To the Graduate Council:

I am submitting herewith a dissertation written by Debra M. Suiter entitled "An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Speech and Hearing Science.

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Interim Vice Provost and
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An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients

A Dissertation
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Debra M. Suiter
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DEDICATION

For Ron McKinney

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ABSTRACT

The purpose of this study was to examine the effects of tracheostomy cuff deflation and Passy-Muir Tracheostomy Speaking Valve placement on the incidence and severity of aspiration. In addition, the effects of cuff deflation and Passy-Muir valve placement on durational swallow measures were examined.

Fourteen non-ventilator dependent patients completed videofluoroscopic swallow studies (VFSS) under three conditions: 1) cuff inflated, 2) cuff deflated, and 3) Passy-Muir valve in place. Four additional patients with cuffless tracheostomy tubes completed VFSS with no cuff and with the Passy-Muir valve in place. The order in which each participant completed these conditions was randomized. Participants were given two 5-mL boluses of thin liquid and two 5-mL boluses of puree. All VFSS were analyzed by a judge who was blinded to the condition under which each swallow was completed. All swallows were analyzed for the presence or absence of penetration or aspiration, the timing of aspiration, if present, and the severity of penetration/aspiration based on an 8-point penetration-aspiration scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996). In addition, swallows

were analyzed for the following duration measures: oral transit duration (OTD), stage transition duration (STD), pharyngeal transit duration (PTD), duration of hyoid maximum elevation (DOHME), duration of hyoid maximum anterior excursion (DOHMAE), duration of cricopharyngeal opening (DOCPO), and total swallow duration (TSD). Maximum hyolaryngeal elevation and anterior excursion were also determined.

Scores on the penetration-aspiration scale were not significantly affected by cuff deflation. The Passy-Muir valve did, however, significantly reduce scores on the penetration-aspiration scale for the liquid bolus. For those patients who had cuffed tracheostomy tubes, there was a significant difference in penetration-aspiration scale scores between the cuff-inflated and the Passy-Muir valve conditions.

The major positive finding in this investigation was that placement of the Passy-Muir valve reduced penetration/aspiration on an 8-point scale. In order to swallow more safely, patients who are able to tolerate Passy-Muir valve placement may benefit from eating with the valve in place.

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CHAPTER ONE

INTRODUCTION

ASPIRATION

Definition

Pulmonary aspiration, which may be defined as, "the penetration of secretions or ingesta below the level of the true vocal folds" (Perlman & Schulze-Delrieu, 1997, p. 492), frequently occurs as a result of oropharyngeal dysphagia. Aspiration is known to occur in normal, healthy individuals without detrimental effects (Crausaz & Favez, 1988; Huxley, 1978). In fact, Finegold (1995) has estimated that 50% of normal subjects aspirate during sleep. However, in patients with compromised medical status, aspiration can lead to serious consequences including bronchospasm, chemical pneumonitis, bacterial pneumonia, mechanical obstruction of the airways, or transient hypoxemia (Kirsch & Sanders, 1988; Passy-Muir, 1996).

Aspiration pneumonia has received considerable attention from individuals working with swallowing problems because it frequently occurs subsequent to the development of dysphagia and hospitalization (Langmore et al., 1998)

and reportedly accounts for between 13% and 48% of all infections in nursing homes (Crossley & Thurn, 1989; Zimmer, Bentley, Valenti, Watson, 1986). In addition, aspiration pneumonia is the second most common type of nosocomial infection in hospitalized patients (Horan, et al., 1986). Langmore and colleagues (1998) report "overall mortality rate ranges from 20% to 50%, with a rate as high as 80% reported in some cases" (p. 69). Wenzel (1989) estimated that the extra hospitalization time directly attributable to pneumonia is 2.5 million days annually in the United States.

Incidence of Aspiration

The incidence of aspiration has been reported in various patient populations. Veis and Logemann (1985) evaluated 38 stroke patients through videofluoroscopic swallowing studies. Of the 38 patients studied, 32% aspirated secondary to pharyngeal phase dysphagia. Logemann and Bytell (1979) reported a 50% incidence of aspiration in head and neck surgical patients. Lazarus and Logemann (1987) observed aspiration in 20 of 53 (37%) patients with head injuries. Studies have estimated the incidence of aspiration in patients with tracheostomy tubes to be as high as 87% (Pannuzio, 1996).

TRACHEOTOMY

Tracheotomy is one of the most commonly performed surgical procedures in acute care hospitals, frequently used to treat patients with chronic or acute upper airway obstruction or chronic respiratory failure. It is also employed by many physicians to aid in the care of patients with chronic aspiration. However, Nash (1988) reports, "the major swallowing disorder associated with tracheotomy is aspiration" (p. 705). In addition, Nash states that while "many physicians conceive of a tracheotomy as a solution to long-term aspiration…in reality a tracheotomy may increase the problem rather than solve it" (p. 705).

TREATMENT FOR ASPIRATION IN TRACHEOSTOMZED PATIENTS

Cuff Deflation

With the high incidence of aspiration in tracheostomized patients and the potential development of aspiration pneumonia, it is essential to carefully evaluate and treat tracheostomized patients for aspiration. Some methods have been proposed for treating aspiration in tracheostomy patients. It has been postulated that simply deflating the tracheostomy cuff may decrease the risk of aspiration. Tippett and Siebens (1991) found that to be

the case. Suiter, McCullough, and Powell (in preparation) found opposite results. They examined 12 non-ventilator dependent patients and found that cuff deflation had no significant effect on the incidence or severity of aspiration.

Passy-Muir Tracheostomy Speaking Valve Placement

Other researchers have suggested that placing a Passy-Muir Tracheostomy Speaking Valve eliminates or significantly reduces aspiration. Dettelbach, Gross, Mahlmann, and Eibling (1995) studied the effects of the Passy-Muir Tracheostomy Speaking Valve on swallowing in 11 patients with tracheostomy tubes. The authors reported that in all patients aspiration was significantly reduced when the Passy-Muir valve was in place. However, the authors did not control for certain factors, such as population, and confounded some of their results by introducing compensatory swallowing strategies. In addition, the authors did not state how they determined amount of aspiration, nor did they report reliability for judgments of degree of aspiration. Thus, the reliability of these findings is highly questionable.

Leder (1999) found opposite results. He used fiberoptic endoscopy to examine the effects of a one-way

valve on swallowing function in 20 consecutive tracheostomized inpatients with various diagnoses. Results indicated that 13 subjects who aspirated without the one-way valve in place also aspirated with the one-way valve. Conversely, seven subjects who did not aspirate without the valve also did not aspirate with the valve in place. Leder concluded that the incidence of aspiration was not affected by use of a one-way speaking valve. However, the author did not seek to quantify the severity of aspiration. Rather, aspiration was reported to be either present or absent. Thus, it is unclear if the valve truly had no effect on swallowing.

PURPOSE OF THE STUDY

The purpose of this paper is to determine whether Passy-Muir valve placement can decrease the incidence and severity of aspiration in tracheostomized individuals. In addition, the effects of cuff deflation on incidence and severity of aspiration were examined.

CHAPTER TWO

REVIEW OF THE LITERATURE

INCIDENCE OF ASPIRATION IN TRACHEOSTOMIZED PATIENTS

Several researchers have reported the incidence of aspiration resulting from tracheostomy. DeVita and Spierer-Rundback (1990) examined swallowing function in 11 patients following prolonged orotracheal intubation. Ten patients had tracheostomy tubes in place at the time of evaluation. Videofluoroscopic swallow studies (VFSS) revealed oral phase dysphagia in four patients and pharyngeal phase dysphagia in all ten patients. Tracheal penetration was noted in five patients.

Bone, Davis, Zuidema, and Cameron (1974) employed the modified Evans blue dye test to assess swallow function in 40 tracheostomized patients. Patients had one of three types of tracheostomy tubes in place at the time of the study: 1) standard tracheostomy tube; 2) high-volume, low-pressure cuff; and 3) sponge-filled cuff. Eighty-seven percent of participants with standard tracheostomy tubes aspirated; 15% of participants with high-volume, low-pressure cuffs aspirated; and 17% of participants with sponge-filled cuffs aspirated. The sensitivity of the blue

dye test has been questioned (Brady, Hildner, & Hutchins, 1999).

Elpern, Jacobs, and Bone (1987) also employed the modified Evans blue dye test to assess swallowing in tracheostomized patients. Thirty-one participants were examined. Swallowing was evaluated over a series of six to 61 observations. The mean number of observations per patient was 28. Seventy-seven percent of participants aspirated during at least one of the observations. Aspiration was most frequently noted when the participants' tracheostomy cuffs were inflated.

Elpern, Scott, Petro, and Ries (1994) sought to determine the incidence of aspiration in 83 ventilator-dependent patients. All participants underwent videofluoroscopic-swallowing studies. Half of the participants aspirated on at least one occasion. Seventy-seven percent of aspiration occurrences were silent. Pharyngeal phase dysfunction was observed twice as frequently as oral phase dysfunction.

The effect of tracheostomy tubes on swallowing has been questioned by Leder and Ross (2000). These scientists used fiberoptic endoscopy to evaluate swallowing in 20 patients pre- and post-tracheotomy. Time from pre-

operative endoscopy to post-operative endoscopy ranged from two days to 63 days. Nineteen of the 20 patients exhibited the same aspiration status post-tracheotomy as they did pre-tracheotomy. In other words, nineteen of the patients who aspirated before tracheotomy also aspirated after tracheotomy. The results of this study are questionable, however, because of the variation and length of time between pre- and post-operative testing. Patients with tracheostomy tubes are frequently medically fragile, and their medical status often changes quickly. Changes in medical status may have affected the outcome of their swallowing examination.

TRACHEOSTOMY EFFECTS ON SWALLOWING

Decreased Hyolaryngeal Excursion

Several theories regarding the effects of tracheostomy on swallowing have been postulated. Several authors (Bonanno, 1971; Elpern et al., 1994; Logemann, 1995; Pinkus, 1973) have observed markedly decreased elevation and anterior rotation of the larynx in a population of patients with tracheostomy tubes, presumably as a result of the tracheostomy tube anchoring the trachea to the strap muscles and skin of the neck. This, in turn, leads to

insufficient relaxation of the cricopharyngeal sphincter, with resultant residue in the pharynx, which eventually spills into the airway and is aspirated. Laryngeal elevation may also be restricted by an inflated tracheal cuff anchoring the larynx or by the weight of ventilator tubing.

Tracheostomy Cuff Problems

Others (Betts, 1965) have postulated that the tracheostomy cuff may impinge on the wall of the esophagus, creating an esophageal obstruction that forces material to remain above the cuff in the proximal esophagus and hypopharynx. When the cuff is deflated, or the patient exhales forcefully, this material may then overflow into the airway. Tippett and Siebens (1991) report that "a tracheostomy cannula with an inflated cuff adversely affects upper airway clearance and laryngeal protection against entry of foodway contents" (p. 97). These authors also state that tracheostomy cuffs provide imperfect protection against aspiration, and "seepage of foodway products is likely" (p. 97).

Decreased Adductor and Abductor Vocal Fold Movement

Yet another theory suggests that tracheostomy has a detrimental effect on adductor and abductor vocal fold

movement. Buckwalter and Sasaki (1984) demonstrated that the threshold of the adductor reflex produced by superior laryngeal nerve electrostimulation nearly doubles after a tracheostomy has been in place for a prolonged period of time (six to eight months). They also found that repetitive stimulation of the superior laryngeal nerve results in significant attenuation of the adductor reflex, which leads to a weakened closure response and, possibly, to aspiration. In addition, abductor vocal fold activity gradually diminishes and eventually disappears with prolonged tracheostomy.

Laryngeal Abnormalities

Tolep, Getch, and Criner (1996) performed direct laryngoscopy on ten patients with tracheostomy tubes. In five of ten of these patients the authors found laryngeal abnormalities, including decreased sensation of the vocal folds, limited vocal fold movement, and edema of the arytenoid cartilages. These abnormalities may limit upper airway protection.

Reduced Subglottal Pressure

Finally, tracheostomy tubes have a negative effect on subglottal pressure (Gross, Dettelbach, Zajac, Eibling,

1994; Sasaki & Isaacson, 1988). Under normal conditions, the trachea acts as a wind tunnel, and increased subglottal pressure relative to supraglottal pressure keeps food and liquid out of the airway. When the trachea is opened (by a tracheostomy tube), subglottal pressure drops, and material can more readily enter the airway.

APPROACHES TO REDUCING ASPIRATION

Non-Oral Means of Nutrition

Several different approaches have been taken to reduce aspiration in patients with tracheostomy tubes. The first and perhaps most frequently employed approach is to place a patient on a non-oral means of nutrition and provide enteral feeding via a nasogastric or PEG tube. However, the presence of a nasogastric tube itself may increase a patient's risk of aspiration. Arms, Dines, and Tinstman (1974) studied a group of patients who had been diagnosed with aspiration pneumonia to determine risk factors for aspiration. These authors concluded that, "the most important high risk factors in patients of the group with operation [versus no operation] included the presence of a nasogastric tube or tracheostomy at the time of aspiration" (p. 138). In this study, 54% of the aspiration occurred

around a nasogastric tube. Gilbert, Bryce, McIlwain, and Ross (1987) theorized that the presence of a nasogastric tube might interfere with relaxation of the cricopharyngeal sphincter and thus lead to residue in the hypopharynx or backflow of material into the pharynx. Material may then be aspirated after the swallow. In addition, nasogastric tubes may interfere with the normal function of the lower esophageal sphincter and allow for gastroesophageal reflux. Kirsch and Sanders (1988) reported that the "proper placement of a nasoenteral tube for the purpose of alimentation is associated with a 38 percent incidence of aspiration in patients who have either endotracheal or tracheostomy tubes" (p. 681).

Laryngotracheal Diversion and Separation

Two other approaches to treating aspiration in the tracheostomized patient are laryngotracheal diversion and separation. These procedures were designed to treat patients with moderate to severe aspiration. Specifically, laryngotracheal diversion, as described by Lindeman, consists of "tracheal division with construction of an end-to-side tracheoesophageal anastamosis and a distal tracheostomy" (Snyderman, Johnson, Eibling, 1994, p. 64). Reportedly, Lindeman was able to preserve laryngeal

function using this procedure with dogs (Snyderman et al.). Laryngotracheal separation, or the modified "Lindeman procedure," consists of "oversewing the proximal trachea to create a blind pouch" (Snyderman et al., p. 64). This procedure is typically used for patients with pre-existing tracheostomies that "preclude the establishment of a tracheoesophageal anastamosis" (Snyderman et al., p. 64). According to Snyderman and associates, aspiration was effectively eliminated in over 100 reported cases of laryngotracheal separation. This procedure, however, has obvious drawbacks, including the obliteration of laryngeal function and the loss of the patient's ability to phonate.

Cuff Deflation

Less invasive methods have been investigated. Tippett and Siebens (1991) suggest that deflation of a tracheostomy cuff could eliminate aspiration. Specifically, the authors studied the effects of cuff deflation on swallowing in five tracheostomized patients. Of the three patients who were receiving non-oral means of nutrition prior to the study, all were able to safely take oral alimentation with their tracheostomy cuffs deflated. Suiter, McCullough, and Powell (in preparation) found opposite results. They examined 12 non-ventilator dependent patients under two

conditions, cuff-inflated and cuff-deflated, using videofluoroscopy. Their results indicated no significant effect of cuff deflation on durational measures of swallowing or the incidence and severity of aspiration.

Tracheostomy Tube Occlusion

Several authors have suggested that placement of an obturator on the tracheostomy tube may reduce or eliminate aspiration by restoring subglottal pressure. Muz, Hamlet, Mathog, and Farris (1994) studied a group of head and neck cancer patients using scintigraphy. In seven patients who aspirated, they examined the effects of occluding the tracheostomy tube while patients swallowed. Their results indicated that in six of the seven patients, tracheopulmonary aspiration was less frequent and less severe when the tracheostomy tube was plugged than when it was unplugged. The authors went so far as to suggest that, for those patients who could tolerate it, the tracheostomy tube should be intermittently occluded during eating. However, many patients, particularly those who are ventilator-dependent, are unable to tolerate total occlusion of their tracheostomy tubes for any period of time.

Logemann, Pauloski, and Colangelo (1998) examined the effects of digital occlusion of the tracheostomy valve in eight head and neck cancer patients and found mixed results. Four out of seven patients exhibited aspiration of thin liquids when their tracheostomy tube was not occluded. Of these, two showed no signs of aspiration when their tracheostomy tubes were occluded. One patient, who aspirated both thin liquid and paste consistencies, demonstrated no aspiration when his tracheostomy tube was occluded; and two patients showed no change or an increase in aspiration when their tracheostomy tubes were occluded. Specific changes in the biomechanics of swallowing thin liquids resulting from tracheal occlusion included: reduced duration of base of tongue contact to the posterior pharyngeal wall, increased laryngeal elevation, increased laryngeal and hyoid elevation at the time of cricopharyngeal relaxation, and delayed anterior movement of the posterior pharyngeal wall in relation to the onset of cricopharyngeal opening. The authors concluded that "light" digital occlusion of a tracheostomy tube for swallowing was a safe procedure.

Less encouraging results were observed by Leder and associates (1996, 1998). They found that occlusion status

of the tracheostomy tube had no effect on the incidence of aspiration in two separate studies. Three design flaws are noteworthy in those investigations. First, in both studies subjects completed the videofluoroscopic swallowing study first with their tracheostomy tubes occluded and then with their tubes unoccluded. Counterbalancing two conditions temporally is important to ensure that one condition does not affect the other. Therefore, the subjects should have started with their tubes unoccluded. Second, the authors state that tubes were sometimes occluded for up to several hours prior to the swallowing study, increasing the likelihood that fatigue could affect the results. Third, the authors only examined videotapes of the swallowing studies for the presence or absence of aspiration. They did not attempt to quantify aspiration. Therefore, although these studies showed that tracheostomy tube occlusion did not eliminate aspiration, it is unclear if the amount of aspiration, or the specific number of aspiration events, was reduced by tube occlusion.

Passy-Muir Tracheostomy Speaking Valve Placement

It has also been postulated that the Passy-Muir Tracheostomy Speaking Valve may improve swallow function in tracheostomized patients. The valve was initially designed

to provide a way for tracheostomized patients to phonate. Specifically, the valve operates with a positive closure valve mechanism, which opens only during inspiration. When the valve is closed, and the tracheostomy cuff is deflated, air is shunted around the tracheostomy tube and is allowed to flow upward through the vocal folds, allowing them to vibrate and produce voicing. In addition to allowing the patient to phonate, the Passy-Muir Tracheostomy Speaking Valve has been shown to have other positive effects, including decreased oral and nasal secretions, increased food intake secondary to improved olfaction, and, reportedly, increased energy levels (Passy, Baydur, Prentice, & Darnell-Neal, 1993).

Several studies have been conducted to examine the effects of Passy-Muir valves on swallowing. Dettelbach, Gross, Mahlmann, and Eibling (1995) studied 11 patients with various diagnoses, including central neurologic disease and partial laryngectomy. Each patient completed a modified barium swallow study both with and without the Passy-Muir valve. Patients were given thin liquids, thick liquids, paste consistencies, and/or cookies. Results indicated that all patients exhibited a significant reduction in aspiration when the valve was in place.

However, the authors failed to control for confounding factors such as diagnosis. In addition, the authors did not explain how they attempted to quantify amount of aspiration. Thus, the reliability of their results is questionable.

Stachler, Hamlet, Choi, and Fleming (1996) obtained scintigraphic quantification of aspiration in patients with and without the Passy-Muir valve. The 11 patients in their study were either pre- or post-treatment for head and neck cancer. Scintigraphy was completed in conjunction with a modified barium swallow study. Results were consistent with Dettelbach and colleagues. Although the Passy-Muir valve did not eliminate aspiration for any of the patients, it did appear to significantly reduce the amount of aspiration.

Leder (1999) examined the effects of the one-way speaking valve on swallowing function in 20 non-ventilator dependent tracheostomized patients using fiberoptic endoscopy. Subjects were observed swallowing with and without the valve in place. The endoscopic examinations revealed that all subjects who aspirated without the valve in place also aspirated with the valve. All subjects who did not aspirate without the valve also did not aspirate

with the valve. The author concluded that the incidence of aspiration was not affected by use of a one-way valve. However, the author did not attempt to quantify the severity of aspiration. Thus, it is not clear if the valve had any effect on swallowing function.

The specific effects of the Passy-Muir valve on swallow physiology have not been determined. Some believe that the valve may help increase subglottal pressure, which is diminished when the tracheostomy tube is open. Gross, Dettlebach, Zajac, and Eibling (1994) used a pneumotachometer and pressure transducer with a patient who demonstrated aspiration of thin liquids when his tracheostomy tube was open. Specifically, they measured subglottal air pressure with the tracheostomy tube open and with a Passy-Muir valve in place. Results indicated a ten-fold increase in subglottal pressure during swallowing with the Passy-Muir valve in place as compared with subglottal pressure with the tracheostomy tube open.

SUMMARY OF THE LITERATURE

Although surgical methods (Snyderman et al., 1994) may eliminate aspiration in tracheostomized patients, the loss of voice reduces patients' quality of life. Though non-

invasive methods of decreasing aspiration are available, further investigations are required to determine their value. One of those methods needing further study is the use of the Passy-Muir Tracheostomy Speaking Valve.

As previously stated, Dettelbach and colleagues (1994) did not use a uniform sample and attempted to use compensatory swallowing strategies in their study. In addition, it is not clear how these authors determined the approximate percentage of aspiration; and the reliability of their ratings is highly questionable. Several authors have investigated inter- and intra-judge reliability in the reading of videofluoroscopic swallowing studies (Kuhlemeir, Yates, and Palmer, 1998; McCullough, Wertz, Rosenbek, Mills, Webb, & Ross, 2001). Reliability for rating aspiration is reported with mixed results at best. When judgments move from a rating of "present" or "absent" to a rating on a three or four point scale, reliability typically deteriorates (Kuhlemeir et al., 1998).

8-POINT PENETRATION-ASPIRATION SCALE

Rosenbek, Robbins, Roecker, Coyle, and Wood (1996) recently developed an 8-point Penetration-Aspiration scale (see Table 1), which may now be employed to determine the

severity of penetration/aspiration based on the depth the bolus travels in the airway and the patient's response. Reliability of this scale is high, with the authors reporting an interjudge intraclass correlation coefficient of .96 and an intrajudge intraclass coefficient ranging from .95 to .97. Research has also demonstrated that the scale may be used with interval level statistics, a methodological advantage that may be employed for treatment studies attempting to demonstrate reductions in the severity of penetration/aspiration (McCullough, Rosenbek, Robbins, Coyle, & Wood, 1998). This scale may be useful in demonstrating whether deflating a tracheostomy cuff or utilizing a Passy-Muir valve reduces penetration/ aspiration.

PURPOSE OF THE STUDY AND RESEARCH QUESTIONS

The purpose of this study is to determine whether cuff deflation and/or Passy-Muir Tracheostomy Speaking Valve placement reduces the incidence and/or severity of penetration/aspiration in subjects with tracheostomy tubes. The 8-Point Penetration-Aspiration scale was utilized to measure potential change in the severity of penetration-

Table 1: Penetration-Aspiration Scale

Score	Description
1	Material does not enter airway.
2	Material enters the airway, remains above the vocal folds, and is ejected from the airway.
3	Material enters the airway, remains above the vocal folds, and is not ejected from the airway.
4	Material enters the airway, contacts the vocal folds, and is ejected from the airway.
5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway.
6	Material enters the airway, passes below the vocal folds, and is ejected either from the trachea into the larynx or completely out of the airway.
7	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.
8	Material enters the airway and passes below the vocal folds, and no spontaneous effort is made to eject it.

aspiration. Specifically, the following questions were addressed:

1) Does Passy-Muir Tracheostomy Speaking Valve placement reduce the incidence and/or severity of penetration/aspiration in subjects with tracheostomy tubes?
2) What, if any, effect does Passy-Muir Tracheostomy Speaking Valve placement have on swallow physiology?
3) Does cuff deflation reduce the incidence and/or severity of penetration/aspiration in subjects with tracheostomy tubes?
4) What, if any, effect does cuff deflation have on swallow physiology?

CHAPTER THREE

METHODS

PARTICIPANTS

Eighteen individuals who had tracheostomy tubes and who were non-ventilator dependent were invited to participate in this study. Fourteen of the eighteen participants had cuffed tracheostomy tubes, and four had cuffless tracheostomy tubes. Participants were recruited from the University of Tennessee Medical Center, Baptist Hospital of East Tennessee, and Ft. Sanders Regional Medical Center. All participants met the following inclusion criteria:

1) The participant was suspected of having swallowing difficulty. This was determined by a bedside swallowing evaluation, which was completed by a licensed, certified speech-language pathologist. Signs/symptoms of possible swallowing difficulty include, but are not limited to, coughing after swallowing and "gurgly" vocal quality after the swallow.
2) The participant was able to tolerate cuff deflation (if the tracheostomy tube was cuffed) and placement of the Passy-Muir Tracheostomy Speaking valve for at least five minutes. Tolerance was assessed by obtaining oxygen

saturation levels and respiratory rate via pulse oximetry. A respiratory therapist was present during the initial trial of cuff deflation and Passy-Muir valve placement. Because acceptable changes in oxygen saturation levels vary from individual to individual depending upon diagnosis, a respiratory therapist was present to help to determine if a patient sufficiently tolerated the procedure. Participants were also given an index card that said "Stop", and were instructed to hold up the card if they became uncomfortable or short of breath.

3) Participants were awake and alert.

Patients were excluded from this study if they had a history of swallowing difficulty prior to their current hospitalization. Participants were given an information sheet about the study (see Appendix A), and they were asked to sign an informed consent form (see Appendix B).

Profiles for each participant are presented in Table 2. Patients presented with a variety of diagnoses, including chronic obstructive pulmonary disease (COPD), head injury, and status-post coronary artery bypass graft (CABG). Seventeen of the eighteen participants had naso-gastric tubes in place at the time of their swallow study.

Table 2: Participant Profiles

Participant #	Diagnosis	Nutrition	Trach Size	Days with Trach	Days on Trach Collar
1	COPD	N-G Tube	6	20	4
2	CHI	N-G Tube	6	9	6
3	COPD	N-G Tube	6	21	8
4	CHI	N-G Tube	8	14	4
5	CHI	N-G Tube	6	15	3
6	CHI	PEG Tube	6	17	5
7	COPD	N-G Tube	6	15	7
8	CHI	N-G Tube	6	5	2
9	s/p CABG	N-G Tube	4	11	9
10	s/p CABG	N-G Tube	6	7	3
11	CHI	N-G Tube	6	13	2
12	CHI	N-G Tube	6	19	4
13	CHI	N-G Tube	6	8	6
14	ARDS	N-G Tube	6	26	19
15	ARDS	N-G Tube	6	25	14
16	COPD	N-G Tube	4	18	15
17	CHI	N-G Tube	6	14	4
18	s/p AAA repair	N-G Tube	8	29	11

The size of each participant's tracheostomy tube was also recorded.

PROCEDURES

All participants completed a videofluoroscopic swallowing study (GE Model 152000G2). Swallow studies were recorded on ¾ inch videotape using a Mitsubishi HS U120 videorecorder. All swallow studies were completed in the Department of Radiology, and a Radiologist, a Respiratory Therapist, and Speech-Language Pathologist were present at each study. Participants completed a series of four swallows under three conditions: 1) cuff-inflated, 2) no cuff or cuff-deflated, and 3) cuff-deflated with the Passy-Muir valve in place. Participants whose tracheostomy tubes did not have cuffs completed the study under two conditions: 1) no cuff or cuff-deflated and 2) Passy-Muir valve in place. The order in which each participant completed these conditions was randomly assigned. During the cuff-inflated condition, all participants' tracheostomy cuffs were fully inflated. A Posey Cuffolator was used to determine if the participant's cuff was sufficiently inflated. The size and type (fenestrated versus non-

fenestrated) of tracheostomy tube were recorded for each participant.

During the videofluoroscopic swallowing study (VFSS), for each of the two (or three) conditions, participants were given two presentations each of 5-mL thin (1 part barium powder to 1 part water) and 5-mL puree (4 parts applesauce to 1 part barium powder) as tolerated. All participants were fed by the clinician completing the VFSS. The liquid and the puree boluses were given by spoon. Participants were seated at a 90-degree angle in a Hausted chair, and lateral view videofluoroscopic images were obtained. A penny was placed at the angle of the participant's left jaw to serve as a marker for measuring hyolaryngeal movement. The swallowing study was stopped if:

1) a participant exhibited more than trace aspiration of thin liquid on two subsequent swallows;
2) if a subject aspirated any amount of pureed texture;
3) or if gross aspiration was noted on either consistency or quantity.

The participant then continued the study under the remaining conditions. Compensatory strategies were used to make management decisions. These strategies were only

utilized after the protocol was completed and were not included in the data analysis.

ANALYSIS OF VIDEOFLUOROSCOPIC SWALLOWING STUDIES

All videofluoroscopic-swallowing studies (VFSS) were analyzed by a judge with five years experience in visual-perceptual analysis of normal and disordered swallowing. This judge was blinded to the condition under which each swallow was completed. Prior to viewing the participants' videotapes, this judge was pre-trained to criterion (90% agreement) for each VFSS measure by the principal investigator. Each participant's videotape was then reviewed. Each swallow was viewed at normal, slowed, and frame-by-frame speeds until a confident analysis could be made. All swallows were analyzed for the following duration measures with the 100 ms timer (see Appendix C): begin posterior movement of the bolus, first barium into the pharynx, head of the bolus into the pharynx, tail of the bolus into the pharynx, begin maximum laryngeal elevation, first maximum laryngeal elevation, last maximum laryngeal elevation, first maximum anterior hyolaryngeal excursion, last maximum hyolaryngeal excursion, hyoid return to rest, cricopharyngeal opening, head of the bolus

into the cricopharyngeus, tail of the bolus into the cricopharyngeus, and cricopharyngeal closure. The time in milliseconds at which each point occurred was recorded and used to calculate the following duration measures: oral transit duration (OTD), stage transition duration (STD), pharyngeal transit duration (PTD), duration of hyoid maximum elevation (DOHME), duration of hyoid maximum anterior excursion (DOHMAE), duration of cricopharyngeal opening (DOCPO), and total swallow duration (TSD). Definitions for how each measure was calculated are provided in Table 3. In order to determine maximum hyolaryngeal elevation and anterior movement, still frames of each participant's hyolaryngeal structures were traced onto overhead transparencies. The distance from resting hyoid position to maximum elevation and the distance from resting hyoid position to maximum hyoid anterior movement were measured in millimeters. In order to determine magnification effect of the x-ray, the video image of the penny placed on each participant's left mandible was traced, and the diameter in millimeters was measured. The maximum distance from baseline position of the hyoid to maximum movement was then multiplied by the magnification correction factor derived from the penny. In other words,

Table 3: Swallow Duration Measures

Measure	Definition
Oral Transit Duration (OTD)	Time from the initiation of posterior bolus movement to arrival of bolus head at the ramus of the mandible.
Stage Transition Duration (STD)	Time from first barium at the ramus of the mandible (not necessarily the head of the bolus) to the beginning of maximum hyoid excursion.
Pharyngeal Transit Duration (PTD)	Time from arrival of the bolus head at the ramus of the mandible to bolus head entering the CP.
Duration of Hyoid Maximum Elevation (DOHME)	Time from first frame showing maximum hyoid elevation to last frame showing maximum hyoid elevation.
Duration of Hyoid Maximum Anterior Excursion (DOHMAE)	Time from first frame showing maximum anterior hyoid movement to last frame showing maximum anterior hyoid movement.
Duration of Cricopharyngeal Opening (DOCPO)	Time from first frame of CP opening to last frame of CP opening.
Total Swallow Duration (TSD)	Time from initiation of posterior bolus movement to hyoid return to rest.

Taken from JoAnne Robbins, 1992, Personal Contact.

if the penny is one-inch wide but appears to be two-inches wide on the x-ray, the distance moved by the larynx was divided by two in order to correct for the magnification from the fluoroscopy (Logemann, 1998). In addition, videotapes of the VFSS were analyzed for the presence or absence of penetration or aspiration, timing of aspiration (before, during, or after the swallow) if present, and severity of penetration/aspiration, based on an 8-point penetration-aspiration scale.

RELIABILITY

Intrajudge reliability was determined by having the primary judge re-analyze 20 percent of the participants' VFSS, blind to the initial results. The principal investigator randomly chose intrajudge reliability tapes. Interjudge reliability was determined by having a second judge, the principal investigator; evaluate 20 percent of the participants' VFSS tapes for all measures. Interjudge reliability tapes were chosen randomly. Prior to analyzing the videotapes, the primary judge and the principal investigator analyzed a videotape of a VFSS of an individual not participating in this study and completed separate analyses. The two judges reviewed and discussed

all swallows on which their measures did not agree. This was done until the judges reached 90 percent agreement for all measures. The second judge then analyzed the videotapes for the duration measures previously described. From those recorded times the primary investigator calculated OTD, STD, PTD, DOHME, DOHMAE, DOCPO, and TSD. In addition, the presence or absence of aspiration based upon an 8-point penetration-aspiration scale was determined.

STATISTICAL ANALYSIS

SPSS 10.0 was used to statistically analyze all of the data. A total of 150 swallows (44 cuff-inflated, 54 cuff-deflated or no cuff, and 52 PMTSV) out of a possible 190 swallows (56 cuff-inflated, 72 cuff-deflated or no cuff, and 72 PMTSV) were analyzed.

In order to answer the first and third research questions, "Does Passy-Muir Tracheostomy Speaking Valve placement reduce the incidence and/or severity of penetration/aspiration?" and "Does cuff deflation reduce the incidence and/or severity of penetration/aspiration?" each swallow was analyzed for potential penetration/ aspiration. Penetration was defined as "entry of

oropharyngeal contents into the larynx above the true vocal folds" (Perlman & Schulze-Delrieu, 1997, p. 504); aspiration was defined as "the penetration of secretions or ingesta below the level of the true vocal folds" (Perlman & Schulze-Delrieu, p. 492). Penetration/aspiration was first rated as present or absent. Timing of aspiration, before, during, or after the swallow, was also noted. Then, in order to improve upon previous investigations, an 8-point penetration-aspiration scale (Rosenbek et al., 1996) was utilized to rate the severity of penetration/ aspiration. Swallows of similar bolus size and consistency were compared between the three conditions (cuff-inflated, cuff-deflated or no cuff, PMTSV). Group means were obtained for each bolus type under each condition. In order to determine if condition (cuff-inflated, cuff-deflated or no cuff, and Passy-Muir valve) significantly affected severity of penetration/ aspiration, a repeated measures analysis of variance (ANOVA) was performed using condition and bolus as factors. An alpha level of .05 was used to determine significance.

To answer the second and fourth research questions, "What, if any, effect does Passy-Muir Tracheostomy Speaking Valve placement have on swallow physiology?" and "What, if

any, effect does cuff deflation have on swallow physiology?", a number of swallowing transit times were calculated (see Table 2). Changes in transit times from one condition to the next should provide insight into specific biomechanical changes that may result from deflating the cuff. In addition, maximum extent of hyolaryngeal excursion and oropharyngeal residue were also determined. Group means were obtained for each durational measure, hyolaryngeal excursion, and oropharyngeal residue under each condition for each bolus type. A doubly multivariate repeated measures analysis of variance (MANOVA) was used to examine the differences between means for each condition and bolus type. A significance level of .05 was used for all measures.

To determine inter- and intrajudge reliability, Pearson's product moment correlations were computed for all duration measures. Kendall's tau correlations were computed for Penetration-Aspiration scale scores and for residue.

CHAPTER FOUR

RESULTS

RELIABILITY

Pearson's product moment correlations were computed for all duration measures. Kendall's tau correlations were computed for scores on the Penetration-Aspiration scale and for oropharyngeal residue. Results for interjudge and intrajudge reliability for all duration measures, scores on the Penetration-Aspiration scale, and oro-pharyngeal residue are presented in Table 4. Correlations for interjudge reliability ranged from .915 to 1.000. Correlations for intrajudge reliability ranged from .906 to 1.000.

PASSY-MUIR TRACHEOSTOMY SPEAKING VALVE

Penetration-Aspiration

The answer to the first research question, "Does Passy-Muir Tracheostomy Speaking Valve (PMTSV) placement reduce the incidence or severity of aspiration?", is yes. Number of penetration/aspiration occurrences and mean scores on the Penetration-Aspiration scale were determined. Results are presented in Table 5. Penetration without

Table 4: Inter- and Intra-Judge Reliability

	Inter-Judge Reliability		Intra-Judge Reliability	
Measure	**Correlation**	**Significance**	**Correlation**	**Significance**
OTD	.963*	.037	.906*	.000
STD	.954*	.046	.976*	.000
PTD	.996*	.004	.986*	.000
DOHME	.979*	.021	.996*	.000
DOHMAE	.915*	.085	.993*	.000
DOCPO	.943*	.057	.985*	.000
TSD	.964*	.036	.948*	.000
P-A	.993**	.007	1.000**	.001
Oral Residue	1.000**	.042	1.000**	.001
Vallecular Residue	.954**	.046	1.000**	.001
PPW Residue	.951**	.049	1.000**	.001
Pyriform Sinus Residue	1.000**	.000	1.000**	.001
C-P Residue	1.000**	.000	1.000**	.001

* Pearson's product moment correlation
** Kendall's tau correlation

Table 5: Penetration-Aspiration

Condition	Bolus	Number of Penetration Occurrences	Number of Aspiration Occurrences	Mean P-A Scale Score
Cuff Inflated	Liquid	2	15	6.571
No Cuff or Cuff Deflated	Liquid	5	16	6.111
PMTSV	Liquid	7	4	3.056
Cuff Inflated	Pureed	2	2	2.623
No Cuff or Cuff Deflated	Pureed	1	4	2.366
PMTSV	Pureed	3	2	2.585

aspiration of the liquid bolus occurred with the following frequency: cuff-inflated = 2, no cuff or cuff-deflated = 5, PMTSV = 7. Penetration without aspiration of the pureed bolus occurred with the following frequency: cuff-inflated = 2, no cuff or cuff-deflated = 1, PMTSV = 3. Aspiration of the liquid bolus was noted with the following frequency: cuff-inflated = 15, no cuff or cuff-deflated = 16, PMTSV = 4. Aspiration of the pureed bolus was noted with the following frequency: cuff-inflated = 2, no cuff or cuff-deflated = 4, PMTSV = 2. Aspiration was most frequently noted during the swallow (40 of 43 occurrences). The majority of aspiration occurrences, 37 of 43, were silent.

The 8-point Penetration-Aspiration scale was utilized to determine severity of penetration-aspiration. The mean score on the Penetration-Aspiration scale with the cuff inflated was 6.571 (Standard Error (S.E.) = .462) for the liquid bolus and 2.623 (S.E. = .745) for the pureed bolus. The mean score on the Penetration-Aspiration scale for the cuff-deflated or no cuff condition was 6.111 (S.E. = .667) for the liquid bolus and 2.366 (S.E. = .542) for the pureed bolus. For the PMTSV condition, the mean score on the Penetration-Aspiration scale was 3.056 (S.E. = .639) for the liquid bolus and 2.585 (S.E. = .705) for the pureed

bolus. A 2 (condition) x 2 (bolus) repeated-measures analyses of variance (ANOVA) ($p \leq .05$) was employed to examine the differences in mean Penetration-Aspiration scale scores for the no-cuff or cuff-deflated condition and the PMTSV condition (see Table 6). Results revealed a significant main effect of condition ($F(1, 17) = 8.042$, $p = .011$) and bolus ($F(1, 17) = 8.112$, $p = .011$). There was also a significant interaction between condition and bolus ($F(1, 17) = 8.834$, $p = .009$). To further examine the interaction between condition and bolus, a repeated-measures ANOVA ($p \leq .05$) was performed for each bolus under each condition. Results for the liquid bolus revealed a significant main effect for condition ($F(1, 17) = 18.204$, $p = .001$). Results for the pureed bolus revealed no significant main effect for condition ($F(1, 17) = .081$, $p = .779$). For the liquid bolus, scores on the Penetration-Aspiration scale were significantly lower (better) for PMTSV condition than for the no cuff or cuff-deflated condition.

For the fourteen individuals who had cuffed tracheostomy tubes, a 2 (condition) x 2 (bolus) repeated-measures ANOVA ($p \leq .05$) was employed in order to examine the differences in mean Penetration-Aspiration scale scores

Table 6: Repeated Measures Analysis of Variance for Penetration-Aspiration—No Cuff or Cuff Deflated versus Passy-Muir Valve

Independent Measure	df	F	Significance	Error df
Condition	1.000	8.042	.011*	17.000
Bolus	1.000	8.112	.011*	17.000
Condition x Bolus	1.000	8.834	.009*	17.000

*Value is significant at $p \leq .05$.

for the cuff-inflated and PMTSV conditions (see Table 7). Results revealed a significant main effect of condition ($F(1, 13) = 16.345$, $p = .001$) and bolus ($F(1, 13) = 56.254$, $p < .001$). Scores on the Penetration-Aspiration scale were significantly lower (better) for the PMTSV condition than for the cuff-inflated condition. In addition, scores on the Penetration-Aspiration scale were significantly lower for the pureed bolus than for the liquid bolus.

Swallowing Physiology

The answer to the second research question, "Does Passy-Muir Tracheostomy Speaking Valve placement affect swallow physiology?", appears to be no. Means were derived for all duration measures, extent of hyolaryngeal excursion, and residue.

Duration Measures

Mean values for all duration measures are presented in Table 8. A two-factor (condition and bolus) doubly multivariate repeated-measures analysis of variance (MANOVA) ($p \leq .05$) (see Table 9) was employed to examine differences in means for duration measures for the no cuff or cuff-deflated condition and the PMTSV condition. Results revealed no significant main effect of condition (F

Table 7: Repeated Measures Analysis of Variance for Penetration-Aspiration—Cuff Inflated versus Passy-Muir Valve

Independent Measure	df	F	Significance	Error df
Condition	1.000	16.345	.001*	13.000
Bolus	1.000	56.254	.000*	13.000
Condition x Bolus	1.000	2.626	.129	13.000

*Value is significant at $p \leq .05$.

Table 8: Mean Duration Measures (in milliseconds)

Measure	Condition	Bolus	Mean	Standard Error
Oral Transit Duration	Cuff Inflated	Liquid	1.190	.344
		Puree	2.316	.740
	No Cuff or Cuff Deflated	Liquid	1.273	.508
		Puree	3.837	1.057
	PMTSV	Liquid	1.067	.444
		Puree	1.709	.387
Stage Transition Duration	Cuff Inflated	Liquid	-.009	.016
		Puree	-.012	.030
	No Cuff or Cuff Deflated	Liquid	-.009	.011
		Puree	-.014	.015
	PMTSV	Liquid	.018	.016
		Puree	-.059	.011
Pharyngeal Transit Duration	Cuff Inflated	Liquid	.207	.018
		Puree	.260	.054
	No Cuff or Cuff Deflated	Liquid	.174	.017
		Puree	.186	.015
	PMTSV	Liquid	.169	.015
		Puree	.197	.020
Duration of Hyoid Maximum Elevation	Cuff Inflated	Liquid	.284	.045
		Puree	.296	.037
	No Cuff or Cuff Deflated	Liquid	.361	.054
		Puree	.332	.037
	PMTSV	Liquid	.313	.042
		Puree	.281	.037
Duration of Cricopharyngeal Opening	Cuff Inflated	Liquid	.527	.029
		Puree	.567	.049
	No Cuff or Cuff Deflated	Liquid	.433	.038
		Puree	.524	.038
	PMTSV	Liquid	.516	.064
		Puree	.474	.029
Total Swallow Duration	Cuff Inflated	Liquid	1.977	.335
		Puree	3.182	.713
	No Cuff or Cuff Deflated	Liquid	2.046	.494
		Puree	2.717	.524
	PMTSV	Liquid	1.825	.429
		Puree	2.375	.379

Table 9: Doubly Multivariate Repeated Measures Analysis of Variance for Swallow Duration Measures—No Cuff or Cuff Deflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	7.000	1.316	.328	11.000
Bolus	7.000	2.684	.070	11.000
Condition x Bolus	7.000	1.419	.290	11.000

*Value is significant at $p \leq .05$.

(7, 11) = 1.316, p = .328) or bolus (F(7, 11) = 2.684, p = .070).

For the fourteen individuals who had cuffed tracheostomy tubes, a two-factor (condition and bolus) doubly multivariate repeated- measures analysis of variance (MANOVA) ($p \leq .05$) (see Table 10) was employed to examine the differences in means for duration measures for the cuff-inflated condition and the PMTSV condition. Results revealed no significant main effect for condition (F(7, 7) = 1.817, p = .225) or for bolus (F(7, 7) = 1.773, p = .234).

Hyolaryngeal Excursion

Mean values for maximum laryngeal elevation and maximum hyoid anterior excursion are presented in Table 11. Mean maximum laryngeal elevation for the cuff-inflated condition was 9.853 mm (S.E. = .763) for the liquid bolus and 9.023 mm (S.E. = .717) for the pureed bolus. For the cuff-deflated condition, mean maximum laryngeal elevation was 9.224 mm (S.E. = .763) for the liquid bolus and 8.840 mm (S. E. = .489) for the pureed bolus. For the PMTSV condition, mean laryngeal elevation was 8.493 mm (S. E. = .718) for the liquid bolus and 9.569 mm (S. E. = .718) for the pureed bolus. A 2 (condition) x 2 (bolus) univariate

Table 10: Doubly Multivariate Repeated Measures Analysis of Variance for Swallow Duration Measures—Cuff Inflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	7.000	1.817	.225	7.000
Bolus	7.000	1.773	.234	7.000
Condition x Bolus	7.000	1.278	.377	7.000

*Value is significant at $p \leq .05$.

Table 11: Mean Values for Hyolaryngeal Excursion (in millimeters)

Measure	Condition	Bolus	Mean	Standard Error
Maximum Laryngeal Elevation	Cuff Inflated	Liquid	9.853	.763
		Puree	9.023	.717
	No Cuff or Cuff Deflated	Liquid	9.224	.763
		Puree	8.840	.489
	PMTSV	Liquid	8.493	.718
		Puree	9.569	.718
Maximum Hyoid Anterior Excursion	Cuff Inflated	Liquid	11.350	.635
		Puree	9.314	.908
	No Cuff or Cuff Deflated	Liquid	11.671	.834
		Puree	10.654	.570
	PMTSV	Liquid	10.736	.866
		Puree	11.465	.734

repeated-measures analysis of variance (ANOVA) ($p \leq .05$) was employed to examine the differences in mean laryngeal elevation for the no cuff or cuff-deflated condition and the PMTSV condition (see Table 12). Results revealed no significant main effect for condition ($F(1, 17) = .000$, $p = .996$) or bolus ($F(1, 17) = .271$, $p = .609$). A separate univariate repeated measures analysis of variance (ANOVA) ($p \leq .05$) was employed to examine the differences in means for laryngeal elevation for the cuff-inflated condition and the PMTSV condition (see Table 13). Results revealed no significant main effect of condition ($F(1, 13) = .297$, $p = .595$) or bolus ($F(1, 13) = .010$, $p = .920$).

Mean hyoid anterior movement for the cuff-inflated condition was 11.350 mm (S. E. = .635) for the liquid bolus and 9.314 mm (S.E. = .908) for the pureed bolus. For the no cuff or cuff-deflated condition, mean hyoid anterior movement was 11.671 mm (S.E. = .834) for the liquid bolus and 10.654 mm (S.E. = .570) for the pureed bolus. Mean maximum hyoid anterior movement for the PMTSV condition was 10.736 mm (S.E. = .866) for the liquid bolus and 11.465 mm (S.E. = .734) for the pureed bolus. A 2 (condition) x 2 (bolus) univariate repeated-measures analysis of variance (ANOVA) ($p \leq .05$) was performed to examine the differences

Table 12: Univariate Repeated Measures Analysis of Variance for Laryngeal Elevation—No Cuff or Cuff Deflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	1.000	.000	.996	17.000
Bolus	1.000	.271	.609	17.000
Condition x Bolus	1.000	2.833	.111	17.000

*Value is significant at $p \leq .05$.

Table 13: Univariate Repeated Measures Analysis of Variance for Laryngeal Elevation—Cuff Inflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	1.000	.297	.595	13.000
Bolus	1.000	.010	.920	13.000
Condition x Bolus	1.000	1.451	.250	13.000

*Value is significant at $p \leq .05$.

in mean hyoid anterior movement for the no cuff or cuff-deflated condition and the PTMSV condition. Results indicated no significant main effect for condition ($F(1, 17) = .019$, $p = .892$) or bolus ($F(1, 17) = .051$, $p = .825$. To examine the differences in mean hyoid anterior movement for the cuff-inflated condition and PMTSV condition, a separate 2 (condition) x 2 (bolus) univariate repeated-measures analysis of variance (ANOVA) ($p \leq .05$) was performed. Results indicated no significant main effect of condition ($F(1, 13) = 2.832$, $p = .116$). There was a significant main effect for bolus ($F(1, 13) = 4.955$, $p = .044$). Specifically, maximum hyoid anterior movement was significantly greater for the liquid bolus than for the puree bolus.

Residue

Residue was rated using a 3-point scale: 0 = "no visible residue"; 1 = "coating"; and 2 = "pooling". Residue in the oral cavity, valleculae, posterior pharyngeal wall, pyriform sinuses, and the cricopharyngeus was noted. Mean values for residue are presented in Table 14. A two-factor (condition and bolus) doubly multivariate repeated-measures analysis of variance (MANOVA) ($p \leq .05$) (see Table 15) was performed to examine the differences in

Table 14: Mean Values for Oropharyngeal Residue

Location	Condition	Bolus	Mean	Standard Error
Oral Cavity	Cuff Inflated	Liquid	.885	.151
		Puree	.952	.183
	No Cuff or Cuff Deflated	Liquid	1.029	.145
		Puree	1.100	.098
	PMTSV	Liquid	1.118	.163
		Puree	1.426	.190
Valleculae	Cuff Inflated	Liquid	1.038	.174
		Puree	1.338	.207
	No Cuff or Cuff Deflated	Liquid	1.118	.163
		Puree	1.366	.157
	PMTSV	Liquid	1.206	.177
		Puree	1.740	.140
Posterior Pharyngeal Wall	Cuff Inflated	Liquid	.231	.108
		Puree	.354	.130
	No Cuff or Cuff Deflated	Liquid	.206	.096
		Puree	.219	.093
	PMTSV	Liquid	.441	.120
		Puree	.561	.192
Pyriform Sinus	Cuff Inflated	Liquid	.538	.215
		Puree	.803	.231
	No Cuff or Cuff Deflated	Liquid	.647	.195
		Puree	.585	.186
	PMTSV	Liquid	.706	.227
		Puree	.930	.229
Cricopharyngeus	Cuff Inflated	Liquid	.000	.000
		Puree	.177	.104
	No Cuff or Cuff Deflated	Liquid	.147	.083
		Puree	.257	.094
	PMTSV	Liquid	.235	.097
		Puree	.152	.125

Table 15: Doubly Multivariate Repeated Measures Analysis of Variance for Oropharyngeal Residue—No Cuff or Cuff Deflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	5.000	2.331	.102	13.000
Bolus	5.000	1.693	.206	13.000
Condition x Bolus	5.000	1.110	.402	13.000

*Value is significant at $p \leq .05$.

mean values for residue for the no cuff or cuff-deflated condition and the PMTSV condition. Results revealed no significant main effect for condition ($F(5, 13) = 2.331$, $p = .102$) or bolus ($F(5, 13) = 1.693$, $p = .206$). A separate two-factor (condition and bolus) doubly multivariate repeated-measures analysis of variance (MANOVA) ($p \leq .05$) (see Table 16) was performed to examine the differences in means for residue for the cuff-inflated condition and the PMTSV condition. Results revealed a significant main effect of condition ($F(5, 9) = 10.280$, $p = .002$). Univariate testing revealed a significant effect of condition on oral residue ($F(1, 13) = 13.760$, $p = .003$), posterior pharyngeal wall residue ($F(1, 13) = 5.799$, $p = .032$), and cricopharyngeal residue ($F(1, 13) = 5.452$, $p = .036$). Specifically, residue in the oral cavity, posterior pharyngeal wall residue, and cricopharyngeus was significantly greater for the PMTSV condition than for the cuff-inflated condition. Bolus type also had a significant effect on oropharyngeal residue ($F(5, 9) = 4.207$, $p = .030$). Residue in the valleculae was significantly greater for the pureed bolus than for the liquid bolus ($F(1, 13) = 14.694$, $p = .002$).

Table 16: Doubly Multivariate Repeated Measures Analysis of Variance for Oropharyngeal Residue—Cuff Inflated versus Passy-Muir Tracheostomy Speaking Valve

Independent Measure	df	F	Significance	Error df
Condition	5.000	10.280	.002*	9.000
Bolus	5.000	4.207	.030*	9.000
Condition x Bolus	5.000	.354	.868	9.000

*Value is significant at $p \leq .05$.

CUFF DEFLATION

To answer the third and fourth research questions, data from the 14 participants who had cuffed tracheostomy tube was analyzed.

Penetration-Aspiration

The answer to the third research question, "Does cuff deflation reduce the incidence and/or severity of penetration/aspiration in tracheostomized patients?", is no. The mean score on the Penetration- Aspiration scale for the cuff-inflated condition was 6.571 (S.E. = .462) for the liquid bolus and 2.623 (S.E. = .745) for the pureed bolus. For the cuff-deflated condition, the mean score on the Penetration-Aspiration scale was 6.321 (S.E. = .741) for the liquid bolus and 2.181 (S.E. = .544) for the pureed bolus. To determine if these means were statistically different, a 2 (condition) x 2 (bolus) repeated measures analysis of variance (ANOVA) ($p \leq .05$) was performed (see Table 17). Results indicated no significant main effect of condition ($F(1, 13) = .518$), $p = .484$). There was a significant main effect for bolus ($F(1, 13) = 48.497$, $p < .001$). Scores on the Penetration-Aspiration scale were significantly lower (better) for the pureed bolus than for the liquid bolus.

Table 17: Repeated Measures Analysis of Variance for Penetration-Aspiration—Cuff Inflated versus Cuff Deflated

Independent Measure	df	F	Significance	Error df
Condition	1.000	.518	.484	13.000
Bolus	1.000	48.497	.000*	13.000
Condition x Bolus	1.000	.053	.821	13.000

*Value is significant at $p \leq .05$.

Swallowing Physiology

The answer to the fourth research question, "Does cuff deflation affect swallowing physiology?" is yes. Means were derived for all duration measures, extent of hyolaryngeal excursion, and residue.

Duration Measures

A two-factor (condition and bolus) doubly multivariate repeated-measures analysis of variance (MANOVA) ($p \leq .05$) revealed a significant main effect for condition ($F(7, 7) = 3.852$, $p = .048$) on swallowing duration measures(see Table 18). Univariate testing ($p \leq .05$) revealed a significant effect for condition on pharyngeal transit duration (PTD) ($F(1, 13) = 5.487$, $p = .036$), duration of hyoid maximum anterior excursion (DOHMAE) ($F(1, 13) = 4.719$, $p = .049$) and duration of cricopharyngeal opening ($F(1, 13) = 4.719$, $p = .005$) (DOCPO). Specifically, mean PTD was significantly longer for the cuff-deflated condition than for the cuff-inflated condition, mean DOHMAE was significantly longer for the cuff-deflated condition than for the cuff-inflated condition, while mean DOCPO was significantly shorter for the cuff-deflated condition than for the cuff-inflated condition. There was no significant main effect of bolus ($F(7, 7) = 2.316$, $p = .145$).

Table 18: Doubly Multivariate Repeated Measures Analysis of Variance for Swallow Duration Measures—Cuff Inflated versus Cuff Deflated

Independent Measure	df	F	Significance	Error df
Condition	7.000	3.852	.048*	7.000
Bolus	7.000	2.316	.145	7.000
Condition x Bolus	7.000	1.340	.355	7.000

*Value is significant at $p \leq .05$.

Hyolaryngeal Excursion

Mean maximum laryngeal elevation for the cuff-inflated condition was 9.853 mm (S.E. = .763) for the liquid bolus and 9.023 mm (S.E. = .717) for the pureed bolus. For the cuff-deflated condition, mean maximum laryngeal elevation was 9.656 mm (S.E. = .944) for the liquid bolus and 8.942 mm (S.E. = .408) for the pureed bolus. A 2 (condition) x 2 (bolus) univariate repeated-measures analysis of variance (ANOVA) ($p \leq .05$) revealed no significant effect of condition ($F(1, 13) = .159$, $p = .696$) or bolus ($F(1, 13) = 2.805$, $p = .118$) (see Table 19).

Mean distance for maximum hyoid anterior excursion for the cuff-inflated condition was 11.350 mm (S.E. = .635) for the liquid bolus and 9.314 mm (S.E. = .908) for the pureed bolus. For the cuff-deflated condition, mean maximum hyoid anterior excursion was 12.076 mm (S.E. = 1.002) for the liquid bolus and 11.055 mm (S.E. = .642) for the pureed bolus. A 2 (condition) x 2 (bolus) univariate repeated-measures ANOVA ($p \leq .05$) revealed a significant main effect for condition ($F(1, 13) = 7.960$, $p = .014$) (see Table 20). Mean maximum hyoid anterior movement was significantly greater for the cuff-deflated condition than for the cuff-inflated condition.

Table 19: Univariate Repeated Measures Analysis of Variance for Laryngeal Elevation—Cuff Inflated versus Cuff Deflated

Independent Measure	df	F	Significance	Error df
Condition	1.000	.159	.696	13.000
Bolus	1.000	2.805	.118	13.000
Condition x Bolus	1.000	.008	.930	13.000

*Value is significant at $p \leq .05$.

Table 20: Univariate Repeated Measures Analysis of Variance for Anterior Hyoid Movement—Cuff Inflated versus Cuff Deflated

Independent Measure	df	F	Significance	Error df
Condition	1.000	7.960	.014*	13.000
Bolus	1.000	32.379	.000*	13.000
Condition x Bolus	1.000	.274	.610	13.000

*Value is significant at $p \leq .05$.

Residue

Residue was rated using a 3-point scale: 0 = "no visible residue"; 1 = "coating"; and 2 = "pooling." Residue in the oral cavity, valleculae, posterior pharyngeal wall, pyriform sinuses, and the cricopharyngeus was noted. A two-factor (condition and bolus) doubly multivariate repeated-measures analysis of variance (MANOVA) ($p \leq .05$) revealed no significant effect for condition ($F(5, 9) = 2.398$, $p = .120$) or bolus ($F(5, 9) = 1.909$, $p = .188$) on residue (see Table 21).

Table 21: Doubly Multivariate Repeated Measures Analysis of Variance for Oropharyngeal Residue—Cuff Inflated Versus Cuff Deflated

Independent Measure	df	F	Significance	Error df
Condition	5.000	2.398	.120	9.000
Bolus	5.000	1.909	.188	9.000
Condition x Bolus	5.000	.701	.637	9.000

*Value is significant at $p \leq .05$.

CHAPTER FIVE

DISCUSSION

Many physicians believe that an inflated tracheostomy tube cuff will prevent spillage of material into the lower airway. Thus, tracheostomy tubes are often placed as a means of treating chronic aspiration. There is substantial evidence in the literature that suggests tracheostomy tubes adversely affect swallowing function. Nash (1988) stated, "the major swallowing disorder associated with tracheostomy is aspiration" (p. 705).

Several investigators (Dettelbach et al., 1995; Stachler et al., 1996) have suggested that Passy-Muir Tracheostomy Speaking Valve (PMTSV) placement may reduce the incidence and severity of aspiration in tracheostomized patients. Dettelbach and colleagues examined the effects of PMTSV placement on swallow function in 11 tracheostomized individuals using videofluoroscopy. They found that all 11 participants exhibited a marked reduction in the incidence and amount of aspiration when the PMTSV was in place. However, the authors did not specifically state how they determined the amount of aspiration. Thus, the results of their study are questionable.

Stachler and associates (1996) also examined the effects of PTMSV placement on incidence and severity of aspiration in tracheostomized patients. They used scintigraphy in conjunction with videofluoroscopy. Results of their study indicated that while the PMTSV did not eliminate aspiration for any of the participants, it did appear to reduce the amount of aspiration.

While these two studies suggest that the Passy-Muir valve has a positive effect on swallow function, there have been conflicting findings reported in the literature. Leder (1999) examined 20 tracheostomized individuals using fiberoptic endoscopy. Swallow function was examined with and without a one-way valve in place. Results indicated that placement of a one-way valve had no significant effect on the incidence of aspiration in tracheostomized individuals.

The purpose of the current study was to examine the effect of Passy-Muir Tracheostomy Speaking Valve placement on the incidence and severity of aspiration in tracheostomized individuals. An 8-point penetration-aspiration scale was used to rate the severity of penetration/aspiration events. Fourteen individuals with cuffed tracheostomy tubes and four individuals with

cuffless tracheostomy tubes were examined. Results indicate that the PMTSV significantly reduces the severity of penetration/aspiration. These results support previous findings in the literature that suggest that PMTSV placement reduces the incidence of aspiration in tracheostomized patients.

In order to determine how the Passy-Muir valve affected specific biomechanical aspects of the swallow, a number of swallow duration measures were calculated. In addition, maximum extent of hyolaryngeal excursion and amount of oropharyngeal residue were determined. Results of this study indicate that, when compared to the cuff-inflated condition, the PMTSV resulted in an increase in oral residue, posterior pharyngeal residue, and cricopharyngeal residue. The reason for the increase in oropharyngeal residue is unclear. Logemann, Pauloski, and Coleangelo (1998) found that tracheostomy tube occlusion reduced duration of tongue base contact to the posterior pharyngeal wall. It is possible that this also occurred with the participants in the current study.

None of the findings related to swallow physiology would account for the significant reduction in incidence and severity of aspiration that was evident in this study.

Several studies (Gross et al., 1994; Sasaki & Isaacson, 1988) have found that the presence of a tracheostomy tube results in a reduction in subglottal air pressure. Eibling and Gross (1996) have suggested that reduction in subglottal air pressure in the primary mechanism responsible for aspiration in tracheostomized patients. Gross and colleagues found that PMTSV placement results in a significant increase in subglottal air pressure. The current study did not examine subglottal air pressure.

In addition, by allowing air to flow through the upper airway, PMTSV placement may improve pharyngeal sensation. Improved pharyngeal sensation could result in improved bolus control and safer swallow function. Pharyngeal sensation was not examined in this study.

Another aim of this study was to examine the effects of cuff deflation on incidence and severity of penetration/aspiration. Several investigators (Bonnano, 1971; Elpern, Scott, Petro, & Ries, 1994; Logemann, 1995; Murray & Brzozowski, 1998) have suggested that the presence of an inflated tracheostomy cuff may interfere with normal swallowing function. An inflated tracheostomy tube cuff may impede hyolaryngeal excursion, resulting in reduced airway protection and decreased cricopharyngeal opening.

Delayed onset of the pharyngeal swallow and the presence of pharyngeal residue have frequently been observed in patients with cuffed tracheostomy tubes who have no additional medical condition that would predispose them to swallowing dysfunction (Murray & Brzozowski). Tracheostomy cuffs do not provide a perfect tracheal seal, and patients can and do aspirate around an inflated cuff. Moreover, if the cuff is improperly inflated, the cuff may impinge on the esophageal wall, effectively preventing the flow of food or liquid through the esophagus. Repeated swallowing with an over-inflated cuff may also create a tracheo-esophageal fistula.

Given the detrimental effects of inflated tracheostomy cuffs on swallowing, one might speculate that deflating the cuff would restore normal swallowing function. Tippett and Siebens (1991) sought to determine if this was the case. They examined five ventilator-dependent, tracheostomized patients with various diagnoses. Swallowing function was examined in three of the five patients using videofluoroscopy. All three of these patients were receiving a non-oral means of nutrition. Individuals were first assessed with their tracheostomy cuffs inflated and then re-assessed at a later date with their cuffs deflated.

The second videofluoroscopic swallow study (VFSS) was postponed until each participant was able to phonate with the cuff deflated. Length of time from the initial VFSS and the second VFSS ranged from 10 to 28 days. All individuals were able to safely swallow with their cuffs deflated. However, for two of the individuals, penetration was only eliminated when their tracheostomy tube was coupled to a ventilator. The authors concluded that deflating a tracheostomy tube cuff "restores safe oral alimentation by mouth" (p.94). Two design flaws are noteworthy. First, because there were a substantial number of days between the initial and second VFSS, any changes in swallowing function may not be attributed solely to cuff deflation. In addition, individuals were ventilator-dependent. In fact, two of the three participants were only able to safely take food by mouth when their tracheostomy tubes were coupled to a ventilator. Thus, it appears that the ventilator, not cuff deflation, may have been responsible for any improvements in swallowing.

This study also examined the effect of cuff deflation on the incidence and severity of aspiration. Fourteen non-ventilator dependent patients participated. No significant differences were observed between cuff-inflated and cuff-

deflated conditions on incidence or severity of aspiration. There are two potential reasons for the discrepancy between our findings and the results reported by Tippett and Siebens (1991). As previously stated, patients in Tippett and Siebens' study were ventilator-dependent. Thus, the ventilator may have affected swallowing function more than cuff deflation. The individuals in our study were off the ventilator in order to eliminate any possible interference. Second, the cuff-inflated and cuff-deflated conditions were completed during the same VFSS study rather than during separate studies in order to eliminate possible time effects; and conditions were randomized to reduce the possibility of an order effect.

It is unclear why cuff deflation had no apparent effect on the incidence of penetration/aspiration. Deflating the cuff does not resolve the problem of reduced subglottal pressure created by the presence of a tracheostomy tube. As previously stated, Eibling and Gross (1996) have suggested that reduction in subglottal air pressure is the primary mechanism responsible for aspiration in tracheostomized patients. Additionally, tracheostomy tubes have been found to increase the sensory threshold of the adductor vocal fold reflex (Buckwalter &

Sasaki, 1984). Although cuff deflation restores airflow through the vocal folds and upper airway, some air is still allowed to escape through the open tracheostomy tube. Thus, cuff deflation may not fully restore sensation in the pharynx and larynx, which is necessary for safe swallowing. We did not attempt to assess laryngeal or pharyngeal sensation in this study.

Cuff deflation was observed to significantly increase pharyngeal transit duration (PTD), duration of hyoid maximum anterior excursion (DOHMAE) and significantly reduce duration of cricopharyngeal opening (DOCPO). In addition, maximum hyoid anterior movement (mm) was significantly increased by cuff deflation. The findings of increased DOHMAE and increased maximum hyoid anterior movement support the suggestion that an inflated tracheostomy tube cuff reduces hyolaryngeal excursion. It is unclear why there was a reduction in DOCPO. All but one participant had a nasogastric tube in place at the time of their swallow examination. Perhaps, as Gilbert and colleagues (1987) suggested, the presence of a nasogastric tube interferes with relaxation of the cricopharyngeal sphincter. The reason for increased PTD is uncertain.

Conclusions and Clinical Implications

The major findings of this study indicate that Passy-Muir Tracheostomy Speaking valve placement significantly reduces the incidence and severity of aspiration in tracheostomized patients. Swallow duration measures and hyolaryngeal excursion were not significantly affected by Passy-Muir valve placement. Thus, the reason for the reduction in penetration/aspiration remains unclear.

This study has important implications for clinicians working with tracheostomized patients. Findings suggest that patients who are able to tolerate cuff deflation and Passy-Muir Tracheostomy Speaking valve placement may benefit from eating with a Passy-Muir valve in place. Clinicians who complete videofluoroscopic swallow evaluations with tracheostomized patients should include several bolus presentations with the Passy-Muir valve in place.

Limitations

There are several limitations of the present study. First, a power analysis completed prior to the initiation of this study indicated that 22 participants were necessary in order to achieve a power of .95. However, only 18 participants met the inclusion criteria for this study.

Scores on the Penetration-Aspiration scale for the cuff-inflated condition versus the Passy-Muir valve condition and for the cuff-deflated condition versus the Passy-Muir valve condition were found to significantly differ. Since statistical significance was found, there would be no gain made by adding four additional participants. However, the fact that we only included 18 participants rather than 22 may account for the lack of statistical significance found for the swallow duration measures and hyolaryngeal excursion when comparing the cuff-inflated condition and the PMTSV condition and when comparing the cuff-deflated condition to the PMTSV condition.

In addition, we did not attempt to control for length of time between tracheostomy tube placement and the videofluoroscopic swallow study (VFSS). Nor did we attempt to control for length of time between initial cuff deflation and the VFSS. Finally, we did not attempt to control for participants' diagnoses, though we did ensure all participants were free of structural damage other than tracheotomy.

Future Research

The findings from the present study suggest the need for further research to investigate the effects of

tracheostomy tubes on swallowing physiology. Specifically, the effect of the Passy-Muir valve on pharyngeal and laryngeal sensitivity needs to be assessed. An investigation designed to determine the effects of Passy-Muir valve placement on subglottal pressure may elucidate the effects of valve placement on penetration/aspiration.

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APPENDICES

APPENDIX A

Patient Information Sheet

Information Sheet
An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients

You are invited to participate in a research study in the Department of Audiology and Speech Pathology at the University of Tennessee, Knoxville. Your help will be greatly appreciated. If you are interested in participating in this study, please contact your speech-language pathologist.

Researchers: Debra Suiter, MA, CCC-SLP and Gary McCullough, Ph.D., CCC-SLP

Participants Needed: 18 adults with suspected difficulty swallowing, have a tracheostomy tube in place, and are non ventilator-dependent. Individuals with a history of previous neurological damage or swallowing problems will not be included in this study.

Number of Sessions: You will be seen for one testing session only.

Risks of the Project: You will be at risk for potential aspiration (water falling into your airway) during your swallow study. Aspiration is a known cause of pneumonia. Precautions will be taken during testing to minimize the likelihood of aspiration. You will also be exposed to a minimal amount of radiation during the x-ray study of your swallowing. This amount of radiation is similar to what you would normally experience in 2 months of natural background radiation.

Benefit of the Project: This study will provide information regarding a means of reducing aspiration in patients with tracheostomy tubes.

Confidentiality: The information in this study will be kept confidential. Data will be stored securely and will be made available only to those directly participating in the project unless permission is provided.

Participation: Your participation is voluntary, and you may decline to participate at any time during the course of this study. If you withdraw, your data will be returned to you or destroyed.

If you have any questions at any time about the study or the procedures, you may contact Debra Suiter at the UT Hearing and Speech Center, 974-8663. If you have questions regarding your rights as a participant, contact the Compliance Section of the Office of Research at 974-3466.

APPENDIX B

Informed Consent Forms

CONTENTS—APPENDIX B

An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients
INFORMED CONSENT FOR PATIENTS

You have been invited to participate in a research study. The purpose of this study is to investigate the effects of two conditions, cuff deflation and Passy-Muir Tracheostomy Speaking valve placement, on swallowing in patients with tracheostomy tubes. Your tracheostomy tube has a balloon-like cuff that can be filled with air. Some physicians believe that keeping air in the cuff (keeping it inflated) helps to prevent material such as food or liquid from falling into a patient's airways. However, having an inflated cuff may actually make it more difficult for you to swallow safely. We want to watch you swallow with the cuff inflated and with it deflated to see which way you swallow more safely. We also want to watch you swallow with a valve over your tracheostomy tube. It's called a Passy-Muir Tracheostomy Speaking Valve, and it allows a person to breathe in through your tracheostomy tube, but it closes when you breathe out so you can speak.

In this study you will complete an x-ray swallowing study under three conditions: cuff inflated, cuff deflated, and cuff deflated with the Passy-Muir valve in place. You will be given two swallows of liquid mixed with barium and two swallows of applesauce mixed with barium to swallow under each condition (total of 12 swallows).

Although every effort will be made to ensure your safety while participating in this study, you will be at risk for potential aspiration of material into your lungs. Aspiration is a known cause of pneumonia. However, we will have you swallow barium, which is known to be less likely to cause an infection than other food or liquid. We will take every precaution to minimize risks to you during the swallow study. Your physician has, and will continue to make, decisions about the management of your tracheostomy tube and your ability to take food by mouth. If you choose to participate in this study, your primary physician will be contacted and asked to share any concerns he has about the risks or benefits of your participation in this study. You will be exposed to a minimal amount of radiation during the x-ray swallowing study. This amount of radiation is similar to what one would normally receive in a 1 year period from our environment.

By signing this consent form, you are not waiving any legal rights or releasing the University of Tennessee from liability or negligence. In the event of physical injury or illness resulting from the research procedures, the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, the University does not provide for reimbursements for such injuries.

You will not be paid for your participation in this study. However, the swallowing study is one which you would complete regardless of your participation in this study. Only the order of liquid and food presentation and the number of swallows you will complete will be changed.

The information in the study records will be kept confidential. Data will be stored in

Subject's Initials _____

An Examination of the Effects Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients
INFORMED CONSENT FOR PATIENTS

the office of the investigator at the University of Tennessee. No reference will be made in oral or written reports which could link you to the study. You will be asked to give permission for the use of videotapes for educational and professional purposes. However, you do not need to give permission in order to participate in this study.

If you have questions at any time about the study or procedures, you may contact Debra Suiter at the University of Tennessee at (865)974-8663.

Your participation in this study is voluntary. You may decline to participate without penalty. If you decide to withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

I have read the description of this study and I have freely volunteered to participate in it. I have had possible risks explained to me. I have had an opportunity to ask questions of the principle investigator and have received acceptable answers. I understand that I may withdraw from this study at any time without penalty. As the swallowing study is one which my doctor has already ordered and my completing the swallowing examination is not dependent on whether or not I participate in this research study, I understand that I will be responsible for the cost of the swallowing study.

Participant's Signature _____ Date_____

Witness' Signature _____ Date _____

Investigator's Signature _____ Date _____

An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients
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In this study you will complete an x-ray swallowing study under three conditions: cuff inflated, cuff deflated, and cuff deflated with the Passy-Muir valve in place. You will be given two swallows of liquid mixed with barium and two swallows of applesauce mixed with barium to swallow under each condition (total of 12 swallows).

Although every effort will be made to ensure your safety while participating in this study, you will be at risk for potential aspiration of material into your lungs. Aspiration is a known cause of pneumonia. However, we will have you swallow barium, which is known to be less likely to cause an infection than other food or liquid. We will take every precaution to minimize risks to you during the swallow study. Your physician has, and will continue to make, decisions about the management of your tracheostomy tube and your ability to take food by mouth. If you choose to participate in this study, your primary physician will be contacted and asked to share any concerns he has about the risks or benefits of your participation in this study. You will be exposed to a minimal amount of radiation during the x-ray swallowing study. This amount of radiation is similar to what one would normally receive in a 1 year period from our environment.

By signing this consent form, you are not waiving any legal rights or releasing the University of Tennessee or the University of Tennessee Medical Center from liability or negligence. In the event of physical injury or illness resulting from the research procedures, the University of Tennessee does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, the University does not provide for reimbursements for such injuries.

You will not be paid for your participation in this study. However, the swallowing study is one which you would complete regardless of your participation in this study. Only the order of liquid and food presentation and the number of swallows you will complete will be changed.

The information in the study records will be kept confidential. Data will be stored in

Subject's Initials _____

the office of the investigator at the University of Tennessee. No reference will be made in oral or written reports which could link you to the study. You will be asked to give permission for the use of videotapes for educational and professional purposes. However, you do not need to give permission in order to participate in this study.

If you have questions at any time about the study or procedures, you may contact Debra Suiter at the University of Tennessee at (865)974-8663. If during the course of this study you have questions concerning the nature of the research or your rights as a subject, please contact the office of the Institutional Review Board at (865)544-9781.

Your participation in this study is voluntary. You may decline to participate without penalty. If you decide to withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

I have read the description of this study and I have freely volunteered to participate in it. I have had possible risks explained to me. I have had an opportunity to ask questions of the principle investigator and have received acceptable answers. I understand that I may withdraw from this study at any time without penalty. As the swallowing study is one which my doctor has already ordered and my completing the swallowing examination is not dependent on whether or not I participate in this research study, I understand that I will be responsible for the cost of the swallowing study.

Participant's Signature _____ Date_____

Witness' Signature _____ Date _____

Investigator's Signature _____ Date _____

Subject's Initials _____
Page 2 of 2

An Examination of the Effects of Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients
INFORMED CONSENT FOR PATIENTS

You have been invited to participate in a research study. The purpose of this study is to investigate the effects of two conditions, cuff deflation and Passy-Muir Tracheostomy Speaking valve placement, on swallowing in patients with tracheostomy tubes. Your tracheostomy tube has a balloon-like cuff that can be filled with air. Some physicians believe that keeping air in the cuff (keeping it inflated) helps to prevent material such as food or liquid from falling into a patient's airways. However, having an inflated cuff may actually make it more difficult for you to swallow safely. We want to watch you swallow with the cuff inflated and with it deflated to see which way you swallow more safely. We also want to watch you swallow with a valve over your tracheostomy tube. It's called a Passy-Muir Tracheostomy Speaking Valve, and it allows a person to breathe in through your tracheostomy tube, but it closes when you breathe out so you can speak.

In this study you will complete an x-ray swallowing study under three conditions: cuff inflated, cuff deflated, and cuff deflated with the Passy-Muir valve in place. You will be given four swallows of liquid mixed with barium to swallow under each condition (total of 12 swallows).

Although every effort will be made to ensure your safety while participating in this study, you will be at risk for potential aspiration, or inhalation of material into your lungs. Aspiration is a known cause of pneumonia. However, we will have you swallow barium, which is known to be less likely to cause an infection than other food or liquid. We will take every precaution to minimize risks to you during the swallow study. Your physician has, and will continue to make, decisions about the management of your tracheostomy tube and your ability to take food by mouth. If you choose to participate in this study, your primary physician will be contacted and asked to share any concerns he has about the risks or benefits of your participation in this study. You will be exposed to a minimal amount of radiation during the x-ray swallowing study. This amount of radiation is similar to what one would normally receive in a 1 year period from our environment.

By signing this consent form, you are not waiving any legal rights or releasing the University of Tennessee or Ft. Sanders Regional Medical Center from liability or negligence. In the event of physical injury or illness resulting from the research procedures, the University of Tennessee and Ft. Sanders do not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, the University and Ft. Sanders do not provide for reimbursements for such injuries.

You will not be paid for your participation in this study. However, the swallowing study is one which you would complete regardless of your participation in this study. Only the order of liquid and food presentation and the number of swallows you will complete will be changed.

The information in the study records will be kept confidential. Data will be stored in

Subject's Initials _____

the office of the investigator at the University of Tennessee. No reference will be made in oral or written reports which could link you to the study. You will be asked to give permission for the use of videotapes for educational and professional purposes. However, you do not need to give permission in order to participate in this study.

If you have questions at any time about the study or procedures, you may contact Debra Suiter at the University of Tennessee Department of Audiology and Speech Pathology at (865) 974-8663 between the hours of 8:00 a.m. and 5:00 p.m. Monday through Friday. If during the course of this study you have questions concerning the nature of the research or your rights as a subject, please contact the office of the Covenant Health System Institutional Review Board at (865) 541-1814.

Your participation in this study is voluntary. You may decline to participate without penalty. If you decide to withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

I have read the description of this study and I have freely volunteered to participate in it. I have had possible risks explained to me. I have had an opportunity to ask questions of the principle investigator and have received acceptable answers. I understand that I may withdraw from this study at any time without penalty. As the swallowing study is one which my doctor has already ordered and my completing the swallowing examination is not dependent on whether or not I participate in this research study, I understand that I will be responsible for the cost of the swallowing study.

Participant's Signature _____ Date_____

Witness' Signature _____ Date _____

Investigator's Signature _____ Date _____

Subject's Initials _____

Patient Information/Consent Form

An Examination of the Effects of Cuff Deflation and Passy-Muir Tracheostomy Speaking Valve Placement on Incidence and Severity of Aspiration in Tracheostomized Patients

To be conducted at

Baptist Hospital of East Tennessee
137 Blount Avenue
Knoxville, TN 37920

PRINCIPAL INVESTIGATOR: Debra M. Suiter, MA, CCC-SLP, Doctoral Student in Speech Science

SUBINVESTIGATOR: Gary H. McCullough, Ph.D., CCC-SLP

You have been invited to participate in a research study. The purpose of this study is to investigate the effects of two conditions, cuff deflation and Passy-Muir Tracheostomy Speaking Valve placements, on swallowing in patients with tracheostomy tubes. Your tracheostomy tube has a balloon-like cuff that can be filled with air. Some physicians believe that keeping air in the cuff (keeping it inflated) helps prevent material such as food or liquid from falling into a patient's airways. However, having an inflated cuff may actually make it more difficult for you to swallow safely. We want to watch you swallow with the cuff inflated and with it deflated to see which way you swallow more safely. We also want to watch you swallow with a valve over your tracheostomy tube. It's called a Passy-Muir Tracheostomy Speaking Valve, and it allows a person to breathe in through your tracheostomy tube, but it closes when you breathe out so you can speak. In this study you will complete an x-ray swallowing study under three conditions: cuff inflated, cuff deflated, and cuff deflated with the Passy-Muir valve in place. You will be given four swallows of liquid mixed with barium to swallow under each condition (total of 12 swallows).

Although every effort will be made to ensure your safely while participating in this study, you will be at risk for potential aspiration of material into your lungs. Aspiration is a known cause of pneumonia. However, we will have you swallow barium, which is known to be less likely to cause an infection than other food or liquid. We will take every precaution to minimize risks to you during the swallow study. Your physician has made, and will continue to make, decisions about the management of your tracheostomy tube and your ability to take food by mouth. If you choose to participate in this study, your primary physician will be contacted and asked to share any concerns he has about the risks or benefits of your participation in this study. You will be exposed to a minimal amount of radiation during the x-ray study. This amount of radiation is similar to what

Patient Initials _____
Witness Initials_____

Initiated:

One would normally receive in a one year period from our environment. You will not benefit directly from participating in this study. However, this study will help other patients and clinicians by providing information regarding swallowing function in tracheostomized patients.

Your participation in this study is voluntary. No compensation for participation will be given.

You are free to withdraw your consent to participate in this research study at any time without prejudice to your subsequent care. Refusing to participate will involve no penalty or loss of benefits. You are free to seek care from a physician of your choice at any time. If you do not take part or withdraw from the study, you will continue to receive care.

If you know or suspect that you are pregnant, it is your obligation to inform the investigators. Individuals who are or may be pregnant should not participate in this study, as the radiation received during the x-ray swallowing study may be harmful to the fetus.

Any information learned from this study will be kept confidential and disclosed only with your permission. Your records will be made available to Baptist Hospital of East Tennessee and the study sponsor. If information learned from this study is published in a journal, you will not be identified by name.

No compensation is available for participating in this study. Also, no compensation is available for a physical or psychological injury which might occur as a result of this study. While medical care will be available should an injury occur, you will be billed for the costs of providing this care.

If you have any questions about your rights as a participant in this study, about the study itself or if you have any problems or complaints or study related injuries you may call Mr. Jon Foster, Administrator, at (865) 632-5210.

_____
Signature of Investigator

Patient Initials _____
Witness Intials_____

Initiated:

PATIENT CONSENT

I agree to participate in the study described above. This consent is given based on the verbal and written information provided to me. My physician has told me that I am medically and physically qualified to participate in this study. I am free to ask questions at any time. I may seek information from any resource which might help my understanding of this study.

The clinician responsible for the study at this institution (Principal Investigator: Debra Suiter, MA, CCC-SLP) may take me off the study if required to guarantee that my best interests will be served. If I encounter medical problems or complications, or have any questions about the study, I have been given the telephone number of my physician, (865) _____.

The purpose of this study is to investigate the effects of the Passy-Muir Tracheostomy Speaking valve on swallowing in tracheostomized patients.

By consenting to participate in this study, I realize am responsible for carrying out instructions and that I must relate to my doctors, nurses, and other study personnel any information that might be pertinent to the study, such as side effects of a treatment or procedure. Any new information regarding this study and any treatment it involves which might affect my willingness to continue my participation in the study will be related to me in an appropriate way.

I will receive a signed copy of this informed consent.

_____	_____
Date	Signature of Patient
_____	_____
Date	Witness

APPENDIX C

Data Sheet for Swallow Duration Measures

Timing Measures

Participant #: _____ **Date :** _____

Project : _____ **Tape #:** _____

Initials: _____

Bolus Type						

TONGUE

Begin Post. Movement						
Barium Enter Pharynx						
Head Enter Pharynx						
Tail Enter Pharynx						

HYOID

Begin Max. Elevation						
First Max. Elevation						
Last Max. Elevation						
First Max. Anterior						
Last Max. Anterior						
Return to Rest						

CRICOPHARYNGEUS

Open						
Head into CP						
Tail into CP						
Closed						

RESIDUE

Oral Cavity						
Valleculae						
Post. Pharyngeal Wall						
Pyriform Sinus						
Crico-pharyngeus						

PENETRATION-ASPIRATION SCALE

Score						

VITA

Debra Suiter was born in Burlington, Vermont on June 8, 1968. She attended schools in the public system of New Richmond, Ohio where she graduated from New Richmond High School in June 1986. She entered the University of Evansville in August 1986 and completed a Bachelor of Arts degree in English Literature in May 1990. She entered the Master's program in Speech Pathology at the University of Tennessee, Knoxville in August 1991 and received a Master of Arts degree in Speech Pathology in December 1993. After graduation, Ms. Suiter worked as a speech-language pathologist at Baptist Hospital of East Tennessee and the University of Tennessee Medical Center. She returned to the University of Tennessee, Knoxville in June 1998 to pursue the Doctorate of Philosophy degree in Speech and Hearing Science. The doctoral degree was received in August 2001.

Ms. Suiter has accepted a position as a speech-language pathologist at the Carl T. Hayden Veteran's Affairs Medical Center in Phoenix, Arizona. She will perform clinical and research duties there.