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dissertation entitled

Objective Pressure Measurements in Two Groups of Laryngectomees

presented by

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has been accepted towards fulfillment of the requirements for

Ph.D. degree in Audiology and Speech Sciences

Major professor

Date 3-8-94

OBJECTIVE PRESSURE MEASUREMENTS IN TWO GROUPS OF LARYNGECTOMEES

By

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A DISSERTATION

Submitted to
Michigan State University
in partial fulfillment of the
requirements for the degree of

DOCTOR OF PHILOSOPHY

Department of Audiology and Speech Sciences

1994

ABSTRACT

OBJECTIVE PRESSURE MEASUREMENTS IN TWO GROUPS OF LARYNGECTOMEES

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In order to establish the intraluminal pressures associated with tracheojejunal (TJ) speech production, objective air insufflation was performed transtracheally in 4 subjects with jejunal interposition and TJ puncture following laryngopharyngectomy during sustained vowel production and counting. Peak pressure measurements were compared to the intraesophageal peak pressures of 9 laryngectomees with tracheoesophageal (TE) puncture who served as controls.

TJ subjects demonstrated significantly greater pressure than TE subjects during sustained vowel production. No significant pressure difference was found between groups during counting; however, experimental subjects did demonstrate higher pressure than controls.

Decreased pressure was associated with longer lengths of time from surgery. No significant differences were found based on gender. Stronger correlations for females demonstrated decreased pressure associated with longer time since surgery, whereas males showed less pressure variability during counting.

A significant difference in pressure variability between groups was found during sustained vowel production. Both groups demonstrated greater pressure variability during counting than during sustained vowel production. Higher variances and small sample size may have prevented findings of statistical significance.

A power analysis of the data projected a minimum requirement of 12 subjects per group in order to detect significance with an 80% chance of accuracy. Given the high mortality and morbidity rates and the rare incidence of carcinoma of the laryngopharynx requiring jejunal interposition, longitudinal study with retrospective analysis appears more practical for ongoing study in this population.

None of the experimental subjects used the voice prosthesis for communication. All of the controls used the voice prosthesis to speak. While the results of this study do not provide conclusive evidence to indicate increased pressure as the sole reason for failure of TJ speakers to use the voice prosthesis for communication, increased pressure was a limiting factor. A discussion of possible influencing factors is provided. Further questions need to be answered in order to determine the efficacy of TJ puncture and voice restoration as a viable alaryngeal alternative for speech production in patients with jejunal interposition following laryngopharyngectomy.

To my mom and dad, Rosalyn and Melvin Lewin,
my best friends and wisest teachers

ACKNOWLEDGEMENTS

There is no doubt that many long hours have been spent in the preparation and completion of this manuscript. However, to suggest that this dissertation belongs only to me would not be true nor would it be fair. There are several people who shared in the work and the stress to whom I am truly grateful.

I am indebted to the Chair of my committee, Dr. Peter LaPine, who quietly and patiently guided me through the challenges and obstacles one encounters during the pursuit of a doctoral degree. His commitment to my education will never be forgotten.

I would like to further acknowledge the members of my committee -- Drs. Paul Cooke, David Daly, and Leo Deal -- who willingly agreed to accept me as their student and gave freely of their time and knowledge. They allowed me the freedom to pursue my interests through independent projects while demanding excellence in the quality of the results. I am truly grateful to them for their support of my endeavors.

I would like to thank my colleague and friend, Mr. Marc Haxer who covered the clinic, worked in the extra patients, ran to the library to pick up an article, and postponed his vacations when the demands of classes and writing became overwhelming. Without his help, I am not sure I would have been able to meet the deadlines and fulfill the requirements in a timely manner. He remains a true friend.

This manuscript would never have been possible without the continued help of Ms. Yvonne Beerens whose mastery of computer word processing transformed the thoughts and handwritten notes into a professionally produced manuscript. Her expedient assistance and calm management of never-ending dilemmas will always be appreciated.

I would also like to acknowledge Mr. James Bruce for transforming my "stick-figure" scrawlings into artistically drawn figures in a moment's notice. He remains responsible for the graphic precision of this document. He is a fine artist and a true friend.

To my family, my mother and father, my sister, Carol, and my friends who never failed me when I needed them, I will be eternally grateful. There is no way to measure or to repay the hours of listening, the perpetual support, and the undying faith in me they continued to show. I wish that my grandparents could be here to see the completion of this work because I know that they too would be proud.

Finally, I would like to thank the faculty of the Department of Otolaryngology at the University of Michigan Medical

Center for allowing me the time to complete my doctorate and supporting my research endeavors. Most importantly, I respectfully acknowledge all of the laryngectomees who agreed to participate in this investigation, for without them this research could not have been done.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

Introduction

Surgical/prosthetic restoration of speech dates back to the time of the first laryngectomy performed by Billroth in 1874. The early technique of laryngectomy was to create a fistula in the gullet through the neck. Gussenbauer, a resident under Billroth, developed a tubular device with a vibrating reed, much like the present day fenestrated tracheostomy tube, which was inserted into the hypopharynx and trachea, respectively. An obturator was inserted to block the pharyngeal extension during deglutition while a plug was inserted for pharyngo-tracheal respiration. The patient inserted a "flutter valve" (Montgomery & Toohill, 1968, p. 500) for speech. The device not only prevented aspiration but also restored the patient's voice. As the surgical technique for laryngectomy changed so, too, did the design of the prosthetic devices used for vocal rehabilitation. The vocal prostheses in general became more complicated and harder to manage with variable patient and physician satisfaction (Panje, 1981; Montgomery & Toohill, 1968).

A review by Holinger (1975) suggests that surgical procedures for the removal of the larynx initially involved the creation of both a laryngostome into the patient's trachea as well as a pharyngostome into the pharynx. Primary closure of the pharynx following laryngectomy as pioneered by Gluck and Sorensen in 1894 eliminated the need for the external pharyngostome, but it also eliminated the use of the prosthetic devices which depended on both openings to shunt air from the trachea into the pharynx for alaryngeal speech production. Following the introduction of primary closure and the elimination of the prosthetic shunts for speech production, patients learned that vibration of the esophageal walls could be used to produce voice. Soon esophageal speech production became the chief method for alaryngeal voice restoration for the laryngectomized patient. It has continued to remain a viable alternative for alaryngeal speech production to the present day.

Speech rehabilitation of the laryngectomee remained basically unchanged until 1952 when Briana proposed the creation of a controlled pharyngocutaneous fistula into the pharyngoesophagus with the use of a rubber tube to join the trachea and pharynx so that air could again be shunted into the esophagus for voice production. The procedure was complicated by aspiration of food and secretions. In an attempt to reduce the contamination from the esophagus to the trachea, Conley (1958) and colleagues (Conley, DeAmesti, & Pierce, 1959) offered two methods for shunting air from the trachea into the esophagus. The first method involved the creation of a mucosal tunnel taken from the lining of the esophagus that was looped over the omohyoid muscle. Upon swallowing, the tunnel was compressed by muscular contraction and depression on the tunnel. The procedure was complicated by stenosis of the tract and aspiration. It also had limited use in irradiated patients. In 1959, Conley switched to the use of an autogenous vein graft to replace the tubed muscular tunnel; but again the usefulness of the procedure was limited by the same complications: stenosis and aspiration.

Asai, in 1965, modified Conley's approach and offered a three-stage laryngoplasty in which a dermal tube connected a pharyngostome and tracheostome for internal shunting of pulmonary air for voice production. The procedure was introduced to the United States in 1967 by Miller. Unfortunately, both procedures continued to be complicated by aspiration and stenosis of the dermal tube. Various modifications of both procedures were offered by others. Again, all were limited by the same problems, aspiration and stenosis (Karlan, 1968; Montgomery & Toohill, 1968; McGrail & Oldfield, 1971; Calcaterra & Jafek, 1971; Komorn, Weyeer, Sisson & Malone, 1973; Amatsu, 1980).

Continued interest in laryngeal surgery with primary voice restoration sparked other investigators to attempt new procedures. Staffieri (1969) and Arslan and Serafini (1972) pioneered the neoglottic procedure which created a primitive valved glottis with a flap of mucosal remnant. The procedure was actually a tracheo-hypopharyngeal shunt in which the trachea was transected at the subcricoid level with the hyoid bone left in place. A flap of posterior cricoid mucosa was created. The flap was placed over the top of the trachea and the trachea was slanted at the top to avoid aspiration. Arslan and Serafini (1972) modified the technique by preserving a remnant of the epiglottis and suturing it to the anterior edge of the top of the trachea. The procedure was limited by the extent of cancer. Complications also included aspiration, limited usefulness in irradiated patients, need for revision surgery, and failure to develop voice. Sisson, Bytell, Becker, McConnel, and Singer (1978) introduced Staffieri's technique to the United States. They reported their experience with 12 cases. Although strict surgical criteria were advocated for the procedure in order to ensure complete tumor removal, three patients developed recurrent tumor and only 6 achieved permanent vocalization. Leipzig, Griffiths, and Shea (1980) reported 4 of 30 patients (13%) recurred in the neck and 12 of the 30 patients (40%) aspirated, half of which necessitated surgical closure of the neoglottis. Attempts at neoglottic reconstruction continued, although the usefulness of these procedures was limited.

The high rate of failure of the shunt and neoglottic procedures prompted a renewed interest in the use of prosthetic devices for voice production. In 1972, Taub and

Spiro introduced their removable air bypass prosthesis, the "VoiceBak," a valved bypass cannula that allowed air from the tracheostome into the esophagus for voice production through an esophagotomy. While the device did restore speech to some, it was cumbersome, expensive, and had limited use in radiated patients or patients with neck dissection because of the potential injury to the carotid artery (Henley & Souliere, 1986). Sisson, McConnel, Logemann, and Yeh (1975) reported 26 cases in which two deaths occurred from carotid rupture. They reported that the main problem with the device was the development of a salivary fistula.

Tracheoesophageal (TE) puncture and voice restoration following total laryngectomy, as described by Singer and Blom in 1980, has probably become the most common method of prosthetic alaryngeal speech restoration. The method involves the surgical creation of a controlled fistula which forms a communication between the trachea and esophagus. A small, one-way valved prosthesis stents the puncture tract and allows pulmonary airflow into the esophagus for voice production but prevents aspiration of food and saliva. The TE puncture as originally described was performed as a secondary procedure following laryngectomy. It was done under general anesthesia and required a short hospitalization (Singer & Blom, 1980; Maniglia, Lundy, Casiano, & Swim, 1989). However, the procedure can also be performed as a primary procedure at the time of laryngectomy immediately after laryngeal resection (Lau, Wei, Ho, & Lam, 1988; Maniglia, 1982; Maves & Lingeman, 1982; Hamaker, Singer, Blom, & Daniels, 1985).

The vibration of the pharyngoesophageal mucosa functions as a substitute sound generator for the larynx. TE puncture is reportedly simple with successfully restored speech production between 50 percent and 97 percent (Donegan, Gluckman, & Singh, 1981; Juarbe, Shemen, Eberle, Klatsky, & Fox, 1986; Juarbe et al., 1989; Panje, 1981). In those cases in which TE speech production has not been achieved, pharyngeal constrictor myotomy, pharyngeal constrictor myectomy, or pharyngeal plexus neurectomy has been performed to facilitate conversational speech production (Baugh, Lewin, & Baker, 1987).

Historically, interest has continued in identifying those patients who would be good candidates for surgical and prosthetic voice restoration prior to surgical intervention. Various investigators have introduced air into the esophagus prior to surgical and prosthetic intervention in an attempt to determine the vibratory response of the esophagus to air insufflation. Air-blowing, or insufflation, has been used to determine the location of esophageal vibration for the production of esophageal sound for speech production. It has also been used to assess possible obstructions to the flow of air that might impede or prevent esophageal vibration within the cervical esophagus. These obstructions are often not visualized during a routine barium swallow.

Reports have suggested that speech production resulting from preoperative air insufflation of the esophagus is a good indicator of postoperative TE speech production ability (Blom, Singer, & Hamaker, 1985; Singer & Blom, 1980; Singer & Blom, 1981; Taub, 1975, 1981). VandenBerg and Moolenaar-Bijl (1959) were the first, followed by Seeman (1967), to use objective measurements of intraesophageal pressures to predict esophageal voice production. Taub (1975, 1981) reintroduced esophageal insufflation to determine the location of maximum sound production in the esophagus for placement of his VoiceBak prosthesis. He later used it to determine the patient's potential for successful speech results using his device. He suggested that the insufflation test could be used to determine the esophageal speech potential for all laryngectomees. However, the variations in esophageal insufflation including insufflation force and sound duration were not addressed.

Singer and Blom (1980) included esophageal air insufflation as part of their preoperative assessment for TE voice restoration following total laryngectomy and again as part of their self-insufflation test in 1985. Both methods lacked clear operational definitions as to the level of airflow and amount of air presentation as well as definitions for postoperative TE speech success versus failure. Its advocates, Singer and Blom (1980, 1981), experienced both false positive and false negative results. They also reported data with inconclusive results. Others found esophageal air insufflation to be of limited prognostic value (Panje, 1981; Donegan et al., 1981; Wood, Tucker, Rusner, & Levine, 1981; Johns & Cantrell, 1981). The lack of objectivity and specificity of esophageal air insufflation testing prompted suggestion of its abandonment (Panje, 1981).

In 1987, Lewin, Baugh, and Baker introduced an objective method of air insufflation using intraesophageal pressure measurements to predict those patients who would acquire fluent TE speech following TE puncture and those patients who would require myotomy of the pharyngeal constrictor musculature to achieve conversational fluency. Patients were insufflated preoperatively, and their peak intra-esophageal pressures were recorded. Following TE puncture, three groups of TE speakers were identified and were found to be statistically different ($p < .001$) based upon their pressure measurements using the Kruskal-Wallis One-Way Analysis of Variance by Ranks. Patients with low intraesophageal peak pressure measurements (< 20 mm Hg) obtained fluent TE speech without the need for myotomy. Fluent speakers demonstrated abilities comparable to normal laryngeal speakers (i.e., greater than 10 seconds of uninterrupted vowel duration and a minimum production of

10-15 syllables per breath). Non-fluent speakers demonstrated sound and word production abilities below the fluent criterion. Non-speakers demonstrated sound durations below one second and no word production capability. Both the non-fluent speakers and non-speakers had preoperative intraesophageal peak pressure measurements above 20 mm Hg.

An inability to sustain sound for ten seconds and/or produce ten to 15 syllables was interpreted as being associated with elevated pharyngeal constrictor muscle resistance. A pharyngeal nerve plexus blockade of 1-3 cc of 1% lidocaine injection into the paraesophageal and parapharyngeal tissues was performed. Testing was repeated. A reduction in intraesophageal pressure measurements with improved ability to perform speech tasks clinically confirmed pharyngeal constrictor hypertonicity and the need for myotomy to achieve fluent speech post-TE puncture.

The authors therefore offered a method of assessment to quantify and predict TE speech fluency as well as to identify those patients in need of myotomy to achieve conversational speech ease. Since testing was performed prior to TE puncture, a negative test result supported myotomy at the time of the TE puncture rather than at a later date after the patient experienced conversational speech failure. Therefore, an additional surgery could be avoided along with patient frustration associated with further speech delay.

The majority of current documentation concerning surgical and prosthetic methods of alaryngeal voice production focuses on tracheoesophageal voice restoration following simple laryngectomy. However, new reconstructive procedures for radical surgery of the laryngopharynx and cervical esophagus have resulted in a limited experience with vocal rehabilitation of patients undergoing such extended surgeries. Realistically the goal for rehabilitation has been "to provide an adequate conduit to allow peroral alimentation at a single operation synchronous to the resection" (Coleman, 1993, p. 85). Success of the procedure has been determined by the ability of the patient to swallow following surgery (Shumrick & Savoury, 1988).

Malignant tumors arising in the hypopharynx and cervical esophagus, or laryngopharynx, are associated with the worst prognosis amongst neoplasia arising in the upper aerodigestive tract. The overall incidence of cancer of the hypopharynx in the United States is approximately 8 per 1 million population. The highest incidence occurs twice as often in males usually in the seventh and eighth decades of life (Shah, 1993).

Discussion of the surgical management of hypopharyngeal and cervical esophageal carcinomas has centered around the ideal method of reconstruction following tumor ablation (Wenig, Mulooly, Levy, & Abramsom, 1989). Long-term survival following radical surgery for advanced stage III and IV carcinoma of the laryngopharynx and cervical esophagus is extremely poor with reported two and five year survival rates of zero to 50% (Gluckman, Weissler, & McCafferty, 1987). Consequently, the optimal reconstructive procedure must provide the lowest mortality and morbidity, the shortest hospitalization, and the highest rate and most rapid functional restoration of oral alimentation (Surkin, 1984). Since speech restoration is not critical to patient survival, it has not been a primary consideration in the choice of surgical reconstruction.

Various methods have been used for functional reconstruction of the pharynx, larynx, and cervical esophagus after extirpative tumor resections. These techniques include prostheses, skin grafts, cervical flaps, tubed cutaneous and myocutaneous chest flaps, visceral reconstruction with stomach, colon, and free jejunal autografts. The problems associated with skin grafts and flaps are well documented. They include use for limited pharyngoesophageal resections, multi-staged procedures, and prolonged hospitalization. They have high postoperative morbidity and mortality rates and are frequently associated with flap necrosis and distal anastomotic stricture. They result in a poor swallowing mechanism (Biel & Maisel, 1987; Schechter, Baker, & Gilbert, 1987; de Vries et al., 1989; Gluckman et al., 1985; Gluckman et al., 1987; Urken, 1989; Fisher, Cole, Meyers, & Seigler, 1985).

Immediate jejunal autograft interposition was first proposed by Seidenberg, Rosenak, Hurwitt, and Som in 1959 for reconstruction of defects of the hypopharynx and cervical esophagus. During the mid 1970s, experience with and refinement of microvascular techniques and instrumentation facilitated the use of free jejunal autografts to successfully reconstruct complete pharyngoesophageal defects resulting from total laryngopharyngectomy and cervical esophagectomy (Fisher et al., 1985). Biel and Maisel (1987) reported that in addition to allowing for extensive local tumor resections, the method has the advantage of being a single-staged procedure with low mortality and morbidity rates and with relatively short hospitalization and restoration of near-normal swallowing function. Bradford, Esclamado, and Carroll (1992) have corroborated these findings.

Physiologically, the jejunal autograft is well suited for the reconstruction of circumferential pharyngoesophageal defects. Its luminal diameter of approximately 3.0 cm is comparable to that of the hypopharynx and cervical esophagus. It is mucosally lined and therefore has the advantage of mucous secretion which enhances food passage through the segment. In contrast, skin flaps, for example, do not secrete mucus and result in an adynamic, dry passage which does not assist food transit. Transplanted jejunum also tolerates irradiation with good preservation of function. The intrinsic peristalsis associated with the jejunum may also facilitate swallowing and food transit (Jacob, Francone, & Lossow, 1982, Ch. 14; Gullane, Havas, Patterson, Todd, & Boyd, 1987; Fisher et al., 1985).

Alternatively, the viability of the jejunal segment to serve as a vibratory source for alaryngeal voice production has received much less attention because of the lack of emphasis on speech restoration and is, therefore, not well known. The twofold necessity of adequate tumor extirpation and physiologic restoration of swallowing function has overshadowed other considerations. To date, little attention has been given to vocal rehabilitation of patients undergoing removal of the larynx and significant portions of the hypopharynx and cervical esophagus (Wenig et al., 1989).

The few studies that have examined vocal restoration have focused on surgical/prosthetic methods of voice restoration using either tracheojejunal (TJ) shunts or tracheojejunal puncture. Recently, Denk, Grasl, Frank, Deutsch, and Ehrenberger (1992) and Grasl (1993) proposed a surgical technique for creating a tracheojejunal shunt which includes immediate cervical anastomoses with previously chosen arteries and veins. The procedure, similar to the tracheoesophageal shunt first proposed by Conley et al. in 1958 for voice restoration following total laryngectomy, requires an end-to-end anastomosis of the graft to the remaining tracheal stump located above the tracheostome. It is then pulled up and a loop is formed with its turn close to the floor of the mouth where it is fixed to the digastric muscles. The distal end of the transplant is then drawn inferiorly and inserted end-to-side into the reconstructed wall of the hypopharynx which contributes to the anterior circumference of the distal part of the neopharynx.

Kinishi, Amatsu, Tahara, and Makino (1991) suggested alternative surgical modifications including tubed mucosal flaps to create the tracheojejunal shunt. However, the method of "shunting" air into the reconstructed hypopharynx for voice production remains the same.

The exact location of the vibratory section in patients with jejunal graft interposition remains under investigation (Kinishi et al., 1991; de Vries et al., 1989; Grasl, 1993). Denk et al. (1992) suggested that "the sound source for voice production seems to be a pseudoglottis in the area of the anastomosis between the hypopharynx and the jejunal graft" (p. 249). Following tracheo-hypopharyngeal shunt with jejunal transplantation, the authors described postoperative voice rehabilitation in 32 of the 40 patients who underwent the procedure as successful with adequate communication for everyday purposes.

Kinishi et al. (1991) reported acquisition of voice capability in three of three patients with the tracheojejunal shunt operation and consistent use of tracheojejunal shunt speech by all patients. Zeismann, Boyd, Manktelow, and Rosen (1989) reported good speech results in two of three patients who underwent neoglottic and neopharyngeal reconstruction using jejunum. Unfortunately, an operational definition of the term "good" is lacking. Two other investigations reported similar results in their studies of patients who underwent a tracheohypopharyngeal shunt for voice restoration with free jejunal autografts. Handl-Zeller et al. (1992) and Grasl (1993) reported successful voice rehabilitation in 19 of 20 patients (95%) and 31 of 39 patients (79%) respectively using the "speech-siphon" (p. 98).

The studies that have examined vocal restoration following tracheojejunal puncture are also limited in number and methodological description. Wenig et al. (1989) reported satisfactory communication in 5 patients, 4 of whom had jejunal grafts and 1 a radial forearm graft to replace a complete hypopharyngeal/esophageal defect. Although the investigators reported "coarse" vocal quality and lack of projection, all patients did achieve fluent voice as judged by 2 "voice" professionals and one independent non-professional listener. The investigators felt that the bowel segment did not provide as good a vibratory source as the residual pharyngeal wall. Conversely, de Vries et al. (1989) reported that only 2 of 17 patients who underwent free jejunal interposition were able to speak with

Blom-Singer voice prostheses through a TJ fistula. One patient used neoglottic speech, whereas four relied on an electronic speech aid and one on paper and pencil to communicate. Eight of the 17 patients died of their disease or other causes, whereas one patient remained alive at the time of publication with metastatic lesions in the lung. The authors concluded a better potential for speech rehabilitation in patients after free jejunal interposition.

In a study by Salamoun et al. in 1987, three of 32 patients who had undergone free jejunal transfer were using TJ speech through a voice prosthesis. Unfortunately, no other information was provided as to vocal quality or prosthetic use.

Medina, Nance, Burns, and Overton (1987) compared the vocal quality of 10 patients who used a TE voice prosthesis and had previously undergone total laryngopharyngectomy or laryngopharyngoesophagectomy with the vocal quality of 10 patients who had a total laryngectomy and TE puncture who served as the controls. Five of the 10 experimental subjects underwent laryngopharyngectomy. Only one subject had reconstruction of the circumferential defect using a free jejunal graft. The remaining four were reconstructed with either a myocutaneous flap or colon interposition. The authors reported adequate voice and an ability to carry on a conversation for all patients; however, all subjects exhibited lower overall pitch and loudness than the laryngectomized control group as well as a "wet" vocal quality. Although the authors concluded that the TE voice prosthesis could be used for speech rehabilitation following total laryngopharyngectomy, the long term use by such patients for daily communication was not addressed.

Similar vocal results were reported by Mendelsohn, Morris, and Gallagher in 1993. The vocal qualities of 22 laryngectomees and seven laryngopharyngectomees with jejunal graft reconstruction were compared with that of a group of 10 normal control subjects. All experimental subjects used a voice prosthesis for speech production. The laryngopharyngectomized patients consistently scored lower in fundamental frequency, intelligibility and social acceptability than both the laryngectomized group and normal subjects ($p \leq 0.05$). The vocal quality of the laryngopharyngectomized patients was perceived as "wet." The investigators concluded that the operative decision of total laryngopharyngectomy may profoundly affect the patient's ability to communicate.

Juarbe et al. (1989) reported an overall 50% success rate for speech production in 10 patients who underwent total laryngopharyngectomy. Nine patients who had flap closure initially achieved acceptable voice with TE puncture. The single patient reconstructed with jejunal graft had difficulty voicing and ultimately removed his voice prosthesis permanently. He was unable to produce esophageal speech as well and ultimately used an electronic speech aid for communication.

These findings contrast the findings of Schechter et al. (1987) who reported on a 12-year experience involving the functional evaluation of 115 patients who had pharyngoesophageal resections for cancer treatment. Each patient received reconstruction by one of four major techniques: deltopectoral flaps (n = 43), pectoralis myocutaneous flaps (n = 36), gastric pull-ups (n = 19), and free jejunal autografts (n = 17). Their findings suggested that the major functional problem with the jejunal autograft was the failure to develop adequate neoesophageal speech. They attributed the failure to the large lumen of the jejunal segment which limits effective vibration for speech by standard techniques of oral air implosion. Fisher et al. (1985) also concluded that a disadvantage of the free jejunal graft interposition is that "it causes limited esophageal speech" (p. 752).

The two previous studies assessed alaryngeal speech production using standard methods of oral air implosion as opposed to surgical/prosthetic alternatives. The critical point is the inability to achieve voice production following jejunal graft interposition. The only reports of successful voice restoration in patients with jejunal graft interposition have involved surgical and prosthetic methods. This finding may imply the need for a greater insufflation force beyond that which can be produced using the standard methods of oral implosion to initiate and maintain tissue vibration for speech production following jejunal graft interposition.

Although documentation indicates some successful voice production using surgical/prosthetic methods, the sole reliance on TJ voice for conversational speech purposes remains unclear. Acquisition does not equal functional use for daily conversational needs. As Baugh, Lewin, and Baker (1990) suggested, "The correlation between long-term tracheoesophageal prosthetic use and final tracheoesophageal speech fluency suggests that the restoration of communication skills to near pre-laryngectomy speech status may be an important factor for long-term tracheoesophageal prosthetic use" (p. 72). Just as tracheoesophageal speech has been compared to and striven for pre-laryngectomy status as the standard of speech fluency, so must tracheojejunal voice attempt to meet the same criteria to remain a viable alaryngeal speech alternative.

A major factor associated with conversational speech fluency involves the ease in which speech production can be produced. If speech cannot be readily and easily spoken, it is unlikely that the method will prove a viable alternative for functional restoration of communication. Various studies have been undertaken to determine those factors which might be associated with postoperative TE voice production following laryngectomy. Schuller, Jarrow, Kelly, and Miglets (1983) proposed a formula that reportedly predicted successful development of TE speech based upon two parameters: alcohol abuse and stoma size. While both alcohol abuse and inadequate stoma size may negatively influence successful TE prosthetic use, neither is a determinant factor in TE sound production, the fundamental requirement for the development of successful TE speech. The authors also studied eight other parameters: current mode of communication, concomitant medical problems, eye-hand coordination, educational level, age, hearing acuity, work status, and living environment. Again, these factors should be considered extrinsic complications to functional TE speech restoration. Donegan et al. (1981) also suggested that such personal characteristics as motivation, persistence and a high energy level are important extrinsic determinants of successful long-term TE speech use. However, personal characteristics like all extrinsic factors are relevant only if TE methods of voice production are successful in restoring communication skills to the fluency and communicative ease of pre-laryngectomy status.

The shunting of pulmonary air into the esophagus induces oscillations of the lining of the pharynx and upper esophagus thereby causing a vibrating column of air to be produced. The sound thus produced is articulated by the structures of the oral cavity. The amount of oscillation of the lining of the pharynx and cervical esophagus then is the major determinant of successful TE voice production and conversation fluency. Hence, various methods of intraesophageal air insufflation have been proposed to measure the intraesophageal pressures associated with tracheoesophageal voice production during the superior egress of airflow for speech purposes (Singer & Blom, 1980; Baugh et al., 1987; Lewin et al., 1987; Blom, Singer, & Hamaker, 1985).

Three etiologies of tracheoesophageal speech failure have been identified: the hypotonic pharyngoesophageal segment, hypopharyngeal stricture, and pharyngeal hypertonicity of the constrictor musculature which Singer and Blom (1980) first referred to as "pharyngoesophageal spasm."

The breathy voice is the clinical correlate of the flaccid or hypotonic pharyngoesophageal segment (Perry, Cheesman, McIvor, and Charlton, 1987). As the severity of the hypotonia increases, the egress of air from the pharynx and esophagus may not generate sufficient tissue vibration to result in TE sound. Digital pressure to the neck segment or the use of a pressure band around the neck will usually facilitate tissue vibration and improve sound production (Cheesman, Knight, McIvor, & Perry, 1986).

Hypertonicity of the pharyngeal constrictor musculature, or "pharyngoesophageal spasm," has remained the most common reason for TE speech failure (Blom, Singer, & Hamaker, 1986; Perry et al., 1987; Baugh, Baker, & Lewin, 1988). Surgical myotomy or myectomy of the pharyngeal constrictors or neurectomy of the pharyngeal plexus compromises the pharyngeal contraction which occurs in response to esophageal distension, thereby allowing fluent TE speech production (Singer & Blom, 1981; Baugh et al., 1990).

A constriction or stricture of the hypopharynx can be an important cause of failure to achieve TE speech. A stricture is best classified as a structural or anatomical abnormality which hinders TE speech ability by impeding airflow from the pharynx and esophagus thereby limiting sound production. Simpson, Smith, and Gordon (1972) referred to one type of permanent, organic stricture above the pharyngoesophageal junction as a constant area of narrowing that does not distend even during swallowing. This type of stricture is most likely related to loss of excised mucosa or fibrosis and scarring secondary to delayed healing. Ogura and Thawley (1979) reported various types of organic strictures. However, management usually entails repeated dilation or surgical reconstruction of the stenotic area. Organic strictures do not improve with relaxation or voice therapy.

In the cases of hypertonicity of the constrictor musculature and hypopharyngeal stricture, increased resistance to airflow has been associated with decreased TE speech fluency and increased intraesophageal pressures. The result is in an inferior egress of airflow with gastric filling and limited to no volitional speech production. Speech therapy has not been successful in relieving the complaints of increased vocal effort, discomfort, and lack of conversational speech fluency associated with pharyngeal constrictor hypertonicity or stricture. Surgical relief improves tracheoesophageal speech fluency (Baugh et al., 1990; Singer & Blom, 1981; Singer, Blom, & Hamaker, 1986; Henley & Souliere, 1986).

Mendelsohn et al. (1993) reported that six of seven patients (86%) who had undergone jejunal graft reconstruction were unable to sustain phonation for longer than eight seconds, compared with 16 of the 22 patients (71%) who had undergone laryngectomy. An explanation for this finding may be related to the swallowing difficulties some patients experience following jejunal graft reconstruction. It has been estimated that 40% of patients with jejunal graft interposition have some degree of delay in bolus transit time through the grafted segment (Kerlin, McCafferty, Robinson, & Thiele, 1986). The motility problems in these grafts seem to result from continued, unmodulated peristalsis and segmental contractions mediated by the myenteric plexus. Although the grafts are extrinsically denervated, these autonomous plexi continue to function.

Findings such as these have led some investigators to propose that the intrinsic contractions of the jejunal graft could potentially lead to dysphagia and could inhibit tracheojejunal phonation. It has been suggested that jejunal myotomy may assist TJ voice production similar to the performance of pharyngeal constrictor myotomy to improve TE speech production by relieving graft contractions. Wenig et al. (1989) advocated myotomy above and below the pharyngoesophageal defect in combination with a tightly stretched jejunal segment. The authors advised against redundant or loose tissue in order to create a resonating area, or "neoglottis." The investigators felt that failure to establish these conditions would hinder phonatory and swallowing ability.

Haughey and Forsen (1992) developed a canine model to assess the functional effects of myotomy on transplanted jejunum. Five of nine animals underwent complete longitudinal myotomy and four underwent a sham procedure. Results demonstrated no significant difference in motility between myotomized grafts and sham-operated grafts. Furthermore, pressure parameters between the myotomy group and the sham group were not significantly different as indicated by manometric testing. The authors concluded that their results suggested that myotomy was ineffective in eliminating the intrinsic contractions seen in free jejunal graft transplantations.

Juarbe et al. (1989) reported failure to develop speech in a patient with jejunal graft reconstruction despite the performance of a posterior myotomy. The patient ultimately removed his prosthesis because of his inability to use it.

History has shown that most tracheoesophageal puncture patients acquire the fluency necessary for effective daily communication without specific intervention. However, early studies reported removal of the voice prosthesis in voice failures without myotomy with spontaneous closure of the TE puncture. The majority of these failures were associated with limited speech production as a result of the increased pharyngeal resistance to the superior egress of voluntary airflow associated with either hypertonicity of the pharyngeal constrictor musculature or hypopharyngeal stricture. However, other reasons for removal of the voice prosthesis included an inability to care for and manage the prosthesis, an unrealistic expectation of voice production, difficulty removing and reinserting the voice prosthesis and motivational factors (Singer & Blom, 1980; Wood et al., 1981; Donegan et al., 1981; Atkinson, 1984; Wetmore, Krueger, Wesson, & Blessing, 1985).

Several authors have suggested that the resistance of the voice prosthesis to airflow through it should influence the efficiency with which TE voice is produced. In 1981, Panje described a surgical-prosthetic method of voice restoration for patients who received laryngectomy. Similar to other surgical methods, a tracheoesophageal fistula is created and a Voice Button is inserted seven to 14 days later. The Panje method of voice restoration also requires occlusion of the tracheostome to divert pulmonary air into the esophagus to produce sound. In 1982, Weinberg compared airflow resistance values for the Panje Voice Button with the Blom-Singer voice prosthesis, the pharyngoesophageal segment during voicing, and the human larynx during vowel production. Average laryngeal airway resistance as reported by Smitheran and Hixon (1981) is about 35 cm H_2O/L/s. The airway resistance offered by the Voice Button was about ten times greater than that normally produced by the larynx during vowel production. The Voice Button also always exceeded that offered by Blom-Singer voice prostheses. Airway resistance of Blom-Singer prostheses ranged from 45-120 cm H_2O/L/s. The Panje Voice Button was 2.5 to ten times greater than that offered by Blom-Singer prostheses. Weinberg also demonstrated that airway resistance offered by the Voice Button also exceeded that offered by the voicing source, the pharyngoesophageal segment, used by esophageal speakers during speech production. Weinberg, Horii, Blom, and Singer (1982) reported a source resistance between 155-270 cm H_2O/L/s for five esophageal speakers who had laryngectomies.

Weinberg's results revealed a substantial airway resistance offered by the Panje Voice Button ranging between 285 and

440 cm H_2O/L/s. He commented, "These results are discouraging. Speakers using this method must work to overcome larger opposition to airflow...This circumstance would be expected to greatly reduce the efficiency with which tracheoesophageal voice is produced" (p. 500). Personal experience suggests that current use of the Panje Voice Button for TE voice restoration has markedly if not completely declined. Too much effort on the part of the patient was required to sustain easy conversational speech production using the device.

In patients who have undergone free jejunal graft interposition following laryngopharyngectomy and cervical esophagectomy, little is known about the vibratory properties of the jejunal mucosa, specifically airflow resistance factors. Ehrenberger et al. (1985) suggested a low resistance to airflow with an average "total phonation pressure" between 50 and 60 cm H_2O. The authors stated, "Acting together with the air chamber effect of the jejunal graft, the low phonation pressure produces a corresponding phonation" (p. 222). Unfortunately this statement is difficult to interpret with relationship to restoration of functional conversational speech since methodology and terminology are not well defined.

Grasl (1993) also attempted to measure airflow resistance for voice production in patients with "speech-siphons." In vivo airflow resistance was measured with a U-shaped, open, water-filled measurement device coupled to the tracheostome. Values were measured at the start of phonation and expressed in kilopascals (kPa). A mean maximum phonation time of 8.3 seconds with a range of 5-14 seconds and a mean of 5.2 kPa with a range of 3.5-8.5 kPa was reported. The study also reported a mean of 17 syllables per exhalation with a range of 12-23 syllables. Again, the relationship of these results to everyday reliance of TJ speech for functional communication is unclear.

The purpose of this investigation was to determine the intrajejunal pressure measurements associated with tracheojejunal speech production by comparing the pressures associated with speech production in two groups of laryngectomees. Previous studies have documented the ability of the jejunum to vibrate.

This study was also undertaken to examine tracheojejunal vibration as a viable alternative for conversational speech purposes. It was hypothesized that the patient's use of TJ voice as the method for communication should be a good indicator of functional restoration of speech production. It was further hypothesized that increased intrajejunal pressures during speech tasks should correlate with increased effort to produce and maintain speech production, thus reducing patient use of TJ voice production for conversational speech purposes. Given the low survival rates for patients with this type of advanced carcinoma, it is critical that the selected method of alaryngeal voice restoration provide efficient speech production which is comparable to the patient's premorbid speech abilities. Time is critical. It must not be wasted on less than optimal methods which lack the potential for functional, timely restoration of speech.

CHAPTER II

Methods

Objective air insufflation was performed transtracheally through the TJ puncture in 4 subjects with jejunal autograft interposition following laryngopharyngectomy in order to obtain intrajejunal pressure measurements associated with TJ voice production. Intrajejunal pressure measurements were compared to the intraesophageal pressure measurements obtained from 9 laryngectomized subjects with fluent TE speech who served as the controls.

Fluent speech was defined as an ability to produce speech comparable to normal laryngeal speakers. Fluent speech is greater than 10 seconds of uninterrupted sound duration and a minimum production of 10 to 15 syllables per breath (Blom et al., 1985; Baugh et al., 1987; Lewin et al., 1987).

Results were analyzed based upon the criteria published by Lewin et al. (1987). The criteria were 1) intraesophageal peak pressures $\leq$ 20 mm Hg associated with fluent TE speech production; 2) greater than 10 seconds of uninterrupted sound duration; and 3) a minimum production of 10 syllables per breath. Data from both groups were compared as to their central tendency and dispersion measures and then statistical tests of significance were applied.

Subjects

Four patients, between 51 and 62 years of age, with free jejunal autograft interposition following laryngopharyngectomy and TJ puncture as described in the Surgical Technique Section served as subjects. Nine laryngectomized patients whose primary communication mode was TE speech served as controls. All subjects were referred following medical clearance by their otolaryngologist. No evidence of stricture was reported by the physician at the time of testing. All subjects were able to eat soft to regular diets, thus indicating no overt evidence of stricture. All subjects were previously fit with and wore an appropriately sized Blom-Singer, low-pressure voice prosthesis (International Health Technologies, Inc., formerly Baxter-Mueller, Santa Barbara, California) to ensure uniformity in experimental design and prosthesis type.

Surgical Technique

The surgical technique involves the harvest by the general surgery team as well as placement of a gastrostomy tube. The length of jejunum harvested corresponds to that supplied by the mesenteric pedicle, including the artery and vein. The graft is transferred to the neck and revascularized using standard microvascular techniques. The appropriate length of jejunum required for reconstruction of the circumferential pharyngeal defect is assessed. Redundant length of jejunum is to be avoided as it can lead to postoperative dysphagia. The jejunum is divided into reconstructive and monitoring segments, but both portions are left pedicled on the mesenteric blood supply. The reconstructive portion of the jejunum is sewn into place to restore pharyngeal continuity in the isoperistaltic direction. The monitoring segment of jejunum is brought out through the neck incision for postoperative assessment of viability by checking Doppler pulses. The exteriorized jejunal segment is removed at the bedside on postoperative day seven.

Secondary tracheoesophageal puncture is performed in the operating room. The cervical esophagoscope is introduced to the level of the planned puncture, usually 5-8 mm inferior to the superior edge of the stoma in the midline. A 14 gauge angiocath is introduced at the planned puncture site. The needle is withdrawn and the hub is removed. The puncture site is dilated by passing a filiform then a follower in sequence through the puncture site. The 14 Fr red rubber Robinson catheter is sewed to the follower and all are brought out the mouth. The last step involves directing the red rubber Robinson catheter inferiorly in the esophagus. This is accomplished by partial withdrawal of the catheter under direct visualization with the esophagoscope followed by directing it distally with a cup forceps.

Assessment

A 14 French catheter (Davol, Inc., Ganston, Rhode Island) was passed transtracheally through the puncture tract into the jejunum in subjects with jejunal interposition or into the esophagus in the laryngectomized controls. The length of the subject's voice prosthesis was used to determine the distance of catheter insertion in order to be sure that the distal tip end of the catheter was sufficiently stenting the TJ wall. The catheter was connected to a standard compressed airflow source and a pressure manometer (W.A. Baum Company, Inc., New York City, NY) via a silicone "Y" connector (Seamless Hospital Products Company, Wallingford, Connecticut) and plastic connecting tubing (Sherwood Medical, St. Louis, Missouri). The testing apparatus is illustrated in Figure 1.

The method of assessment as previously described by Lewin et al. (1987) was used to assess subjects. Insufflation was performed under two conditions: sustained vowel production and counting for a minimum of 10 seconds during each trial. Each condition was performed three times. Following each trial the catheter was removed and rinsed to assure that it was clean and clear of debris. Presentation of compressed air from a Thorpe flow meter (Puritan-Bennett Corporation, Kansas City, Missouri) at 3L per minute was used during the two conditions. This flow rate was chosen based on published findings suggesting that 3L of flow sustained esophageal insufflation throughout testing at a rate sufficient to produce vibration and to register intraluminal pressure changes on a pressure manometer (Lewin et al., 1987).

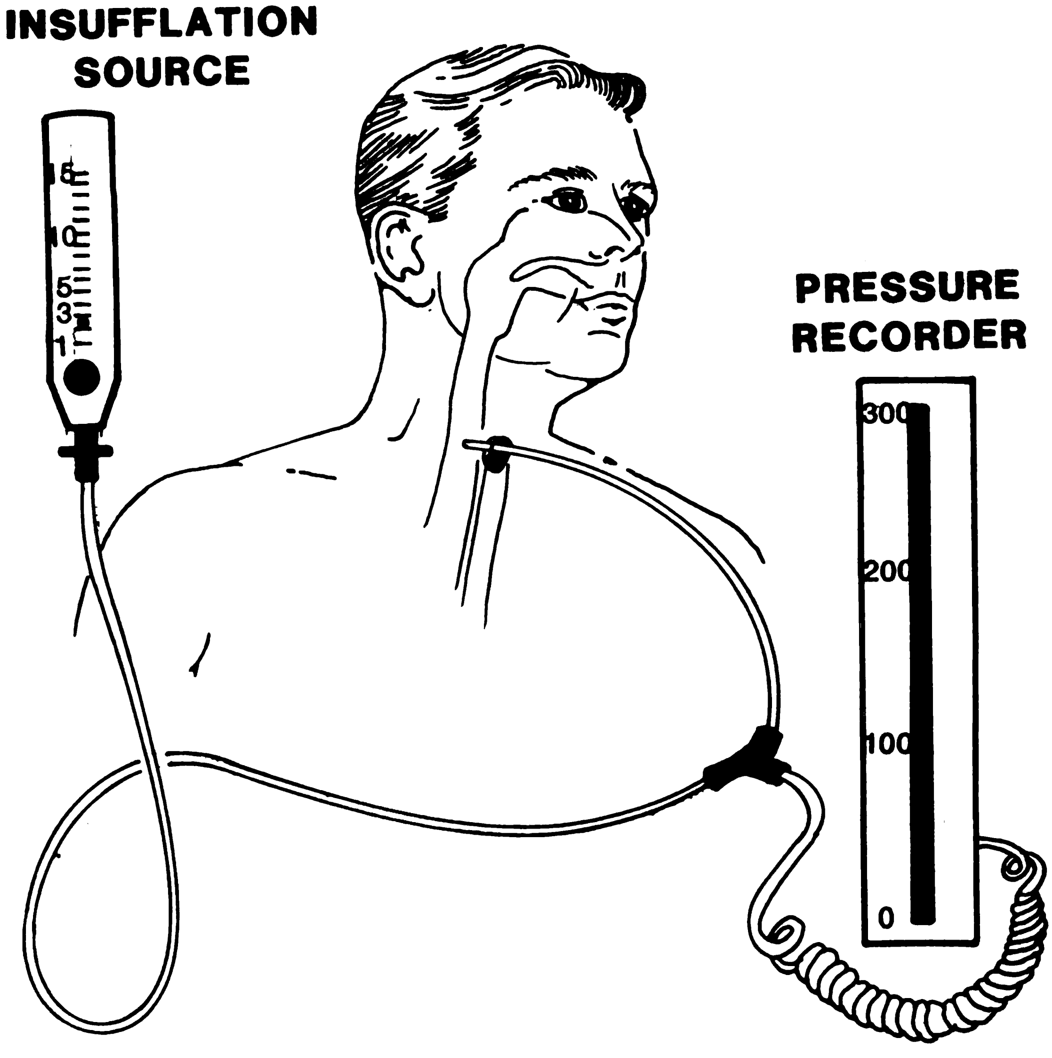

Figure 1. Diagram of testing apparatus demonstrating catheter placement, attachment to pressure recorder, and compressed airflow source.

Prior to insufflation, the patient was instructed to keep the mouth open as if producing the sound /a/ throughout testing. Airflow was initiated slowly. During each trial of insufflation, pressure levels fluctuated throughout the 10 seconds of sustained phonation of the phoneme /a/. The peak pressure was recorded. The maximum level of pressure, peak pressure was recorded since it was felt that the peak level of pressure should most closely represent the maximal jejunal response to ongoing insufflation during speech production. Phonatory duration was monitored using a stop watch and was dependent upon the length of time from the onset to the end of voicing. Air presentation was then stopped to allow the subject to rest. The catheter was disconnected from the "Y" connector and pressure manometer to allow the pressures to return to a baseline of zero. The catheter was then removed and rinsed prior to the next trial. The catheter was reconnected and the next testing was completed.

During the second condition, insufflation was performed as in the previous condition, except that the patient was instructed to count to 10 as sound was produced. The maximum number counted as well as the peak level of pressure were recorded. Again, air presentation was stopped, the patient was allowed to rest and the catheter was disconnected to allow baselines to return to zero. The catheter was removed, rinsed, and reconnected. The next

testing was completed. Again, the task was performed three times. Insufflation was terminated upon completion of each experimental condition or sooner, if the patient reported discomfort.

CHAPTER III

Results

Following continuous air insufflation during two conditions, sustained vowel production and counting, the peak pressure measurements of the control and experimental groups were analyzed to determine whether the groups were significantly different. All individuals were able to sustain sound for a minimum duration of ten seconds and were able to count to ten during ongoing air insufflation. Data were statistically analyzed using the Mann-Whitney test, Student's t-test and Pearson product-moment correlation comparisons because these tests were felt to be the most sensitive tests of samples of such small size (n = 13).

Subject Characteristics

Tables 1a and 1b demonstrate subject demographic and speech characteristics for the control and experimental groups. Three females and 6 males served as controls. Age ranged between 41 and 78 years with a mean of 63 years of age. The length of time since total laryngectomy (TL) and TE puncture to the date of testing for each of the control subjects ranged between 13 and 115 months since TL with a mean of 67.78 months and 13 and 105 months with a mean of 63.22 months since TE puncture. Four of the 9 subjects received their tracheoesophageal puncture primarily at the time of total laryngectomy as reflected by the same number of months in both the TL and TE columns of Table 1a. It is interesting to note that the youngest subject was not the most recent in terms of length of time from either surgery; however, the oldest subject was also the longest in terms of time since both surgeries. Three of the 9 control subjects had not received radiation therapy as part of their overall course of treatment.

Table 1a

Subject Characteristics - Control Group

Subject	Gender	Age	TL	TE	RT	UPC
1	F	59	42	22	Yes	Yes
2	F	41	68	68	Yes	Yes
3	M	60	77	75	No	Yes
4	M	61	13	13	Yes	Yes
5	M	67	88	88	Yes	Yes
6	F	62	63	62	No	Yes
7	M	71	51	51	Yes	Yes
8	M	68	93	85	Yes	Yes
9	M	78	115	105	No	Yes
Mean	-	63	67.78	63.22	-	-

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
TE = Number of months from tracheoesophageal puncture to date of testing
RT = Receipt of radiation therapy
UPC = Use of voice prosthesis for communication

As Table 1a demonstrates, no information regarding jejunal interposition (JI) is supplied. For statistical comparison, the data for time from TL to the date of testing were used to supply data for comparisons with the experimental group since the control group's surgeries did not include jejunal interposition.

Three males and 1 female served as experimental subjects. The youngest subject was 51 years old. Two subjects who were 62 years of age were the oldest. Mean age was 59 years. As Table 1b demonstrates, Subjects 3 and 4 had the shortest times from all surgeries to the time of testing. Subjects 3 and 4 also had all three surgical procedures including total laryngectomy, jejunal interposition and tracheojejunal puncture completed at the same time as indicated by the same number in each of the three columns. Subjects 1 and 2 underwent multi-staged procedures on separate dates. The length of time since total laryngectomy to the date of testing ranged between 1 and 61 months with a mean of 22.75 months. The length of time since jejunal interposition ranged between 1 and 56 months with a mean of 20 months. The range of time since tracheojejunal puncture was between 1 and 54 months with a mean of 19 months. Half of the subjects had received radiation therapy as part of their overall treatment course, whereas the other two had not.

Table 1b

Subject Characteristics - Experimental Group

Subject	Gender	Age	TL	JI	TJ	RT	UPC
1	M	62	61	56	54	Yes	No
2	F	51	25	19	17	No	No
3	M	62	1	1	1	No	No
4	M	61	4	4	4	Yes	No
Mean	-	59	22.75	20	19	-	-

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
JI = Number of months from jejunal interposition to date of testing
TJ = Number of months from tracheojejunal puncture to date of testing
RT = Receipt of radiation therapy
UPC = Use of voice prosthesis for communication

Subjects in both groups wore the voice prosthesis at the time of testing, but only the control group used the voice prosthesis for daily communication. None of the experimental subjects reported routine use of the voice prosthesis for speech purposes. Although Subjects 3 and 4 in the experimental group had limited practice using the device given the short amount of time since TE puncture to the time of testing, one and four months respectively, no attempt to speak with the device was made by either subject. Functional alaryngeal speech restoration with TJ puncture appears equivocal for this group.

Table 2a shows central tendency and dispersion data for age, time from total laryngectomy and TE puncture for subjects in the control group. Mean age was 63 years with a standard deviation of 10.27 years. The average time since total laryngectomy to the time of testing was 67.78 months with a standard deviation of 30.27 months. A mean of 63.22 months since tracheoesophageal puncture to the time of testing with a standard deviation of 30.35 months occurred.

Table 2a

Central Tendency and Dispersion Data - Control Group; n = 9

	Minimum	Maximum	Mean	Standard Deviation
Age	41.00	78.00	63.00	10.27
TL	13.00	115.00	67.78	30.27
TE	13.00	105.00	63.22	30.35

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
TE = Number of months from tracheoesophageal puncture to date of testing

The mean age for the experimental group was 59 years with a standard deviation for the 4 subjects of 5.35 years. The time since total laryngectomy averaged 22.75 months to the time of testing with a standard deviation of 27.65 months. The average time since jejunal interposition (JI) to the time of testing was 20 months with a standard deviation of 25.26 months. The mean time from tracheojejunal puncture to the time of testing was 19 months with a standard deviation of 24.35 months. Central tendency and dispersion data for age, time from total laryngectomy, jejunal interposition and TJ puncture for the experimental group are summarized in Table 2b.

Table 2b

Central Tendency and Dispersion Data - Experimental Group; n = 4

	Minimum	Maximum	Mean	Standard Deviation
Age	51.00	62.00	59.00	5.35
TL	1.00	61.00	22.75	27.65
JI	1.00	56.00	20.00	25.26
TJ	1.00	54.00	19.00	24.35

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
JI = Number of months from jejunal interposition to date of testing
TJ = Number of months from tracheojejunal puncture to date of testing

A comparison between the control and experimental groups reveals slightly less variability overall in the experimental group. However, given an n of only 4, this finding is not surprising. The recent use of jejunal interposition as a routine surgical alternative for reconstruction following resections for carcinoma of the laryngopharynx further decreases the potential variability of time from surgery in the experimental group. In general, both groups appear to be similar in age; however, the control group demonstrated greater time since all surgical procedures. This might imply longer and complete surgical recovery and greater opportunity for practice and use with the voice prosthesis for speech purposes for the control subjects. Given the decreased time since surgery to the time of testing for 2 of the experimental subjects, factors related to incomplete recovery may have influenced results. For example, the influence of unresolved edema on TJ voice production and its use for speech purposes should be considered when making comparisons to the control group.

Correlation Analysis by Subject Characteristics

A correlation of the relationship between subject characteristics and experimental variables is illustrated in Table 3 for both groups of subjects. Inverse relationships between the length of time since each of the three surgical procedures and the intraluminal pressure associated with vowel prolongation and counting and the length of time and intraluminal pressure variability are noted. As length of time from surgery increased, the intraluminal pressures associated with each task and the variability of the pressure decreased. Although none of the correlations were found to be statistically significant ($p \leq 0.05$, tabled value ≤ 0.5529), stronger correlations are demonstrated between length of time since surgery and the intraluminal pressures associated with task performance during sustained /a/ production. The correlation between TL and /a/ was r = -0.3926, r = -0.4150 for TJ and /a/, and r = -0.4594 for TE. The correlation between TL and counting was r = -0.1137, r = -0.1306 for TJ and counting, and r = -0.1974 for TE. Comparatively, weaker correlations are found between length of time since surgery and the variability of the intraluminal pressure measurements associated with task performance. The correlation between TL and the variability of /a/ was r = -0.1443, r = -0.1901 for TJ and the variability for /a/, and r = -0.1503 for TE. The correlation between TL and the variability of counting was r = -0.0962, r = -0.1218 for TJ and the variability of counting and r = -0.0942 for TE. Statistical significance remains difficult to detect because of the small sample size.

Table 3

Correlation Matrix Demonstrating the Relationship Between Subject Characteristics and Task Performance for All Subjects

	Task			
	/a/	Count	/a/SD	Count SD
Age	0.118	0.2628	-0.4139	0.0327
TL	-0.3926	-0.1137	-0.1443	-0.0962
TJ	-0.4150	-0.1306	-0.1901	-0.1218
TE	-0.4594	-0.1974	-0.1503	-0.0942

N = 13
DF = 11
R @ 0.0500 = 0.5529

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
TJ = Number of months from tracheojejunal puncture to date of testing
TE = Number of months from tracheoesophageal puncture to date of testing

Power Analysis

A power analysis of the data suggests that in order to have an 80% chance of detecting a significant correlation at the 0.05 level for a two-tailed test, the correlation coefficient would need to assume a value of 0.70 or higher in a similar study with 13 cases. Alternatively, in order to have an 80% chance of detecting a significant correlation at the 0.05 level for a two-tailed test using a correlation coefficient of approximately 0.40, the number of subjects would need to be increased beyond the current 13 to a total of 45. Given the particular subject characteristics of this population, statistical significance may be difficult to achieve in either circumstance.

Correlation Analysis by Gender

In order to determine the strength and direction of the relationship between intraluminal pressure and task performance based upon gender, a correlation analysis was applied separately for males and females. Tables 4a and 4b illustrate the data. Inspection of the data presented for female subjects in Table 4a suggests stronger correlations for female subjects particularly between the time since all surgeries to the date of testing and both of the tasks including sustained /a/ and counting. The correlation between TL and /a/ was $r = -0.8939$, $r = -0.8794$ for TJ and /a/, and $r = -0.8814$ for TE. The correlation between TL and counting was $r = -0.9151$, $r = -0.8823$ for TJ and counting, and $r = -0.9839$ for TE. The inverse relationship suggests that longer times from surgical procedures are correlated with lower pressures associated with voicing and speech production. Only the males demonstrated an inverse relationship between the time since any of the surgeries and the variability in pressure on the counting task. This might suggest that there is less variability in pressure associated with counting the further one is from surgery for male subjects. Although the time from TE puncture and the peak pressures associated with counting was found to be statistically significant, none of the other correlations were found to be significant for the female subjects ($p \leq 0.05$, tabled value ≤ 0.9500). None of the correlations were found to be statistically significant for the male subjects ($p \leq 0.05$, tabled value ≤ 0.6664) on any variable.

Table 4a

Correlation Matrix Demonstrating Relationship Between Subject Characteristics and Task Performance for Female Subjects

	/a/	Count	/a/SD	Count SD
Age	0.5857	0.4299	-0.1799	0.7008
TL	-0.8939	-0.9151	-0.3234	0.3189
TJ	-0.8794	-0.8823	-0.3910	0.3139
TE	-0.8814	-0.9839	-0.0513	0.3665

n = 4
DF = 2
R @ 0.0500 = 0.9500

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
TJ = Number of months from tracheojejunal puncture to date of testing
TE = Number of months from tracheoesophageal puncture to date of testing

Table 4b

Correlation Matrix Demonstrating Relationship Between Subject Characteristics and Task Performance for Male Subjects

	/a/	Count	/a/SD	Count SD
Age	-0.0284	-0.0653	-0.1781	-0.2599
TL	-0.3304	0.0070	-0.0827	-0.1553
TJ	-0.3482	-0.0052	-0.1186	-0.1914
TE	-0.3821	-0.0388	-0.1165	-0.1867

n = 9
DF = 7
R @ 0.0500 = 0.6664

Age = Number of years old at time of testing
TL = Number of months from total laryngectomy to date of testing
TJ = Number of months from tracheojejunal puncture to date of testing
TE = Number of months from tracheoesophageal puncture to date of testing

Peak Pressure Measurement Analysis

Individual peak pressure measurements are presented for both the control and experimental groups in Tables 5a and 5b. Of interest are the peak pressure measurements above 20 mmHg for the control group during both tasks. Previously published data by Lewin et al. (1987) suggested a level of 20 mmHg as the maximal elevation in pressure for fluent TE speakers during similar tasks of sustained vowel duration and counting. It should be noted that while peak pressures did demonstrate mild elevations above 20 mmHg for some control subjects, no simultaneous phonatory deterioration in task performance occurred during either task for any of the subjects. All subjects in the control group were able to sustain /a/ for a minimum of 10 seconds during insufflation and were able to count to 10 without interruption.

Table 5a

Individual Peak Pressure Recordings in mmHg for /a/ and Counting - Control Group

	/a/ Trial 1	/a/ Trial 2	/a/ Trial 3		Counting Trial 1	Counting Trial 2	Counting Trial 3
1	22	20	22	1	24	20	22
2	20	8	8	2	10	8	8
3	8	8	8	3	18	14	14
4	16	16	16	4	15	14	16
5	14	12	10	5	14	15	14
6	22	8	26	6	8	7	22
7	20	21	14	7	20	12	14
8	20	26	22	8	28	26	28
9	18	18	20	9	18	20	18
mean	17.778	15.222	16.222	mean	17.222	15.111	17.333

Peak pressure recordings in the experimental group as shown in Table 5b demonstrated higher peak pressure measurements during sustained /a/ compared to the control group. None of the experimental subjects demonstrated the same peak pressure elevations during any of the 3 trials under either condition, sustained /a/ or counting, whereas Subjects 3 and

4 in the control group produced the same peak pressure elevations during all three trials of sustained /a/ as shown in Table 5a.

Table 5b

Peak Pressure Recordings in mmHg for /a/ and Counting - Experimental Group

	/a/ Trial 1	/a/ Trial 2	/a/ Trial 3
1	30	38	12
2	20	40	12
3	22	18	20
4	22	32	32
mean	23.500	32.000	19.000

	Counting Trial 1	Counting Trial 2	Counting Trial 3
1	40	14	18
2	20	24	20
3	10	22	12
4	30	28	28
mean	25.000	22.000	19.500

The means for each of the 3 trials for each task were computed and compared. To determine whether the 2 groups were significantly different from one another based on their pressure measurements during either task, a Mann-Whitney test was performed. Results are illustrated in Table 6. The statistically significant difference that was found between the groups during sustained /a/ production, ($U=2$, $p \leq 0.01$), was extrapolated from Siegel (1956) in Table K (p. 275). The experimental group demonstrated significantly greater pressure measurements than the control group during sustained vowel production. No significant difference in peak pressure measurements was found during counting nor in pressure variability during either task using the Mann-Whitney test ($U=9$, $p \geq 0.05$) as extrapolated from Siegel (1956) in Table K (p. 277).

Table 6

Mann-Whitney Test for Tasks and Variability in Task Performance Between Groups

Variable	U-Statistic	P-value (one-tailed)
/a/	2.00	$p \leq 0.01$
count	9.00	$p \geq 0.05$
/a/SD	6.50	$p \geq 0.05$
count SD	8.50	$p \geq 0.05$

Further analysis of the data using a two-sample t-test confirmed findings of the Mann-Whitney test. Data are presented in Table 7. Statistical significance was found between groups during the sustained vowel production ($0.0106 = p \leq 0.05$). T-test analysis also revealed a statistically significant difference in the pressure variability between groups during sustained /a/ production ($0.0402 = p \leq 0.05$). Although no significant difference was found between groups in peak pressure measurements during counting, an examination of the means for both groups (control $\bar{x}$ = 16.556; experimental $\bar{x}$ = 22.167) reveals higher pressure associated with counting by the TJ speakers than the TE speakers.

Table 7 also shows higher variances associated with counting (control variance = 30.083; experimental variance = 34.185) than with sustained vowel production (control variance = 23.383; experimental variance = 14.037) for both groups. These results suggest higher pressure variation for both groups during the counting task. The higher variances along with the small sample size reduce the ability to statistically demonstrate a significant difference between groups on the counting task.

Table 7

Two-sample t-test Analysis of Intraluminal Pressures Associated With Task Performance

Variable	Group	c	e	Test Statistic	DF	Significance
/a/	Mean Variance N	16.407 23.383 9	24.833 14.037 4	T = 3.0719 F = 1.6658	11 8,3	0.0106 0.3673
Count	Mean Variance N	16.556 30.083 9	22.167 34.185 4	T = -1.6716 F = 1.1363	11 3,8	0.1228 0.3911
/a/SD	Mean Variance N	3.0589 10.432 9	8.8781 35.795 4	T = -2.3249 F = 3.4313	11 3,8	0.0402 0.0725
Count SD	Mean Variance N	2.4334 6.1300 9	5.9733 33.760 4	T = -1.5935 F = 5.5073	11 3,8	0.1393 0.0239

c = control group
e = experimental group

A statistically significant difference between groups in pressure variability was detected during sustained vowel production as represented in Table 7 by the variable /a/SD, throughout the three trials using the t-test analysis ($0.0402 = p \leq 0.05$). An examination of the means for /a/SD for both groups and their variances (control $\bar{X} = 3.0589$, variance = 10.432; experimental $\bar{X} = 8.8781$, variance = 35.795) demonstrates less variability in pressure for the controls during sustained vowel production throughout the three trials. The greater variability for the experimental group may suggest greater difficulty in regulating and controlling sound production by individuals with jejunal interposition as compared to tracheoesophageal speakers. This variability may also be the result of the small sample size.

Power Analysis

A power analysis for independent groups and one-tail test for unequal ns was performed in order to project the number of cases needed to extract a valid number for significance between groups during counting. The results of the analysis are presented in Table 8. The table shows that the present results allow for a 50% chance measurement of significance based on the available raw data. Assuming these data are representative of the true means of the total population, the number of subjects would need to be increased to 12 in each group in order to have an 81% chance of detecting a significant difference between groups. A subject pool of 20 in each group would allow for a 95% chance of detecting significance, whereas 30 in each group would allow for a 99% chance of finding a significant difference between groups. The extremely poor rates for long-term survival in this population, as well as the relatively rare occurrence of such advanced stage III and IV carcinomas of the laryngopharynx which necessitate jejunal interposition, suggest the practicality of locating even a subject pool of 12 per group may be difficult. The results of the present power analysis suggest that longitudinal study with retrospective analysis of this population may be the more practical investigative design.

Table 8

Power Analysis for Counting - Independent Groups and One-tail Test for Unequal ns

t-test Parameters				
Significance level	0.05			
Mean in Group 1	16			
Mean in Group 2	22			
Standard deviation	5.656854			
Number of cases in Group 1	9.0	12	20	30
Number of cases in Group 2	4.0	12	20	30
Power	0.50	0.81	0.95	0.99

CHAPTER IV

Discussion

These findings provide support for the hypothesis that following jejunal interposition and tracheojejunal puncture, TJ voice and speech production are associated with increased pressure measurements when compared to pressure measurements associated with tracheoesophageal speech production in patients following total laryngectomy and TE puncture. While all of the control subjects used the voice prosthesis for communication, none of the four TJ speakers in this study used the voice prosthesis for speech purposes. Although functional speech restoration as indicated by the patient's use of the voice prosthesis for communication appears reduced for patients with TJ puncture, the findings do not provide absolute confirmation of increased pressure as the sole reason for lack of reliance on TJ voice for communication. The recency of surgery for half of the experimental subjects and the limited time using the prosthesis along with the possibility of incomplete recovery from all surgeries may have limited vocal competency and, therefore, the use of the prosthesis for communication. Possible delays in postoperative healing and associated complications such as continued edema and reduced familiarity with the prosthesis must be considered when using the results of this study to examine the efficacy of this method for alaryngeal speech restoration in patients with jejunal interposition and TJ puncture. These factors and the number of experimental subjects in this study make it difficult to statistically substantiate findings.

Despite the limitations of the subject pool, several significant findings and trends are clear. As the length of time from surgery increased, the intraluminal pressures associated with each task and the variability of the pressure decreased. This inverse relationship between length of time from surgery and pressure suggests that the greater the length of recovery from surgery the easier it becomes to speak. One possible explanation for this finding may involve the stability and tone of the musculature following surgery. Immediately following total laryngectomy, a temporary but complete compromise of the musculature occurs as a result of the resection and removal of the larynx. However, over time vascularization and partial reinnervation occurs concomitantly with healing, improving the tone and stability of the resected musculature. These changes may, in fact, assist phonatory vibration by providing greater consistency in muscle tone.

While statistical analysis did not reveal a strong relationship between length of time from surgery and the variability of pressure measurements, there was an overall decrease in the pressure variability. Two of the control subjects demonstrated the same peak pressure measurements over three trials of sustained vowel production suggesting greater stability, tone and control of the vibratory segment during phonation with longer postoperative recovery.

One other explanation for the decreased pressure variability in TE speakers compared to TJ speakers may be that the pharyngeal wall has a better ability to vibrate than the jejunal wall making it a superior vibratory replacement for alaryngeal sound production. Pharyngeal physiology may in itself provide more regularity and stability than the jejunum during vibration.

Greater pressure variation associated with speech production may occur in patients following jejunal interposition as a result of the continued, unmodulated peristalsis and segmental contractions which occur in the transposed graft. Although the grafts are extrinsically denervated, the intrinsic contractions of the graft may continue for several months post-surgery (Kerlin et al., 1986) and potentially inhibit tracheojejunal phonation. Interestingly, experimental Subject 1 who had the longest duration since all surgeries, approximately 5 years, was continuing to demonstrate intrinsic peristaltic activity as indicated by his physician following recent direct laryngoscopy. The same subject also demonstrated consistently higher pressure elevations during the two phonatory tasks.

The results of this study do not support any significant differences between males and females based on pressure measurements during performance of either task. Although correlations appear to be stronger for female subjects between the length of time from surgery and lower pressure levels for phonatory tasks, male subjects demonstrated stronger correlations between length of time from surgery and decreased pressure variability during counting. Female subjects also demonstraed a statistically significant correlation between the time from TE puncture and peak pressure measurements during counting. None of the other correlations for any task by either gender were found significant. These findings may actually be a result of the small size of the sample rather than a true finding in the population.

Intraesophageal peak pressure measurements varied between 8 and 26 mmHg during sustained vowel production for the TE speaker group, whereas the TJ speakers produced a sustained vowel production associated with a pressure range of 12-40 mmHg. Both groups were able to sustain /a/ for 10 seconds without vocal deterioration. Statistical analysis of the difference in pressure ranges for both groups was found to be statistically significant. Again, this finding supports the hypothesis that TJ sound production is associated with higher pressures than TE sound production.

Individual peak pressure measurements between 7 and 28 mmHg occurred for the control group during counting. Peak pressure measurements occurred between 10 and 40 mmHg for the 4 experimental subjects during the counting task. Although no significant difference was found, higher pressure measurements were associated with counting by the TJ speakers as compared to the control group of TE speakers. Despite a lack of a statistically significant difference, the pressure variation during counting for both the control and experimental subjects was consistently higher than the pressure variation during sustained vowel production by both groups. This finding may suggest an influence of articulation on connected speech sounds.

Before examining the pressure differences between the two groups during task performance, it is interesting to note the particular range of pressure associated with fluent TE speech for the control group during performance of both tasks. Previous documentation by Lewin et al. (1987) suggests pre-TE puncture pressure measurements less than or equal to 20 mmHg are a good predictor of fluent postoperative TE speech. Patients who obtained fluent TE speech without myotomy post-TE puncture had low intraesophageal peak pressure measurements (< 20 mmHg), a minimum of 10 seconds of uninterrupted sound production and an ability to produce at least 10 syllables per breath preoperatively. Patients whose peak pressure measurements were above 20 mmHg also demonstrated phonatory and speech deterioration below the established criterion prior to TE puncture. They achieved fluent speech production following myotomy of the pharyngeal constrictor musculature. Pressure measurements post-myotomy were similar to preoperative pressure measurements for the fluent speakers (< 20 mmHg) pre-TE puncture.

All subjects who served as controls in the current study were at least 1.5 years post-TE puncture. The subject with the longest time since TE puncture was 8.75 years. All subjects were fluent speakers. No vocal deterioration occurred during air insufflation in subjects whose peak pressure measurements were above 20 mmHg as had occurred in non-fluent subjects prior to TE puncture in the Lewin et al. (1987) study. Several explanations may be considered.

In the original study, subjects were tested prior to surgery. Those patients who received myotomy were then retested shortly after surgery. Again, it is possible that changes in the tone of the musculature continues to improve with the passing of time post-surgery. Therefore, the current elevations in peak pressure measurements during insufflation may represent the pressure needed to overcome the resting tone of the pharyngoesophageal (PE) segment post-healing in patients who served as control subjects in the present study. Unlike subjects in the original study, elevated peak pressure measurements in the present subjects were not associated with deterioration in vocal tasks nor did pressure measurements continue to rise as occurred in patients with hypertonicity of the PE segment in the original study. Clearly, the elevations in peak pressure measurements in control subjects in the current study are different from the elevations associated with deterioration in speech tasks by patients in the original study.

Another possible explanation for the extended pressure range in the present control subjects may involve possible over-insufflation of air. Given the presumed improvement in muscular tone of the vibratory segment over time post-surgery, 3L per minute of airflow may have been excessive resulting in elevated pressure measurements and an inferior egress of the unused portion to the stomach. In the study by Lewin et al. (1987), gastric filling with air was reported by subjects and was indicated by marked elevations in pressure. In the present study, air eructation was noted in some subjects following air insufflation.

The method of air insufflation may also be a factor affecting intraluminal pressure measurements. Transtracheal air insufflation was performed in the present study, whereas transnasal air insufflation, as illustrated in Figure 2, was used in the original study by Lewin et al. (1987). While both methods were found to adequately insufflate the esophagus for sound production, the placement of the catheter into the esophagus may inadvertently affect resulting pressure measurements.

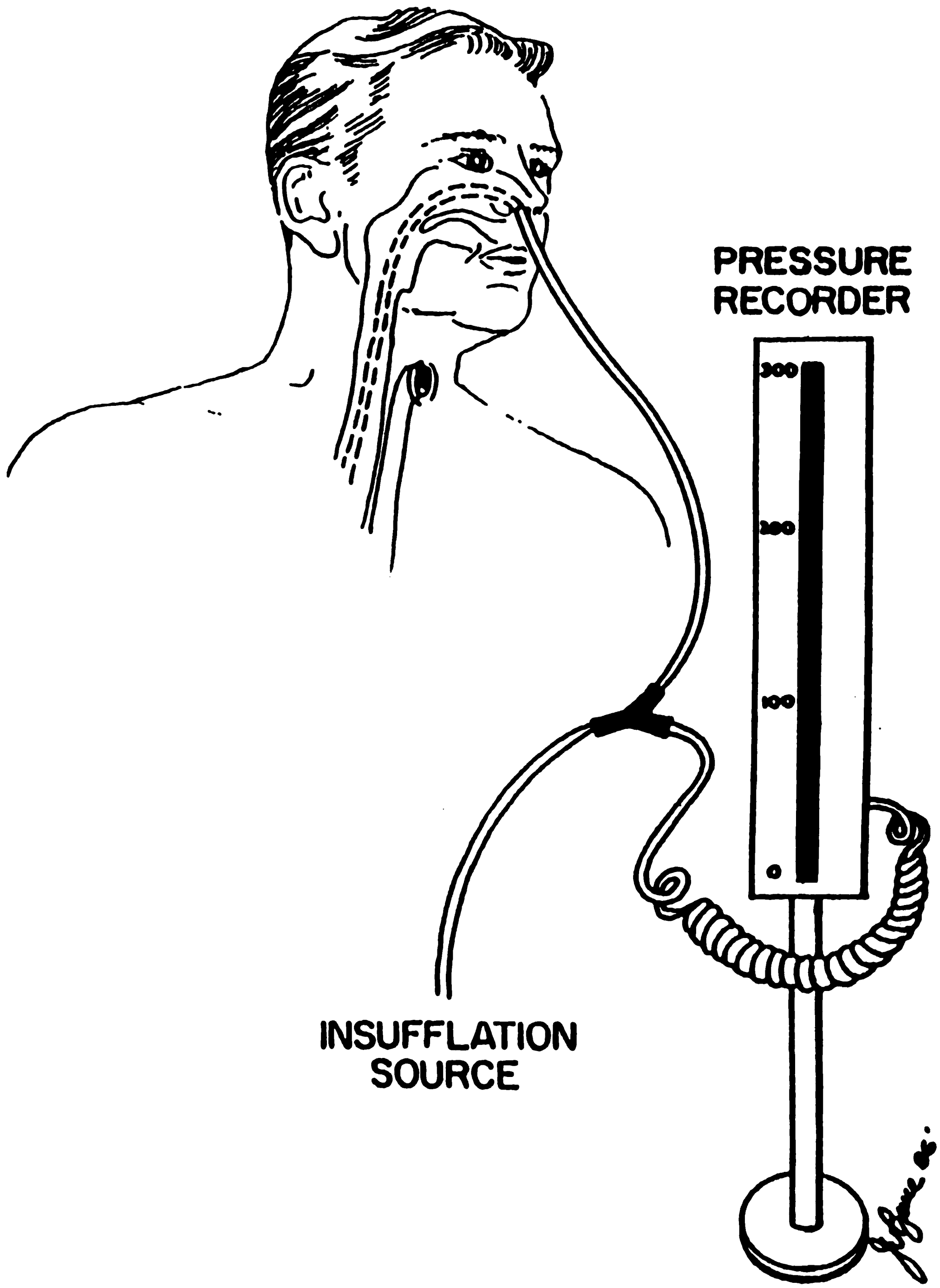

Figure 2. Diagram of testing apparatus demonstrating catheter placement, attachment to pressure recorder, and insufflation source for preoperative prediction of postoperative TE speech.

Many TE speakers are also able to speak using traditional esophageal methods of oral air implosion. It has been suggested that self-injection of air through oral implosion as used by traditional esophageal speakers may interfere with external methods of air insufflation by falsely elevating pressure measurements. Again, inadvertent non-volitional control over the vibrating segment may have resulted in an increase in pressure measurements in control subjects.

Returning to the current results, a statistically significant difference in peak pressure measurements between the control and experimental subjects during sustained vowel production was found. A trend towards increased pressure associated with counting by the experimental subjects compared to lower pressure generated on the same task by the control subjects was also found. Both findings support the original hypothesis of elevated pressure associated with TJ speech production.

The need for increased air pressure by TJ speakers for jejunal vibration may be a reason for the increased effort often reported by TJ speakers to maintain TJ speech production. While increased intraluminal pressure may not be the sole reason for failure of the TJ speakers in this study to use the voice prosthesis for routine communication, it can certainly be considered a barrier to the ease of speech production. When combined with the need to overcome the resistance of the various voice prostheses to airflow (Weinberg, 1982), increased patient effort to speak may be a limiting factor to the use of voice prostheses for TJ communication. Patient effort is an important consideration when evaluating the method as a viable and efficacious alternative for communication in patients with jejunal interposition.

Greater pressure variability was also demonstrated for both groups during counting than during sustained vowel production. Greater variation in pressure measurements during speech tasks may reflect the influences of phrasing and articulatory valving on continuous airflow compared to a sustained phonatory production. The significance of possible influences on TJ speech production warrants further investigation.

A significant difference between groups in the pressure variability during sustained /a/ throughout the three trials was demonstrated. Less variability in pressure occurred in control subjects than experimental subjects. Although the jejunum is well suited in its physical similarities to the pharynx and esophagus as an appropriate substitute for reconstruction of the laryngopharynx and cervical esophagus after extirpative tumor resections, the inherent differences in its physiology, lumen diameter and wall thickness most likely provide greater resistance to phonatory vibration. Again, the greater variability for the experimental group may suggest greater difficulty in the regulation and control of sound production for individuals with jejunal interposition as compared to TE speakers.

Although no significant difference was found in pressure measurements between the control and experimental groups during counting, the limited number of subjects in the sample may have reduced the actual detection of a real difference. Based on a power analysis of the data, the possible recruitment of a minimum of 12 subjects per group may allow for a significant detection of a real difference between the groups. However, the high mortality and morbidity rates in patients with advanced Stage III and IV carcinoma of the laryngopharynx and cervical esophagus, as well as the relatively rare occurrence of such tumors, make the practicality of locating even a subject pool of 12 per group difficult for assessment in a single short term study. Furthermore, the variation in surgical technique from surgeon to surgeon -- including the placement of the TJ puncture -- offer further challenges to obtaining similar samples of adequate size. It appears that the answers to the questions posed in this investigation based on the results of the present power analysis may be better found through longitudinal study and retrospective analysis of this population.

CHAPTER V

Conclusions and Future Directions for Research

Summary

This investigation has attempted to examine tracheojejunal voice production by assessing the intraluminal pressure associated with its production and comparing the results to the intraesophageal pressure produced by tracheoesophageal speakers during the production of two tasks in two groups of laryngectomees. It has been the experience of this examiner that patients who have undergone tracheojejunal puncture following jejunal interposition for extirpative removal of malignant tumors involving the laryngopharynx are able to produce tracheojejunal phonation. However, the use of TJ sound production for routine communication by TJ speakers is markedly less than the use of TE sound production for speech purposes by patients following simple laryngectomy and TE puncture. A review of the literature reveals a myriad of subjective descriptions of tracheojejunal sound production; however, little objective evaluation of TJ voice production is available to either support or refute the method as a viable, efficacious alternative for alaryngeal speech restoration in patients with extended tumor resections involving the hypopharynx and cervical esophagus. This study, therefore, proposed that increased pressure measurements were associated with TJ speech production and may be one factor which might negatively affect the use of TJ voice production for routine communication.

Although the results of this study generally supported the hypothesis of increased pressure associated with tracheojejunal voice production, only the task associated with sustained vowel production was found to be significantly different based on pressure measurements between the two groups of laryngectomees. Although statistical significance was not found between the groups during the counting task, the experimental group did demonstrate greater pressures associated with task production supporting the proposed hypothesis. Greater variability in pressure responses during counting and the small size of the sample made the detection of significance during this task difficult.

The possibility of differences in pressure associated with task performance based on gender could not be definitively determined. Stronger relationships which demonstrated decreased pressure variability over time associated with counting was found for male subjects. Female subjects demonstrated less pressure associated with the production of either task the longer they were recovered from the time of surgery. Whether this distinction between genders is an accurate reflection of the population is questionable given the limitations of the sample. Personal experience has not found this distinction to be true.

Questions regarding the tone and stability of the vibratory segment in relationship to the length of time from surgery and other factors -- including adequate healing of tissue and adequate practice using the voice prosthesis -- suggest that a longitudinal analysis of subjects may be needed to better assess these factors. A power analysis of the data has suggested that a minimum of 12 subjects in each group would be needed in order to have approximately an 80% chance of finding a significant difference between groups based on pressure measurements.

Future Research

Given the poor rates for long-term survival in patients with carcinoma of the hypopharynx and cervical esophagus as well as the extremely rare incidence of these types of tumors which require jejunal reconstruction, a multi-institutional investigation involving longitudinal study with retrospective analysis is probably the more practical investigative method to answer questions regarding statistical significance. Despite a lack of statistically significant results, the clinical relevance of findings should not be overlooked. A trend in results may be as important to decisions regarding quality of life as finding statistical significance in this population.

As part of the assessment method of this investigation, three successive trials per task were completed by each patient. Only 2 control subjects were able to replicate the same pressures on each trial per task. All other patients produced different peak pressure measurements during each trial of either task. Future research is needed to investigate the factors which influence the intra-subject variability in pressure associated with TE and TJ voice production. An understanding of these factors may offer the possibility of greater volitional control over the vibratory segments following laryngectomy or laryngopharyngectomy, thus enhancing the efficiency and success of speech restoration in both populations of laryngectomees.

The results of the present study demonstrated a difference in the level of air pressure required to produce a steady state vowel versus speech production. Further investigation is needed to determine the factors affecting the changes in intraluminal air pressure associated with each type of production so that voice prostheses which offer the least resistance to airflow can be chosen to meet individual patient requirements for speech production.

A better physiological understanding of the jejunal autograft including its continued ability to produce peristaltic contractions is also suggested as an avenue for further research with respect to its viability as a phonatory source for alaryngeal voice production. Mucous secretion, which is one of the advantages of the jejunal autograft for enhancing the act of swallowing, may in fact be responsible for the "wet" or liquid quality of the resulting voice which many patients find unattractive.

Future studies are also needed to answer questions regarding the location of TJ vibration in patients with TJ puncture following jejunal interposition. The results may provide valuable information regarding surgical decisions as to the actual placement of the puncture site during surgical resections. Specific information as to the location of tracheojejunal vibration may also help speech pathologists provide more appropriate treatment to facilitate tracheojejunal speech production. Such information may also be beneficial in optimizing current prosthetic designs while prompting new types of voice prostheses.

In this study none of the experimental subjects used their voice prostheses for routine speech production. While the results of this study do not provide conclusive evidence to contradict the method of tracheojejunal puncture and voice restoration for patients with jejunal interposition, they do provoke further questions which need to be answered in order to ultimately provide the optimal method of communication while avoiding patient frustration and communicative failure in this population.

APPENDICES

APPENDIX A

OBJECTIVE AIR INSUFFLATION FORM

APPENDIX A

SPEECH-LANGUAGE PATHOLOGY
Department of Otolaryngology - Head & Neck Surgery
University of Michigan Hospitals
(313) 763-4003

Patient:
Reg #:
Date of Birth:
Date of Evaluation:
Referral Source:

OBJECTIVE AIR INSUFFLATION

Catheter Placement: Transtracheal catheter distance - _____cm

Sustained /a/

Trial 1	Trial 2	Trial 3
_____mmHg _____sec.	_____mmHg _____sec.	_____mmHg _____sec.
_____mmHg _____sec.	_____mmHg _____sec.	_____mmHg _____sec.
_____mmHg _____sec.	_____mmHg _____sec.	_____mmHg _____sec.

Counting

Trial 1	Trial 2	Trial 3
#s_____ _____mmHg	#s_____ _____mmHg	#s_____ _____mmHg
#s_____ _____mmHg	#s_____ _____mmHg	#s_____ _____mmHg
#s_____ _____mmHg	#s_____ _____mmHg	#s_____ _____mmHg

APPENDIX B

MICHIGAN STATE UNIVERSITY INFORMED CONSENT FOR EXPERIMENTAL PROCEDURE

APPENDIX C

The University of Michigan Medical Center

INFORMED CONSENT FOR EXPERIMENTAL PROCEDURE

(Version January 1992)

1. Title of research project.

Objective Pressure Measurements in Two Groups of Laryngectomees

2. Names of the researchers.

Jan S. Lewin, M.S.

3. Purpose of the research.

This investigation is being done to compare the pressure measurements of individuals who have undergone laryngectomy with the pressure measurements of individuals who have undergone laryngopharyngectomy with free jejunal graft reconstruction. This information will provide a better understanding of tracheojejunal sound production as an alternative for alaryngeal speech production.

4. Number of subjects included in the study.

Ten patients who have had laryngopharyngectomy with jejunal reconstruction and ten patients who have had laryngectomy.

5. Description of the experiments.

A small catheter will be gently inserted into the puncture site and air will gently insufflate the esophagus and/or jejunum. The catheter will be connected to a pressure recorder. Pressure measurements will be recorded during two tasks. You will be asked to keep your mouth open while air is gently insufflated simulating the production of an "ah." During the second task you will be asked to count during gentle insufflation. Again, pressure measurements will be recorded.

6. Risks, discomforts and inconveniences of the research.

There are no known risks associated with air insufflation. Some patients may experience gastric filling with air and experience mild discomfort associated with air in the stomach.

7. Measures to be taken to minimize risks, discomforts and inconveniences.

At any time should you complain of discomfort the procedure will be terminated. You will be tested in the University of Michigan Hospital, Otolaryngology Clinic. A physician will be available at any time within the clinic, should assistance be needed.

8. Expected benefits to subjects or to others.

It is important that the selected method of voice restoration attempt to obtain rapid and effective vocal rehabilitation. This investigation will provide information as to the value of tracheojejunal voice for alaryngeal speech purposes. The results of this study may also have ramifications to surgical decisions.

9. Appropriate alternative procedures.

This assessment procedure is done routinely as part of the preoperative voice examination. If you decide that you do not wish to participate in this study, you will still receive this examination as part of your preoperative assessment.

10. Costs to subject or insurance carrier resulting from participation in the study.

I understand that my participation in this research project will not involve any additional costs to me or my health care insurer.

11. Payments to subject for participating in the study.

Subject participation will be strictly voluntary. Subjects will not be paid for research participation.

12. Confidentiality of information collected.

I understand that I will not be identified in any reports on this study. The records will be kept confidential to the extent provided by Federal, State, and local low.

13. Management of physical injury.

You will be tested in the Otolaryngology Clinic. In the event of a physical injury, which may result from research procedures, the University of Michigan will provide first-aid medical treatment. Additional medical treatment will be provided in accordance with the determine by the University of its responsibility to provide such treatment. However, the University does not provide compensation to a person who is injured while participating as a subject in research.

14. Availability of further information.

If significant new knowledge is obtained during the course of this research which may related to your willingness to continue participation, you will be informed of this knowledge. To find out more about any aspect of this study, including your rights, you may contact the persons whose names, addresses, and telephone numbers appear below:

Jan S. Lewin, M.S.
Department of Otolaryngology
(313) 936-8013

If you have any questions or concerns regarding your rights as a research subject, you may also contact the Office of Patient/Staff Relations, 1500 E. Medical Center Drive, C246 Med Inn Building, Ann Arbor, MI 48109-0822, telephone #(313) 763-5456.

15. Voluntary nature of participation.

I understand that my participation in this project is voluntary and that I may refuse to participate in or withdraw from the study at any time without penalty or loss of benefits to which I may otherwise be entitled.

16. Documentation of the consent.

One copy of this document will be kept together with our research records on this study. A second copy will be placed in your Hospital record. A third copy will be given to you to keep.

17. Consent of the subject.

I have read the information given above. I understand the meaning of this information. Jan S. Lewin has satisfactorily answered my questions concerning the study. I hearby consent to participate in the study.

18. Names and signatures of consenting persons and witnesses.

Signature of Participant	Date	Jan S. Lewin, M.S., CCC-SLP Witness	Date

APPENDIX C

THE UNIVERSITY OF MICHIGAN MEDICAL CENTER INFORMED CONSENT FOR EXPERIMENTAL PROCEDURE

LIST OF REFERENCES

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