expensive than the patient-inserted devices. As of January 30,

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2006, InHealth's patient-inserted duckbill v.p. was the least expensive prosthesis, costing \$28.00 and their low-pressure v.p. was only \$45.00. By comparison, InHealth's clinician-inserted indwelling voice prosthesis was \$130.00 and their Advantage indwelling voice prosthesis was \$199.00 (InHealth Technologies patient price list, 2005). As of January 23, 2006, the Provox 2 voice prosthesis was \$199.00 (Atos Medical price list, 2005). As of 7/1/05, Medicare's reimbursement for all voice prostheses, regardless of actual cost, was \$88.09. Aetna's was \$78.69, United Health Care's reimbursement was \$136.00, and Medical Mutual's reimbursement was \$74.00 (Lee, 2005). As a result, while the patient-inserted devices are over compensated for, the cost of the clinician-inserted devices exceed the rate of reimbursement.

The duckbill, low- pressure, ultra-low resistance, and Provox NID v.p.s are four styles of patient-inserted devices (See Appendix E). The duckbill voice prosthesis is a 16 or 20Fr. silicone, one-way slit valve. It is slightly higher in resistance to airflow through it than the low-pressure style. This actually makes it the device of choice for a patient who experiences a problem with "inhaling" air through a low- pressure prosthesis during quite inhalation resulting in excessive stomach gas (Blom, 1996). It is available in nine sizes, ranging in lengths from 6mm to 28mm and custom order sizes and styles are available (Inhealth Technologies ENT Product Catalog, 2005).

The low-pressure voice prosthesis is the most frequently used Blom-Singer prosthesis (Blom, 1996). It is a silicone, one-way flapper valve prosthesis. It is available in two diameters, 16Fr. and 20Fr. This v.p. comes in a range of lengths from 6mm to 28mm and custom order sizes and styles are available (Inhealth Technologies ENT Product Catalog, 2005). The low-pressure has a recessed valve and a low profile tip

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making it more difficult to insert into the fistula. To make insertion of the low-pressure v.p. easier the Blom-Singer Gel Gap Insertion System has been created (Stemple, Glaze, & Klaben, 2000).

The Bivona ultra-low resistance voice prostheses were available in seven varying lengths ranging from 1.4cm to 3.0cm, and in two diameters of 16 and 20Fr. This particular device contains a thinner retention collar and can be inserted and removed easier. This is beneficial to patients with a sensitive TEF (Stemple, Glaze, & Klaben, 2000). In late 2004 Bivona ceased manufacture of all v.p.s.

Finally, the Provox NID is available in six varying lengths ranging from 6mm to 18mm, and in two diameters of 17 and 20Fr (Atos Medical Catalog, 2005). The Provox NID is a patient inserted device with all the quality features of a clinician inserted device. This v.p. is attached to a strong polypropylene cord with a safety medallion that is too wide to fall into the tracheostoma, has a low airflow resistance, and has tools available that make in-situ cleaning possible (Atos Medical Catalog, 2005).

InHealth's Indwelling voice prosthesis, InHealth's Advantage Indwelling, Atos's Provox II, the Provox ActiValve, the Panje voice button, and the Voice Master are six examples of clinician inserted devices. (See Appendix F). The Indwelling voice prosthesis has enhanced retention collar dimensions, i.e., larger and thicker which secure it without the need for a neck strap and tape. This device is ideal for patients who are unable or unwilling to routinely remove, clean, and reinsert regular style voice prosthesis. The patient cleans it in situ without removal (Blom, 1996). Indwelling voice prostheses are silicon one-way valves and are available in two diameters, 16 and 20Fr. The 16Fr. device comes in 8 lengths ranging from 4mm to 18mm while the 20Fr. device is available



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in 8 lengths ranging from 6mm to 25mm. Patients may also order custom lengths if needed (InHealth Technologies ENT Product Catalog, 2005).

The Blom-Singer Indwelling Advantage is a device that contains silver oxide in the silicone flap valve in order to prevent candida colonization. This device includes an easy-fold esophageal retention flange and flange introducer, a brush and flush cleaning system with built-in safety features, and taper-tip gel cap insertion. It is available in two diameters: 16Fr. and 20Fr. It is available in a range of 10 lengths from 4mm to 22mm (InHealth Product Catalog, 2005).

The Provox II is another clinician-inserted device that was introduced in 1997. This second generation indwelling silicone device has many valuable features: low airflow resistance, easy maintenance, safe placement, detectable in x-ray, and high success rate. It is available in only one diameter, 21Fr, and comes in six standard sizes ranging from 4.5mm to 15mm (Atos Medical Catalog, 2005).

The Provox ActiValve is designed for patients who have experienced short device lifetime with the Provox 2 caused by leakage due to candida growth or leakage due to unintended valve opening during swallowing or deep inhalation. The valve flap and valve seat of the Provox ActiValve are made of a candida resistant material to prevent excessive candida overgrowth. To prevent unintentional opening, the valve and valve-seat of this device contain magnets which are available in three opening forces: Light, Strong, and XtraStrong. All three opening forces are available in a range of five lengths from 4.5mm to 12.5mm. The manufacture suggests that the Provox ActiValve be considered following 5 consecutive short durations (4 to 8 weeks) of use with the Provox 2. As well, they stress that this device is not intended for primary or secondary insertion

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at the time of surgery (Atos Product Catalog, 2005). The largest drawback of the Provox ActiValve is that it is very expensive, \$1600 (Atos Medical Pricelist, 2005).

The Panje Voice Button is an indwelling, 14Fr, biflanged silicone one way valve. It comes in three different lengths short (6mm), regular (9mm), and long (12mm). It is manufactured in both standard and low pressure styles (Hood Labs, 2005). The Panje Voice Button has numerous factors, including a small inner diameter and multiple valve slits, which qualify it as one of the higher resistance voice prostheses. (Blom, Singer, & Hamaker, 1998).

Finally, the VoiceMaster is an indwelling voice prosthesis that comes in 3 lengths, 6mm, 8mm, and 10mm. Rather than the conventional flap valve the VoiceMaster has a ball valve system that reduces airflow resistance by over 30% when measured against conventional flap devices (Hood Labs, 2005). This reduced resistance device has a delicate titanium sleeve that reinforces the lumen, providing an open pathway for air flow (see Table 1 for a complete breakdown of v.p.s. in the present study).

While the development of tracheoesophageal speech and voice prostheses has improved significantly over the past few decades, there are still numerous prospective complications. Complication in this instance can be viewed as anything that prevents, delays, or interferes with voice restoration via tracheoesophageal speech (Lee, 2005). These complications can be broken down into two subcategories, patient-related issues (Leder, et al., 1995), and prosthesis-related issues (Mäkitie, et al., 2003). Patient-related issues involve self care issues and prosthesis-related physical issues (Leder, et al., 1995), such as pharyngeoesophageal spasm, radiation-induced fibrosis, pneumonia, emphysema, recurrent cancer, excessive stomach gas, and dysphagia.

Self-Care issues involve removing, cleaning, and reinserting the v.p., and these issues are usually addressed when the patient has his/her initial visit with a speech-language pathologist. Visualization of the puncture site and access to the posterior tracheal wall are mandatory for successful v.p. replacement. The removal of the prosthesis is typically accomplished by firmly grasping the v.p. and pulling forward. Immediately following removal the patient or clinician should insert a catheter or tracheoesophageal puncture dilator to prevent aspiration and stenosis. Once the v.p. is cleaned or replaced according to the manufacturers standards it can be (re)inserted (Stemple, Glaze, & Klaben, 2000). It is very helpful for the SLP to direct the patient during the initial insertion learning process and physically guide his movements. Upon independent insertion, the patient can either sit or stand in front of a good mirror with a good light source directed into the stoma. When working in front of a mirror, movements are perceived in reverse. The patient needs to adjust to this visual perspective in order to successfully reinsert the v.p. (Blom, Singer, & Hamaker, 1998).

Another patient-related issue is incomplete stoma closure. This occurs when the patient does not completely occlude the tracheostoma with a finger or thumb, resulting in an air leak. The patient is encouraged to experiment in front of a mirror to determine which finger, and at what position result in optimum occlusion of the tracheostoma. The stoma may alternatively be occluded by a tracheostoma valve. Most tracheostoma valves have a housing collar that is taped and glued around the stoma. Alternately, the Barton-Mayo Tracheostoma button is an adhesive free valve (Graham, 1997). A valve is inserted into the housing collar and when the patient develops sufficient pulmonary air pressure to

produce speech, the valve will close. Valve closure occludes the stoma and air passes into the esophagus via the v.p. (Stemple, Glaze, & Klaben, 2000).

Quite the opposite of the patient being unable to completely occlude the stoma, the laryngectomy may also occlude the stoma too tightly. Too much pressure on the stoma may push the prosthesis deep into the posterior esophageal wall causing airflow to be restricted and sound quality to be altered or airflow may become completely blocked, cutting off sound completely (Salmon, 1999).

Elevated tonicity of the pharyngoesophageal (PE) segment after total laryngectomy is another patient-related issue resulting in the failure to acquire TE speech. When there is excessive tension in the PE segment (e.g., hypertonicity or spasm), the air entering the esophagus is unable to overcome the muscular resistance to vibrate the PE segment. A relaxed hypopharynx, PE musculature, and upper esophagus are prerequisites for easy passage of air through the region. An insufflation test is a reliable test method for determining the functionality of the PE segment for TE speech (Graham, 1997). Techniques for management of PE spasm include secondary and primary pharyngeal constrictor muscle myotomy, pharyngeal neurectomy, and Botulinum neurotoxin injections. Botulinum neurotoxin (Botox) injections eliminate muscle spasms, thus allowing the PE segment to vibrate. A myotomy involves cutting muscle fibers of the pharyngeal constrictors to prevent spasms when voicing and a pharyngeal neurectomy resections all branches in the nerve plexus to eliminate hypertonicity (Stemple, Glaze, & Klaben, 2000). The patient may also choose to do nothing, because PE spasm is not a health hazard, or they can have the TEF resized to accommodate a

larger diameter v.p. (Lee, 2005). The higher volume of airflow may assist the patient in managing the spasm (Stemple, Glaze, & Klaben, 2000).

Another physical issue that affects the patient's ability to produce voice is radiation induced fibrosis. Radiation may be used prior to total laryngectomy to shrink the lesion and following surgery radiation may be used to destroy any cancerous cells that are not detected and removed at the time of surgery. Patients obtain the best results with postoperative radiation therapy if treatments begin within 6 weeks following surgery and end within 100 days after surgery (Stemple, Glaze, & Klaben, 2000).

Prosthesis-related issues break down into three categories, leakage through the v.p, leakage around the v.p.(Mäkitie, et al., 2003), and issues relating to the length of the prosthesis (too long or too short). Prior to deciding what the cause of the leakage is, it is very important that the speech-language pathologist illuminate the stoma with a bright light and observe the v.p. in situ as the patient drinks to confirm that leakage is in fact through the prosthesis rather than around the prosthesis. Leakage through the valve of a v.p. results from one of several possible causes. If the leakage occurs immediately upon routine assessment of a newly inserted v.p. it can be attributed to either a valve that is defective, one that has been distorted into the open position, or occasionally a small piece of the gel cap used during insertion is lodged between the flap valve and its seating ring. If these latter problems are suspected the prosthesis should be removed and its valve mechanism should be inspected for competence of closure and debris. Other causes of leakage through prostheses include the end of the valve's natural life span, and microbial colonization (candida colonization) of the valve (Blom, Singer, & Hamaker, 1998). The candida organism deteriorates the silicone in the v.p. valve and is commonly found in

head and neck cancer patients, particularly those who have been treated with radiation or chemotherapy (Blom, 1995).

On the other hand, leakage around the tracheoesophageal voice prosthesis results when the puncture dilates or when the tissues fail to naturally tighten around the shaft of the prosthesis. When a prosthesis is too long for the puncture it moves back and forth within the tract and this unyielding motion results in mechanical dilation. If this occurs the TE puncture should be re-measured and an appropriate shorter v.p. inserted. The placement of the shorter v.p. will allow the tract to tighten and within approximately 24 hours the leakage will subside. A puncture that leaks despite an appropriately fitting v.p. requires further medical evaluation. Factors that may be causing leakage include: radiation, uncontrolled diabetes, significant nutritional imbalance, and recurrent cancer (Blom, 1997).

While there are many factors to consider in speech rehabilitation using TE speech and voice prostheses, the focus of the present study is on the voice prosthesis itself, specifically on alterations or trends occurring within the first two years of recovery. A group of 11 patients who were available for two years of recovery post total laryngectomy were analyzed in this study. There are seven particular questions this study will evaluate:

- 1) How frequently is it necessary to alter v.p. dimensions and why?
- 2) How many patients switch from a patient-inserted v.p. to a clinician inserted v.p. and vice versa in the first and second years of recovery?
- 3) Are there gender-related differences in the pattern of speech rehabilitation in the first and second years of recovery?

- 4) Do clinician-inserted v.p.s really last longer than patient-inserted v.p.s?
- 5) How long do these v.p.s. last before they wear out?
- 6) Are there factors in patient speech rehabilitation more commonly found following radiation?
- 7) Does the patient eventually become more independent of the clinician regarding care and use of the v.p.? If so, when does the shift toward independence occur?

Past studies have addressed some of these issues, but they have primarily focused on one or two types of v.p.s or only one manufacturer. Akbas and Dursun focused on the Low Pressure Blom Singer Voice Prosthesis (Akbas & Dursan, 2003) and Laccourreye, et al. focused only on the Provox clinician-inserted v.p (Laccourreye, et al., 1997). However, the present study focuses on six different types of v.p.s from three different manufacturers in both the first and second years of recovery and addresses these issues in hopes of identifying trends that may be beneficial in the clinical decision making process.

## **Materials and Methods**

### **Data Collection Procedure**

The present study was a retrospective chart review of patients with total laryngectomy and TEP treated at the Arthur G. James Cancer Hospital and Richard Solove Research Institute at the Ohio State University. Twenty-nine patients were analyzed in regard to their first year of recovery following total laryngectomy and TEP in a prior research study completed by Ashley Lee. Lee analyzed changes in selected v.p.s and reasons for such changes in the first year post-surgery (Lee, 2005). The present study expanded that research into its second year of recovery. Only 11 of the 29 patients

were available for follow-up through the second year of recovery. Data collection focused on patients who had their surgery not earlier than January, 2003 and who had completed 24 months of recovery by the end of 2005. Information was gathered from their voice therapy and physician notes and compiled into an Excel spreadsheet. The data consisted of gender, age, date of laryngectomy, related surgeries including flap reconstruction, pre or post-operation radiation treatment (if applicable), date of voice therapy session, type and manufacturer of v.p., length of v.p., diameter of v.p., the patient's ability to care for the v.p., reason for altering the v.p., competency in tracheoesophageal speech (functional TE speech refers to the ability to produce understandable sentence-length adult utterances), related health conditions, related health treatment, insurance, physician, and speech-language pathologist. The goal is to identify changes in voice prosthesis selection and reasons for such changes in the first and second years post-surgery, thus identifying trends that may be beneficial in the clinical decision making process.

### **Participants**

The data collected consists of 6 men and 5 women with an age range from 41 years, 2 months to 81 years, 6 months at the time of surgery. There are two pathways post surgery. The more common was that immediately after surgery a catheter is put in place, with the result that the fistula remains open until a v.p. can be fitted and inserted. Voice prosthesis length was determined during the initial speech therapy session using a v.p. sizing device, a hollow silicone tube used to measure the width of the common wall between the trachea and the esophagus. Incremental millimeter markings correspond to a range of v.p. lengths ((Inhealth Technologies ENT Product Catalog, 2005). Ten of the



patients were fitted with a v.p. between 21 and 279 days following total laryngectomy. In the second pathway the surgeon inserted a voice prosthesis in one patient at the time of the laryngectomy. The advantages of primary placement are elimination of the need to dilate and fit the prosthesis postoperatively and reduction of the likelihood of accidental catheter dislodgement. The disadvantage is that when edema subsides the v.p. may be too long and require replacement only after a few weeks (Blom, Singer, & Hamaker, 1998). The earliest initial speech therapy session took place 21 days after total laryngectomy, and the latest was at 279 days, with a mean period of 66 days and a median of 31 days.

As stated earlier, all 11 of these patients had their total laryngectomy and TEP treated at the Arthur G. James Cancer Hospital and Richard Solove Research Institute at the Ohio State University. The James is a tertiary care hospital and is one of the few freestanding cancer research and treatment hospitals in the United States, and the only one in Ohio (Arthur G. James, 2005). Tertiary care hospitals provide specialized consultative care, usually on referral from primary or secondary medical care personnel, by specialists working in a center that has personnel and facilities for special investigation and treatment (Johns Hopkins, 2005). As a tertiary care center, the patients treated at the Arthur G. James Cancer Hospital may not be typical of other hospitals; many of the patients treated here have been referred from other hospitals due to their inability to serve the patient. As a result, many patients may elect to return to their local resources for follow-up care.

## **Tracheoesophageal Prostheses**

The two main types of voice prosthesis, clinician-inserted and patient-inserted, were used. These two different types of prostheses fulfill the same purpose: to keep the fistula open, to prevent food and liquid from passing from the esophagus into the trachea, and to act as a shunt through which exhaled air enters the esophagus and activates the sound-generating mechanism, usually the pharyngoesophageal (PE) junction (Salmon, 1999). While the patient inserted device can be removed, cleaned, and replaced by the patient, the clinician inserted device must remain in place until a problem arises. Then, the patient must see a clinician to remove and replace the voice prosthesis (Stemple, Glaze, & Klaben, 2000).

For this sample three main types of patient-inserted voice prosthesis were used: duckbill, low- pressure, and ultra-low resistance. The low-pressure voice prostheses is the most frequently used Blom-Singer prosthesis (Blom, 1996) and thus proved true in this review as well. The Bivona ultra-low resistance voice prostheses were used by patients in this study, but in late 2004 Bivona ceased manufacture of all v.p.s.

For the patients in this sample there were two main types of clinician-inserted voice prostheses used: Inhealth's Indwelling voice prosthesis and Atos's Provox 2. The Blom-Singer Indwelling Advantage was also used, but only by one patient.

## **Results**

### **Participants**

The present study was a retrospective chart review of 29 patients with total laryngectomy and TEP who had completed one or two year(s) of recovery. These

patients had first year data collected on them in a prior research study completed by Ashley Lee.

Of the original 29 patients from Lee's study, only 11 had completed two years of recovery with chart notes accessible at this institution. Two laryngectomees had TEP closure and another transferred care just prior to 24 months (range 21-23 months) but they were retained, as their experience basically reflected two years of recovery. The other 18 patients were lost for follow-up within the second year of recovery for various reasons: 4 transferred care closer to home, 3 had TEP closure earlier in the second year, 4 ceased returning to the clinic, 4 had a recurring disease, and 3 expired. Of the 11 remaining patients 5 were female and only 6 were male with an age range from 41 years, 2 months to 81 years, 6 months at the time of total laryngectomy. The mean age of the males was 56 years with a range from 41 years, 11 months to 81 years, 6 months, and the mean age of the women was 60 years with a range of 51 years, 1 month to 73 years, 3 months (See Table 2).

### **Prosthesis Lifetime**

Of the 11 patients who were available for review during 2 years of recovery, 5 of them required v.p. resizing in the second year of recovery. Four patients required replacement prostheses which were shorter. Two of the patients required shorter prostheses because their current v.p.s were leaking and upon the SLP measuring the tract length it was evident that a shorter prosthesis was needed (after 299 and 82 days of use). Another prosthesis was replaced with a shorter one because the patient reported that the v.p. became dislodged (after 124 days of use), and one wore out (after 82 days of use). Three of the 4 patients who required a shorter prosthesis in the first year of recovery

retained the same type of v.p., 2 were using low-pressure devices and 1 was using an InHealth Indwelling. The fourth patient switched from a low-pressure v.p. to a InHealth duckbill v.p. The final patient who experienced v.p. resizing in the second year of recovery required a replacement prosthesis that was longer (after 203 days) and 6 patients' prostheses remained the same length from the end of the first year of recovery to the end of the second year.

In these same patients' first year of recovery all 11 of them required v.p. resizing. Nine of them required replacement prostheses which were shorter and 2 patients required v.p.s that were longer. Six of the nine patients who required a shorter v.p. needed a replacement within 12-49 days following initial placement. Another needed a shorter v.p. after 98 days, another after 208 days (due to aspiration of liquids) and the last patient required a shorter v.p. after 235 days. The longer v.p.s were needed post re-puncture and post pharyngeoesophageal myotomy. In both the first and second year of recovery there is a trend for the replacement v.p.s to be shorter. Also, it is evident that in the second year of recovery the need for resizing decreases.

At the beginning of the second year of recovery, the average v.p. length was 9.64 mm. The range was 8 mm to 14 mm, the mode was 8 mm, and the standard deviation was 1.96 mm. At the end of the second year, the average v.p. length was 9.09 mm. The range was 6 mm to 14 mm, their way a three-way tie for the mode at 6, 8, and 10 mm, and the standard deviation was 2.88 mm (See Table 3). The averages from start to the end of the second year differ by only .55mm; therefore, as the recovery process progresses there is a general trend for the length of v.p.s to remain stable.

## Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

Seven of the 11 patients' prostheses were 16 Fr. in diameter at the beginning of the second year, and only 4 of the 11 patients' prosthesis were 20 Fr. (Inhealth) or 21 Fr. (Atos) at the beginning of the second year. However, 7 of the 11 patients were using a 20 or 21 Fr. v.p. at the end of the second year, and 4 patients were using a 16 Fr. v.p.s. at the end of the second year. Upon initial fitting 10 of these patients' prostheses were 16 Fr. in diameter and only one of them had a prostheses that was 20 Fr. in diameter. In conclusion, the trend for selection of wider prosthesis diameter (as noted over the first year of recovery) continued into the second year of recovery (See Table 4)

Of these 11 patients, 1 patient required re-puncture, and TEP closure was evident in another patient just prior to 24 months. The one re-puncture occurred near the end of the first year of recovery and it is unknown why TEP closure occurred in this patient. This patient was using a clinician-inserted v.p. both prior to and following re-puncture. As well, this patient was able to obtain at least functional TE speech following re-TEP.

The one patient with TEP closure just prior to completion of the second year of recovery was able to obtain phrase length TE speech at some point in the first two years of recovery. TEP closure occurred because the patient reported his clinician-inserted v.p.s fell out. Following TEP closure this patient opted to use an electrolarynx to obtain alaryngeal speech.

A total of 23 v.p.s were removed and/or replaced in the 11 patients available for two years of follow-up. Sixteen of these v.p.s were removed and replaced because the v.p had worn out. Of the 16 that had worn out, 7 had been colonized with candida (average lifetime 112.86 days), 5 were due for a routine change (average lifetime 58.6 days), and 4 were leaking (average lifetime 170.75 days). Three v.p.s were replaced by

## Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

the speech-language pathologist (SLP) because, per patient report, 2 of the old v.p.s fell out (average lifetime 24 days), and one was too short (lifetime 138 days). The final 4 v.p.s were replaced by the SLP because the patient either desired to replace a patient-inserted v.p. with a clinician-inserted v.p. (lifetime 40 days), needed a device with less resistance to airflow (switched from an InHealth duckbill to an InHealth low-pressure) (lifetime 14 days), or needed a more robust retention collar (2 v.p.s with an average lifetime of 7 days).

Six of the 11 patients retained patient-inserted devices throughout their second year of recovery while 3 retained clinician-inserted devices. One patient switched from a patient-inserted device to a clinician inserted device and the last patient started his second year of recovery using a patient-inserted device, switched to a clinician-inserted device, and then finally switched back to a patient-inserted device.

Eighteen of the 23 v.p.s removed (10 low-pressure, 6 clinician-inserted (Indwelling), & 2 duckbill) were InHealth prostheses. Four were Biovana ULR prostheses, and the remaining one was an Atos Provox 2 prosthesis. The average lifetime of the patient-inserted InHealth low-pressure was 97.8 days, of the clinician-inserted InHealth Indwelling was 94.6 days, of the patient-inserted Biovana ULR was 39.25 days, and of the patient-inserted InHealth duckbill was 29 days. The Provox 2 v.p. had a lifetime of 72 days.

In this same patient population 56 v.p.s were removed/or replaced in their first year of recovery. Sixteen of these v.p.s were removed and replaced because the v.p. had worn out. Of the sixteen that had worn out, 11 had been colonized with candida (average lifetime 95.18 days), 4 were leaking (average lifetime 93.33 days), and one was due for a

## Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

routine change (lifetime 60 days). Eleven v.p.s were replaced by the SLP because the old v.p was too long (average lifetime of 49.45 years). Six v.p.s were replaced because the patient improperly inserted or cared for them (average lifetime 7.75 days).

Seven of the 11 patients retained patient-inserted devices throughout their first year of recovery, while the single patient who had a clinician-inserted device placed at the time of laryngectomy selected to use a patient-inserted device when the Provox v.p. required replacement. Also in the first year, two patients switched from a patient-inserted device to a clinician-inserted device, and one patient started his first year of recovery using a patient-inserted device, switched to a clinician-inserted device, and then finally switched back to a patient-inserted device. The last patient began the first year with a clinician-inserted device, then switched to a patient-inserted device, and finally ended the first year with a clinician-inserted v.p.

Forty of the 56 v.p.s removed (28 low-pressure, 6 clinician-inserted (Indwelling), & 6 duckbill) were InHealth prostheses. Fourteen (13 ultra-low resistance & 1 duckbill) were Biovana prostheses, and the remaining two were Atos Provox 2 prostheses. The average lifetime of the patient-inserted InHealth low- pressure was 57.8 days, of the InHealth patient-inserted duckbill was 99.3 days, and of the clinician-inserted InHealth Indwelling was 107.9 days. The average lifetime of the patient-inserted ULR was 56.7 days, of the Atos Provox 2 was 125 days, and the one Biovana duckbill v.p. had a lifetime of 21 days.

In summary, this group consisted of patients who were available for review during their first two years of recovery. During the first year of recovery this sample contained 48 patient-inserted v.p.s and 8 clinician-inserted v.p.s. The average number of

## Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

days between fittings of the clinician-inserted devices was 112.88 days. The range was 23 to 315 days, the median was 100 days, and the standard deviation was 94.04 days.

The average number of days between fittings of the patient-inserted devices was 67.95 days. The range was 2 to 253 days, the median was 42 days, and the standard deviation was 63.72 days (see Table 5).

In the second year of recovery this sample contained 16 patient-inserted and 7 clinician-inserted v.p.s. The average number of days between fittings of the clinician-inserted devices was 96.14 days. The range was 42 to 131 days, the median was 90 days, and the standard deviation was 33.32 days. The average number of days between fittings of the patient-inserted devices was 73.75 days. The range was 7 to 299 days, the median was 51.5 days, and the standard deviation was 66.48 days (See Table 5). This indicates a relatively short life of the clinician-inserted v.p.s (even shorter than in the first year of recovery).

At initial fitting, 10 of the 11 patients used a patient-inserted device, and only one patient used a clinician-inserted device. However, while most patients continued to use patient-inserted devices there was a trend for patients to switch to clinician-inserted devices. Three of the total 11 were using clinician-inserted devices at the end of the first year. This trend continues in the second year of recovery. At the end of the second year 4 patients were using clinician-inserted devices and 7 continued to use patient-inserted devices (See table 6), but during the first year of recovery there was switching back and forth between the two types of v.p.s.

Eleven (20%) of the total 56 v.p.s were removed in the first year of recovery because of candida colonization, including 6 InHealth prosthesis (2 low pressure, 3



duckbill, 1 clinician inserted (Indwelling)), 3 Biovana ultra-low resistance prosthesis, and 2 Atos clinician-inserted v.p.s (Provox 2). Two of 28 InHealth low-pressure v.p.s (5.4%) 1 of 6 InHealth clinician-inserted (Indwelling) v.p. (17%), 3 of 13 Biovana ULR (18%), and 2 of 2 Atos clinician-inserted devices (Provox 2) (100%) appeared colonized by *Candida Albicans* (see Table 10).

Seven (30%) of the total 23 v.p.s were removed in the second year of recovery because of candida colonization, including 6 InHealth prostheses (4 low-pressure, 2 clinician inserted (Indwelling)), and 1 Atos clinician-inserted v.p. (Provox 2). Four of 10 InHealth low- pressure v.p.s (40%), 2 of 6 InHealth clinician-inserted (Indwelling) v.p.s (33%), and 1 of 1 Atos clinician-inserted devices (Provox 2) (100%) were colonized by *Candida Albicans* (see Table 10).

### **Discussion**

The present study was performed to gain a better understanding of how frequently v.p. dimensions are altered in the first and second years of recovery post total laryngectomy, how many patients switch from a patient-inserted v.p. to a clinician-inserted v.p. and vice versa in the first and second years of recovery, whether there are gender-related differences in speech rehabilitation in the first and second years of recovery, whether clinician-inserted v.p.s really last longer than patient-inserted v.p.s, how long their v.p.s. last before they wear out, whether there are factors in patient speech rehabilitation more commonly found following radiation, and when patient's become more independent of the clinician regarding care and use of v.p. and if so, when does this shift occur.

**How frequently is it necessary to alter v.p. dimensions and why?** Of the 11 patients who were available for review during their first 2 years of recovery, 5 of them required v.p. resizing in the second year of recovery. Four patients required replacement prostheses which were shorter. Two of the patient's required shorter prostheses because their current v.p.s were leaking and upon the SLP measuring the tract length it was evident that a shorter prosthesis was needed (after 299 and 82 days of use). Another prosthesis was replaced with a shorter one because the patient reported that the v.p. became dislodged (after 124 days of use), and one wore out (after 82 days of use). Three of the 4 patients who required a shorter prosthesis in the first year of recovery retained the same type of v.p.s, 2 were using low-pressure and 1 was using an InHealth Indwelling. The fourth patient switched from a low-pressure v.p. to a duckbill v.p. The final patient who experienced v.p. resizing in the second year of recovery required a replacement prosthesis that was longer (after 203 days of use) and 6 patients' prostheses remained the same length from the end of the first year of recovery to the end of the second year.

In these same patients' first year of recovery all 11 of them required v.p. resizing. Nine of them required replacement prostheses which were shorter and 2 patients required v.p.s that were longer. Six of the nine patients who required a shorter v.p. needed a replacement within 12-49 days following initial placement. Another needed a shorter v.p. after 98 days, another after 208 days (due to aspiration of liquids) and the last one required a shorter v.p. after 235 days. The longer v.p.s were needed post re-puncture and post pharyngeoesophageal myotomy.

In both the first and second years of recovery there is a trend for the replacement v.p.s to be shorter, but in the second year the need for replacement and resizing is much less. At initial fitting, the start of the second year of recovery, and at the end of the second year of recovery the average v.p.s length was 16.18 mm, 9.64 mm, and 9.09 mm, respectively. As well, in the first year of recovery these patients had a total of 56 v.p.s replaced, in the same 11 patients second year of recovery, only 23 v.p.s were replaced. Therefore, it is evident that in the second year of recovery the need for resizing and replacement drastically decreases.

Seven of the 11 patients' prostheses were 16 Fr. in diameter at the beginning of the second year, and only 4 of the 11 patients' prosthesis were 20 Fr. (Inhealth) or 21 Fr. (Atos) at the beginning of the second year. However, 7 of the 11 patients were using a 20 or 21 Fr. v.p. at the end of the second year, and 4 patients were using a 16 Fr. v.p.s. at the end of the second year. Upon initial fitting 10 of these patients' prostheses were 16 Fr. in diameter and only one of them had a prostheses that was 20 Fr. in diameter. In conclusion, the trend for diameter of the prostheses to increase (as noted over the first year of recovery) continues into the second year of recovery (See Table 4)

**How many patients switch from a patient-inserted v.p. to a clinician-inserted v.p. and vice versa in the first and second years of recovery?** At initial fitting, 10 of the 11 patients available for 2 years of recovery used a patient-inserted device, and only one patient used a clinician-inserted device. However, while most patients continued to use patient-inserted devices there was a slight increase in the number of patients using clinician-inserted devices. Three of the total 11 were using clinician-inserted devices at the end of the first year. This pattern continues in the second year of recovery. At the

end of the second year 4 patients were using clinician-inserted devices and 7 continued to use patient-inserted devices (See table 6).

**Are there gender-related differences in the pattern of speech rehabilitation in the first and second years of recovery?** A progressive reduction of length was evident in both males and females over the first two years of recovery. The average v.p. length at initial fitting, 12 months, and 24 months for women was 16 mm, 9.2 mm, and 8 mm respectively (see Table 7). Similarly, the average length of v.p. at initial fitting, 12 months, and 24 months for men was 16.3 mm, 11.3 mm, and 10 mm respectively (see Table 8).

The number of speech therapy sessions differed very little in the first year of recovery as a function of patient gender. The 11 male and female patients that were available for two years of follow-up were both seen by the SLP more often in the first year of recovery than in the second year. There were a total of 5 females consisting of 37 first year visits and 6 males consisting of 45 visits. This amounts to approximately 7.4 visits per female and 7.5 visits per male. In the second year of recovery the number of voice therapy sessions was reduced; 4.4 visits per female and 3 visits per male.

Of the total 20 male patients who were available for first year follow up, only 6 (30%) were available for second year follow-up; whereas 5 of the 9 (56%) females were available for second year follow-up. Four males were lost to follow-up due to recurring disease, 3 expired, 3 ceased returning to the clinic, 2 had TEP closure, and 2 others transferred care. In comparison 2 women were lost to follow-up due to transferred care, 1 ceased returning to the clinic, and 1 had TEP closure. These numbers suggest that

females are generally healthier than males and quite possibly are more concerned about their health as well.

There was little gender-related difference in age at the time of surgery. The mean age of females and males available for two years of recovery was 60 years and 56 years, respectively (See Table 2).

**Do clinician-inserted v.p.s really last longer than patient-inserted v.p.s?** As noted previously, clinician-inserted v.p.s were created in hopes of solving self-care issues. They have larger tracheal and esophageal retention collars; hence they require greater effort to remove or replace (Blom, Singer, & Hamaker, 1998). Despite the fact that the clinician-inserted v.p.s are intended to last longer (6-12 months), they are also substantially more expensive than the patient-inserted devices (Inhealth Technologies patient price list, 2005).

Unfortunately, the clinician-inserted devices proved to have a shorter than expected lifetime in the present study. In the first year of recovery the sample of 11 patients contained 48 patient-inserted and 8 clinician-inserted v.p.s. The average number of days between fittings of the clinician-inserted devices was 112.88 days. The range was 23 to 315 days, the median was 100 days, and the standard deviation was 94.04 days. The average number of days between fittings of the patient-inserted devices was 67.95 days. The range was 2 to 253 days, the median was 42 days, and the standard deviation was 63.72 days (see Table 5).

In the second year of recovery this sample contained 16 patient-inserted and 7 clinician-inserted v.p.s. The average number of days between fittings of the clinician-inserted devices was 96.14 days. The range was 42 to 131 days, the median was 90 days,

and the standard deviation was 33.32 days. The average number of days between fittings of the patient-inserted devices was 73.75 days. The range was 7 to 299 days, the median was 51.5 days, and the standard deviation was 66.48 days (See Table 5). These data reveal the relatively short life of the clinician-inserted v.p.s. While the average lifetime of patient-inserted devices increased in the second year of recovery by 5.8 days, the average lifetime of clinician-inserted devices actually decreased by 16.74 days.

However, durability and lifetime are not the only reasons why people choose to use clinician-inserted devices. A clinician-inserted device is generally selected due to self-care issues. The patient may not be able to remove, clean, and replace their prosthesis due to poor eyesight, poor fine motor skills, hospitalization because of pneumonia or recurrent cancer, and so forth.

There are also reasons for not selecting a clinician-inserted device. One reason is due to the expense of these devices. Due to the longer purported lifetime of these devices, they are also more expensive. As of January 30, 2006, InHealth's patient-inserted duckbill v.p. was the least expensive prosthesis, costing \$28.00, and their low-pressure v.p. was only \$45.00. By comparison, InHealth's clinician-inserted indwelling voice prosthesis was \$130.00 and their Advantage indwelling voice prosthesis was \$199.00 (InHealth Technologies patient price list, 2005). As of January 23, 2006, the Provox 2 voice prosthesis was \$199.00 (Atos Medical price list, 2005). As of 7/1/05, Medicare's reimbursement for all voice prostheses, regardless of actual cost, was \$88.09. Aetna's was \$78.69, United Health Care's reimbursement was \$136.00, and Medical Mutual's reimbursement was \$74.00 (Lee, 2005). As a result, while the patient-inserted

devices are over compensated for, the cost of the clinician-inserted devices exceed the rate of reimbursement.

**How long do these v.p.s last before they wear out?** A total of 23 v.p.s were removed and/or replaced in the 11 patients available for two years of follow-up. Sixteen of these v.p.s were removed and replaced because the v.p had worn out. Of the 16 that had worn out, 7 had been colonized with candida (average lifetime 112.86 days), 5 were due for a routine change (average lifetime 58.6 days), and 4 were leaking (average lifetime 170.75 days).

In this same patient population 56 v.p.s were removed/or replaced in their first year of recovery. Sixteen of these v.p.s were removed and replaced because the v.p. had worn out. Of the sixteen that had worn out, 11 had been colonized with candida (average lifetime 95.18 days), 4 were leaking (average lifetime 93.33 days), and one was due for a routine change (lifetime 60 days).

**Are there factors in patient speech rehabilitation more commonly found following radiation?** Another trend was the persistent presence of candida colonization of voice prostheses. In the past, studies recognized a link between candida colonization and radiation therapy. Ten of the 11 patients who were tracked underwent radiation therapy. Six of these patients exhibited candida on their v.p.s in the first year of recovery and 4 did not. The final patient did not have radiation treatment but did exhibit candida on his v.p.s. (see Table 9). Five of the seven patients who exhibited candida colonization on their v.p.s in the first year, also did so in the second year. Hence, 4 patients who underwent radiation therapy exhibited candida colonization in their second year of

recovery, and six did not. The final patient did not have radiation treatment but did exhibit candida on his v.p.s. (see Table 9).

As mentioned earlier, only 2 of the 7 patients who exhibited candida colonization on their v.p.s in the first year did not in the second year. Rather, if radiation therapy really is the cause of candida colonization on their v.p.s it is still manifesting itself well into the end of the second year of recovery. These data and the fact that numerous patients not receiving radiation show evidence of candida colonization on their v.p.s runs counter to the expectations of some that candida colonization tends to be a complication of radiation therapy.

Patients who exhibited candida colonization on their v.p.s, or experienced premature valve breakdown, were typically given a prescription for Nystatin oral suspension. One teaspoon of Nystatin twice a day should be swished in the mouth for at least three minutes or longer and then either swallowed or expectorated. It is purported to significantly decrease yeast concentrations with subsequent reduction of yeast colonization of the v.p. (Blom, 1995). One drawback of the study's methodology is that patient compliance in Nystatin use was not measured. Additionally the charts were not always clear on the timing of the prescription for Nystatin. Quite possibly Nystatin would be more beneficial if prescribed prior to radiation therapy or six or so months before surgery. This marks the first limitation to this study, and is a topic of recommendation for future research.

In addition, it is important to note that persistence of candida colonization makes people come into the office to be seen by the SLP because their v.p. is leaking and they need a new one. Therefore, the SLP would naturally see more patients who exhibit



candida colonization on their v.p.s. It would be beneficial to know about the additional patients who are no longer seen at OSU. In this study there were 6 patients who transferred care and the 4 patients who ceased follow-up in their second year of recovery. Hence, there is a need to track patients more closely. In order for a study such as this one, with such a limited number of patients, to provide more concrete results we need to track those patients no longer receiving services at the Ohio State University. This marks the second major limitation to the study.

As well, the chart review did not reveal what the patients are doing on their own time, and in their own homes in regards to v.p.s care. It would be very insightful and helpful to give the patients a diary to keep regarding prosthesis care. Many of these patients receive a 12-24 month prescription for ordering v.p.s. It is possible that some patients were “lost to follow up” merely because they did not require speech therapy services during the second year of recovery; therefore, their charts did not contain entries. This marks a third limitation to this study. A longer time frame would resolve this ambiguity.

**Does the patient eventually become more independent of the clinician regarding care and use of their v.p.? If so when does the shift occur?** As noted earlier, these patients were seen by the SLP much less in their second year of recovery than in their first. The 11 male and female patients that were available for two years of follow-up were both seen by the SLP more often in the first year of recovery than in the second year. There were a total of 5 females consisting of 37 first year visits and 6 males consisting of 45 visits. This amounts to approximately 7.4 visits per female and 7.5 visits per male. In the second year of recovery their number of voice therapy sessions was

reduced; 4.4 visits per females and 3 visits per male. This reduction in visits demonstrated the decline of care related issues in the second year of recovery (at least a decline of issues that patient's cannot handle on their own). As well it was noted that the number of v.p.s used in the second year of recovery by the 11 patients available for 2 years of follow up was substantially lower than those used in the first year of recovery. While 56 v.p.s were used in the first year, less than half that amount was used in the second year of recovery, 23 v.p.s. This is another indication that patient-care related issues are beginning to subside in the second year of recovery.

### **Conclusion**

Today, speech-language pathologists and otolaryngologists face a multitude of decisions when assisting the laryngectomee. In order to maximize alaryngeal phonatory and speech efficiency, correct fitting of and appropriate training with the most well suited v.p. is critical. The correct fitting is also crucial in preventing feelings of depression or isolation for the post-laryngectomy patient. Four trends that are beneficial in the clinical decision making process were identified in the present review. These trends are that the appropriate v.p. length is highly likely to change (get shorter) in the first year of recovery, while there is less change in the second year; clinician-inserted devices are not lasting their purported length, even in the second year; more female laryngectomees are available for review in the second year of recovery than males; and a pervasive presence of candida colonization of v.p.s was evident in both the first and second years of recovery. All four trends involve factors considered in the decision making and treatment processes.

The primary trend in this study was the change in v.p. length in the first year vs. the almost absent change in length in the second year. While all 11 laryngectomees needed a v.p. size change in the first year of recovery, only 5 required change in the second year. Further, in both years the trend was for the new v.p. to be shorter, 9 of the 11 patients in the first year of recovery, and 4 of the 5 patients in the second year of recovery required shorter v.p.s. The average length of their v.p.s at initial fitting, start of the second year, and end of the second year was 16.18 mm, 9.64mm, and 9.09 mm, respectively. As well, while 56 v.p.s were removed and replaced in the first year of recovery, there were only 23 removed and replaced in the second year. This is evidence that the appropriate v.p. length is highly likely to change (get shorter) in the first year of recovery; therefore, careful monitoring of the patient for this change is necessary. This need for careful monitoring for v.p. fit, is less in the second year. As well, it is evident that despite the v.p., breakdown occurs frequently in the first year of recovery; therefore, it seems most logical to select the less expensive patient-inserted device to reduce the overall costs. As noted previously clinician-inserted devices are expensive and exceed the rate of insurance coverage. There are other costs that go along with these devices that we do not know about; costs such as those for emergency room visits if the catheter falls out (prior to fitting the patient with a v.p.), or if the device is aspirated or lost.

However, durability and lifetime are not the only reasons why people choose to use clinician-inserted devices. A clinician-inserted device is generally selected due to self-care issues. The patient may not be able to remove, clean, and replace their prosthesis due to poor eye sight, poor fine motor skills, hospitalization because of

pneumonia or recurrent cancer, and so forth. Cost, therefore, is only one detail factored into the decision making process.

The second trend was that clinician-inserted devices are not lasting their purported length, even into the second year of recovery. Given the cost difference between the patient-inserted (Low Pressure \$45) and the clinician-inserted (Provox 2 \$199) devices, and the relatively small difference in useful life, there was no cost benefit based on extended v.p. life in the use of the more expensive clinician-inserted devices. This conclusion is especially true in the second year of recovery. Actually, in the second year of recovery the average lifetime of the clinician-inserted devices actually decreased while the patient-inserted devices lifetime increased. As mentioned previously, there were a total of 56 v.p.s removed and replaced in the first year of recovery of the 11 patients available for 2 years of follow-up. Of the 56 v.p.s., there were 8 clinician-inserted devices and 48 patient-inserted devices. The average number of days between fittings of the clinician-inserted v.p.s was 112.88 days, and the median was 100 days. The average number of days between fittings of the patient-inserted v.p.s was 67.95 days, and the median was 42 days (See Table 5). On average the clinician-inserted v.p.s were only in place 44.93 days longer than the patient-inserted v.p.s.

In the second year the gap narrows. There were a total of 23 v.p.s removed and replaced in the second year of recovery. Of the 23 v.p.s., there were 7 clinician-inserted devices and 16 patient-inserted devices. The average number of days between fittings of the clinician-inserted v.p.s was 96.14 days, and the median was 90 days. The average number of days between fittings of the patient-inserted v.p.s was 73.75 days, and the

median was 51.5 days (See Table 5). On average the clinician-inserted v.p.s were only in place 22.39 days longer than the patient-inserted v.p.s.

The third trend in the present study was that more female laryngectomees are available for review in the second year of recovery than males. As noted earlier, of the total 20 male patients that were available for first year follow up, only 6 (30%) were available for second year follow-up; whereas 5 of the 9 (56%) females were available for second year follow-up. Four males were lost to follow-up due to reoccurring disease, 3 died, 3 ceased returning to the clinic, 2 had TEP closure, and 2 others transferred care. In comparison 2 women were lost to follow-up due to transferred care, 1 ceased returning to the clinic, and 1 had TEP closure. These numbers suggest that females are generally healthier than males and quite possibly are more concerned about their health as well. This is critical in the clinical decision making process as quite possibly speech-language pathologists and otolaryngologists need to keep a closer watch over male patients and counsel them more regarding health-care related issues.

The fourth and final trend in the present study was a pervasive presence of candida colonization of v.p.s in both the first and second years of recovery. In the past studies have documented that it is common for patients who undergo radiation therapy to colonize candida albicans on their v.p.s. In the present study, 10 of the 11 patients available for 2 years of recovery underwent radiation therapy either before or after their total laryngectomy. Candida was present in only 6 (60%) of these patients, as well as in the one patient who did not receive radiation treatment. Five of the 7 patients that had candida colonization of their v.p.s in the first year of recovery also did so in the second

year (See Table 9). However, only 4 (40%) patients who underwent radiation therapy also displayed candida colonization on their v.p.s, while 6 did not.

Over their first two years of recovery these 11 patients had 79 v.p.s removed and replaced. Six of the 15 (40%) clinician-inserted devices and 12 of the 64 (19%) patient-inserted devices were removed and replaced due to the valve leaking or breaking down, typically associated with candida colonization (See Table 10b). Given the cost of the clinician-inserted devices and the existence of candida colonization, clinicians should give serious consideration to use of Nystatin prior to radiation therapy or six or so months before surgery, rather than waiting for premature breakdown of the valve.

The introduction of TE voice and speech restoration following total laryngectomy has provided an alternative to esophageal and artificial larynx speech. It has provided the TE speaker with a renewed capacity to produce speech with pulmonary air. Although the concept is quite simple, the process continues to evolve. While numerous changes are evident: changes in cancer treatment, and changes in technology allowing new valve designs, the greatest changes are within the patients themselves. Life is greatly altered by those who undergo a total laryngectomy and each laryngectomee possesses patient-specific issues that challenge the clinician in successful management of patient speech rehabilitation. This review has made it quite clear that trends and patterns do exist among patients, but at the same time clinicians and otolaryngologists face the difficult task of considering each individual's patient-related factors. This review found that in the first year frequent modification of v.p.s was prevalent in nearly all patients, whereas in the second year such change was less frequent. This is confirmation that in the first year of recovery speech-language pathologists and otolaryngologists should see the patient on a

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frequent, routine basis to ensure a successful and positive start to years of communication via TE speech.

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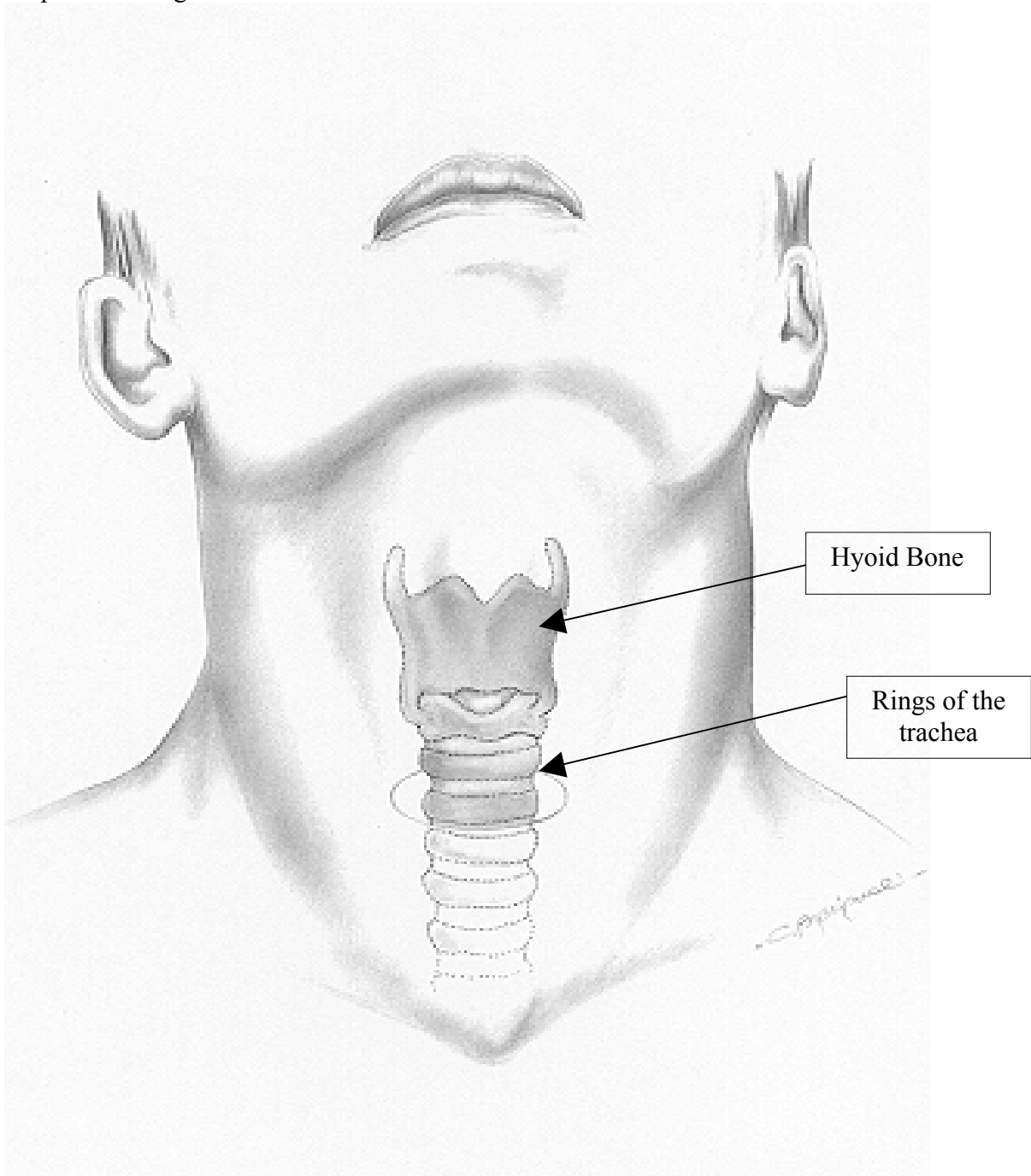
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Appendix A

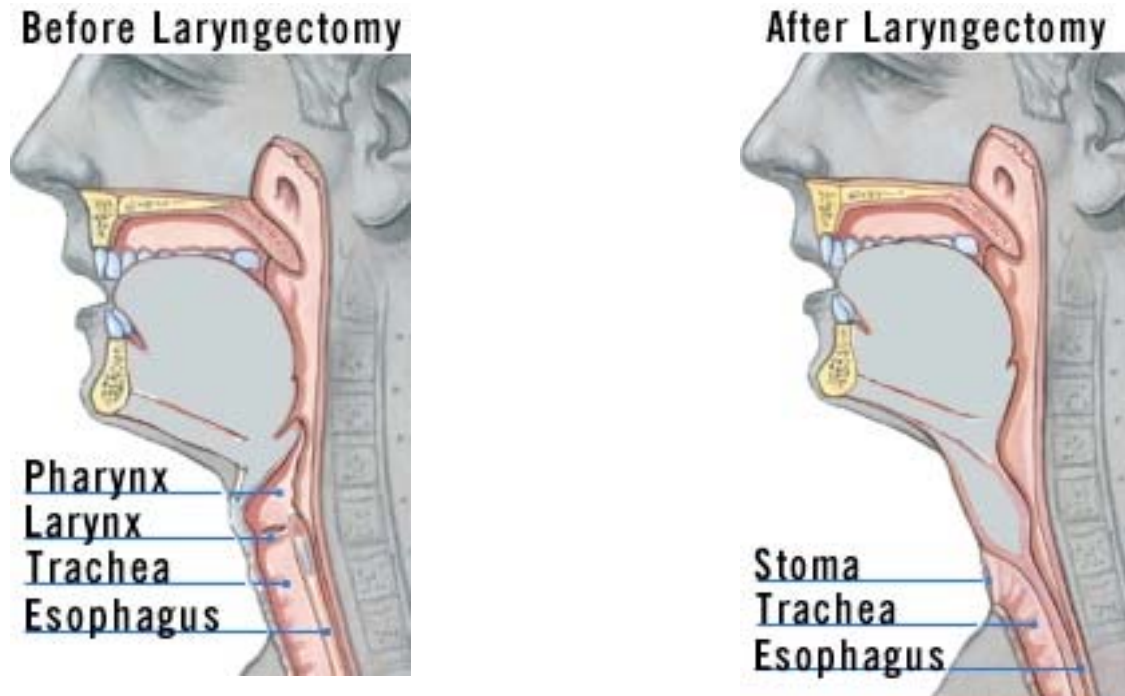
Figure 1. Laryngeal Mechanism (entirely removed during total laryngectomy)

<http://www.origin8.nl/medical/2voice.htm>



Appendix B

Figure 2. Anatomy Before and After Total Laryngectomy  
www.inhealth.com



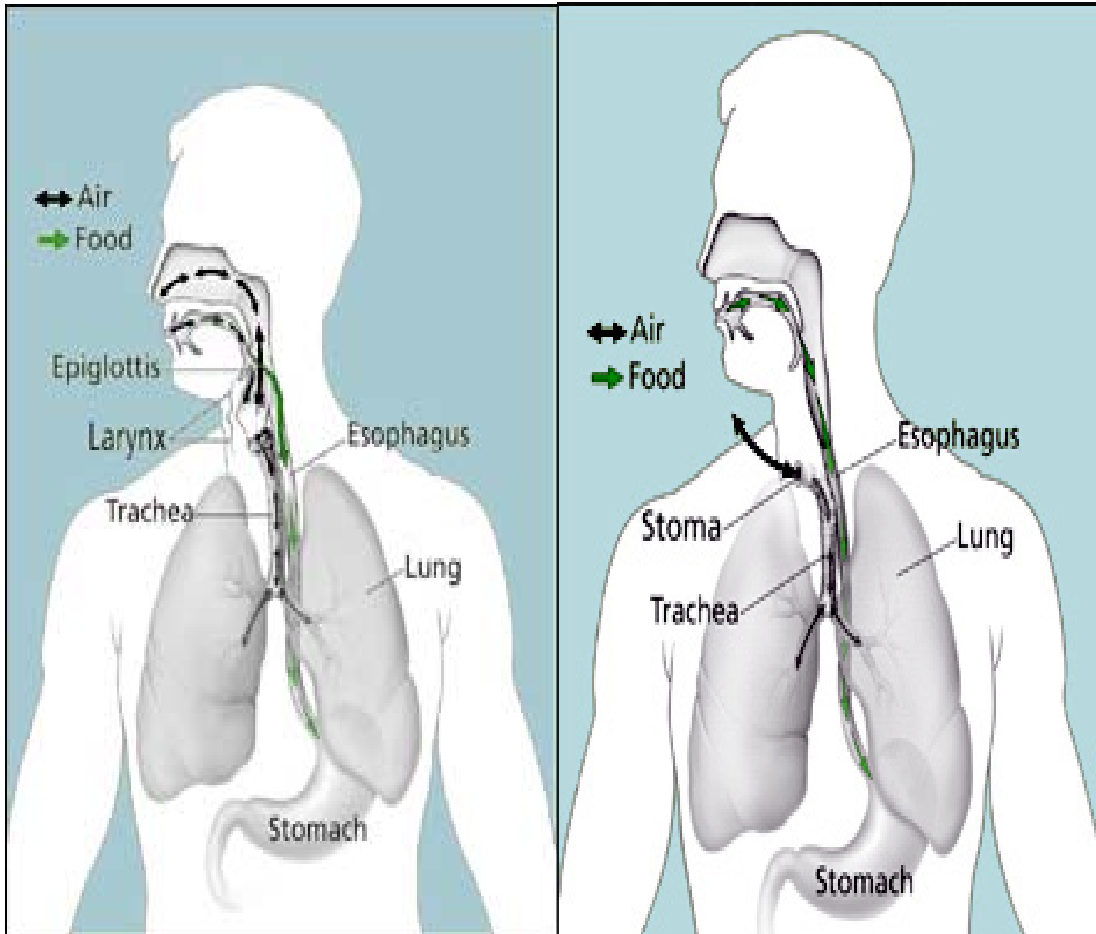
Appendix C

Figure 3: Pathways for Air and Food Before and After a Total Laryngectomy

<http://www.drowings-becker.yourmd.com/ypol/common/commonPrinterFriendly.asp?cid=ZZZZJ5HE38C>

**BEFORE LARYNGECTOMY**

**AFTER LARYNGECTOMY**

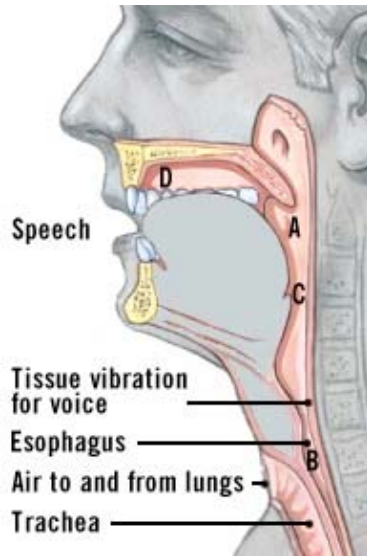


Appendix D

Figure 4. Three forms of voice restoration

<http://www.inhealth.com/educationalresourcmethods.htm>

1) Esophageal Speech

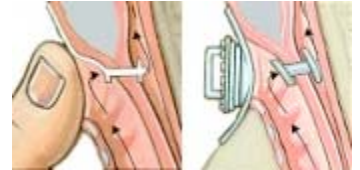


2) Speech via an Artificial Larynx

2a) Pneumatic Artificial Larynx  
<http://www.communicativemedical.com>



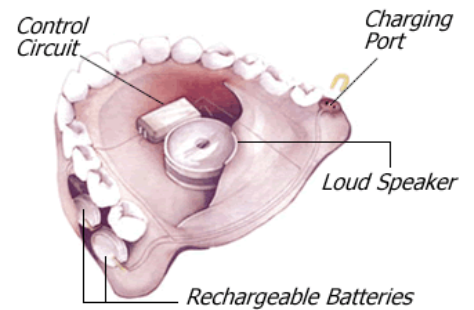
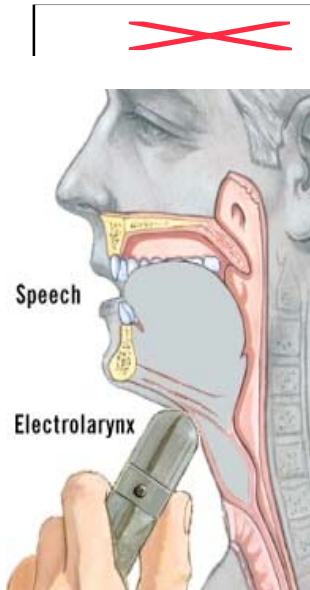
3) Tracheoesophageal (TE) Speech



2b) Electronic Artificial Larynges

Oral Device  
[http://www.luminaud.com/artificial\\_larynges.htm](http://www.luminaud.com/artificial_larynges.htm)

Intraoral Device  
<http://www.ultravoice.com/how.htm>



Appendix E

Figure 5a. InHealth Patient-Inserted Voice Protheses

[www.inhealth.com](http://www.inhealth.com)

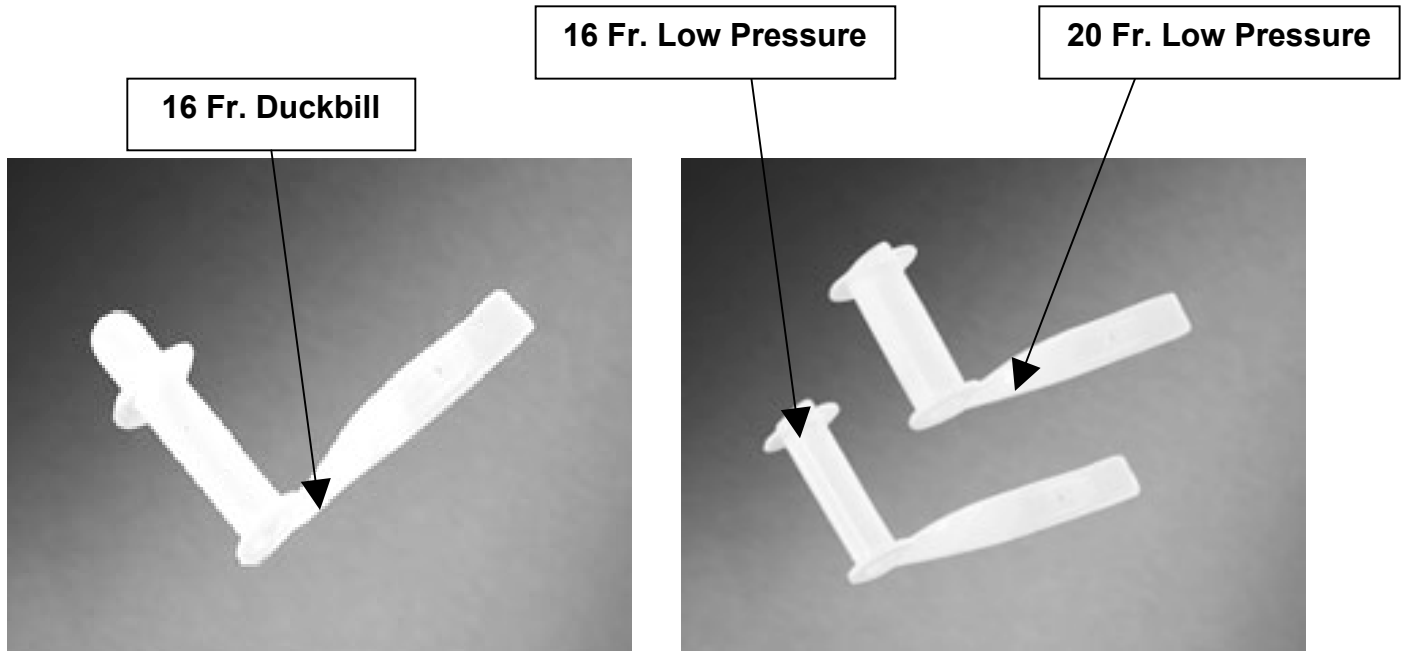
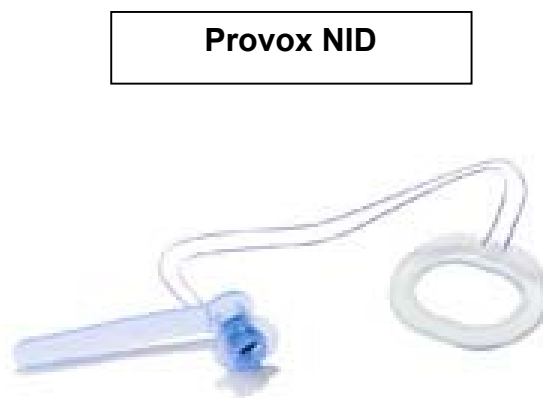


Figure 5b. Atos Provox NID Voice Prosthesis

[www.atosmedical.com](http://www.atosmedical.com)





Appendix F

Figure 6a. Atos Clinician-Inserted Voice Protheses

[www.atosmedical.com](http://www.atosmedical.com)

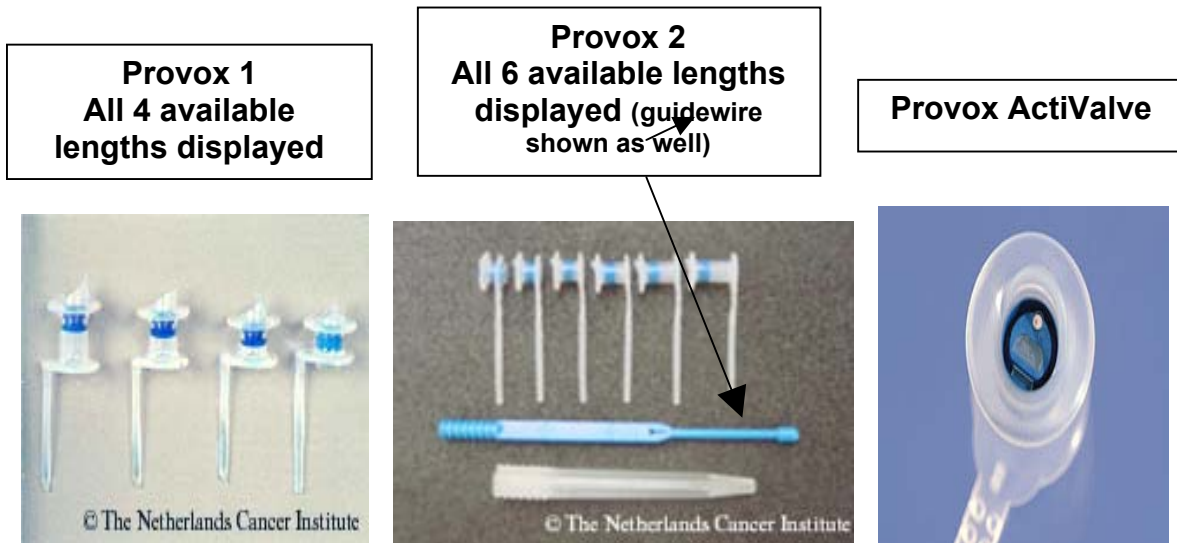


Figure 6b. InHealth Clinician-Inserted Voice Protheses

[www.inhealth.com](http://www.inhealth.com)

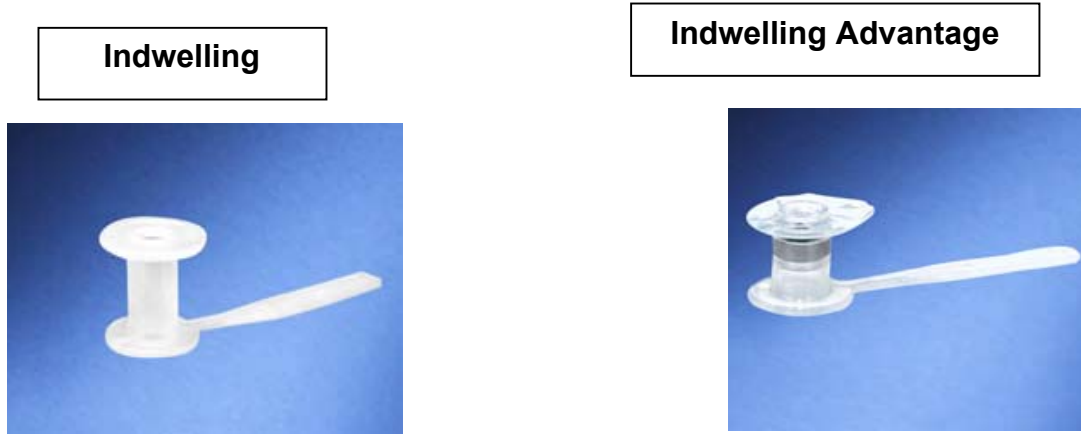


Figure 6c. Hood Labs Clinician-Inserted Voice Protheses

<http://www.hoodlabs.com>

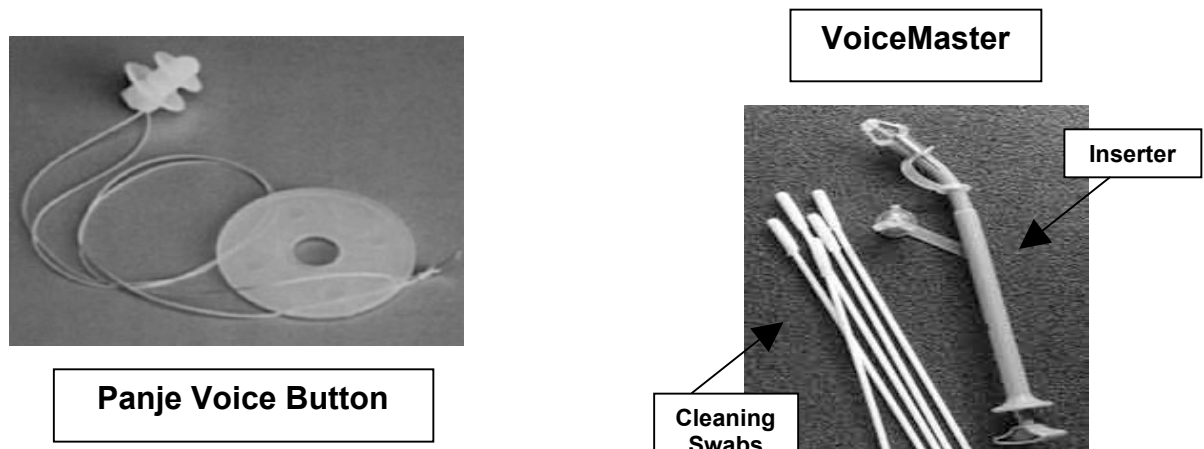


Table 1. Voice Prostheses in the Present Study

Manufacturer	Type	Length	Diameter	Prices
Bivona	Duckbill (Patient-inserted)	8 lengths - 1.4cm to 3.3cm	16 Fr. & 20 Fr.	Ceased Manufacture in 2004
Bivona	Ultra-Low Resistance (Patient-inserted)	7 lengths – 1.4cm to 3.0cm	16 Fr. & 20 Fr.	Ceased Manufacture in 2004
InHealth	Duckbill (Patient-inserted)	9 lengths – 6mm to 28mm	16 Fr.	\$28.00 as of January 30, 2006
InHealth	Low-Pressure (Patient-inserted)	9 lengths – 6mm to 28mm	16 Fr. & 20 Fr.	\$45.00 as of January 30, 2006
InHealth	Indwelling (Clinician-inserted)	8 lengths – 6mm to 25mm	16 Fr. & 20 Fr.	\$130.00 as of January 30, 2006
InHealth	Indwelling Advantage (Clinician- Inserted)	10 lengths- 4mm to 22mm	16 Fr. & 20 Fr.	\$199.00 as of January 30, 2006
Atos	Provox (Clinician- inserted)	5 lengths – 4.5mm to 12.5mm	21 Fr.	\$199.00 as of January 23, 2006
Atos	Provox 2 (Clinician-inserted)	6 lengths- 4.5mm-15mm	21 Fr.	\$199.00 as of January 23, 2006

Table 2. Subjects by Age and Gender (N=11)

	Mean Age (Years)	Range (Years: Months)
Males (6)	56 Years	41:2-81:6
Females (5)	60 Years	51:1-73:3

Table 3. Prosthesis Length at Initial Fitting, Start of 2<sup>nd</sup> year, & End of 2<sup>nd</sup> Year (N=11)

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	16.18	8 mm to 22 mm	18 mm	7.28 mm
Start of 2 <sup>nd</sup> Year	9.64	8 mm to 14 mm	8 mm	1.96 mm
End of 24 Months	9.09	6 mm to 14 mm	6, 8, 10 mm	2.88 mm

Table 4. Prosthesis Diameter at Initial Fitting, Start of 2<sup>nd</sup> year, & End of 2<sup>nd</sup> Year (N=11)

	16 French	20(21) French
Initial Fitting	10	1
End of 1 <sup>st</sup> Year	7	4
End of Second Year	4	7

Table 5. Clinician-Inserted vs. Patient Inserted: Number of days between fittings (N=11)

	# of v.p.	Average	Range	Median	Standard Deviation
Clinician-Inserted (First Year)	8	112.88	23-315	100	94.04
Patient-Inserted (First Year)	48	67.95	2-253	42	63.72
Clinician-Inserted (Second Year)	7 (1 Provox 2, 6 Indwelling)	96.14 days	42-131 days	90 days	33.32 days
Patient- Inserted (Second Year)	16	73.75 days	7-299 days	51.5 days	66.48 days

Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

Table 6. Clinician-Inserted vs. Patient Inserted at Initial Fitting, Start of 2<sup>nd</sup> year, & End of 2<sup>nd</sup> Year (N=11)

	Initial Fitting	Start of 2 <sup>nd</sup> Year	End of Second Year
Clinician-Inserted	1	3	4
Patient-Inserted	10	8	7

Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

Table 7. Prosthesis Length at Initial Fitting, Start of 2<sup>nd</sup> year, & End of 2<sup>nd</sup> Year  
Female Patients (N=5)

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	16 mm	8 to 22 mm	18 mm	5.29 mm
Start of 2 <sup>nd</sup> Year	9.2 mm	8 to 10 mm	10 mm	1.10 mm
End of 2 <sup>nd</sup> Year	8 mm	6- 10 mm	6 & 10 mm	2 mm



Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

Table 8. Prosthesis Length at Initial Fitting, Start of 2<sup>nd</sup> year, & End of 2<sup>nd</sup> Year  
Male Patients (N=6)

	Average Length	Range	Mode	Standard Deviation
Initial Fitting	16.3 mm	10-22 mm	18 mm	4.46 mm
Start of 2 <sup>nd</sup> Year	11.3 mm	8-14 mm	14 mm	3.01 mm
End of 2 <sup>nd</sup> Year	10 mm	6-14 mm	8 & 14 mm	3.35 mm

Table 9. Frequency with which Candida Colonization Co-occurred with Radiation Therapy (N=11)

First Year of Recovery

	Candida	No Candida
Radiation	6	4
No Radiation	1	0

Second Year of Recovery

	Candida	No Candida
Radiation	4	6
No Radiation	1	0

Stroh: Prosthesis use in the First Two Years of Recovery Status Post TLXY

Table 10. Number of Days between Fitting of v.p. and removal due to leakage with signs of Candida colonization (N=11)

First Year of Recovery

	Number of v.p. with/ <b>without</b> Candida	Mean	Range	Standard Deviation
Inhealth Duckbill	3 of 6 (50%) <b>3 of 6 (50%)</b>	126.3 <b>72.3</b>	37 to 253 <b>16 to 173</b>	87.39 <b>112.74</b>
Inhealth Low Pressure	2 of 28 (5.4%) <b>26 of 28 (94.6%)</b>	29 <b>60.04</b>	7 to 51 <b>2 to 203</b>	173.96 <b>59.33</b>
Inhealth Indwelling (Clinician-Inserted)	1 of 6 (17%) <b>5 of 6 (83%)</b>	40 <b>121.5</b>	- <b>41-315</b>	- <b>134</b>
Bivona Duckbill	0 of 1			
Bivona Ultra-Low Resistance	3 of 13 (18%) <b>10 of 13 (82%)</b>	106.7 <b>41.7</b>	70-147 <b>9-82</b>	38.63 <b>22.32</b>
Atos Provox 2 (Clinician-Inserted)	2 of 2 (100%)	125	94-156	43.84

- 11 of the total 56 (20%) v.p.s were colonized by candida.

Second Year of Recovery

	Number of v.p. with/ <b>without</b> Candida	Mean	Range	Standard Deviation
Inhealth Duckbill	0 of 2			
Inhealth Low Pressure	4 of 10 (40%) <b>6 of 10 (60%)</b>	108.5 <b>90.7</b>	16-299 <b>9-182</b>	128.72 <b>61.6</b>
Inhealth Indwelling (Clinician-Inserted)	2 of 6 (33%) <b>4 of 6 (67%)</b>	129.5 <b>85.5</b>	128-131 <b>42-124</b>	2.12 <b>33.64</b>
Bivona Duckbill	0 of 0			
Bivona Ultra-Low Resistance	0 of 4			
Atos Provox 2 (Clinician-Inserted)	1 of 1 (100%)	72	-	-

- 7 of the total 23 (30%) v.p.s were colonized by candida.