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Effects of Alterations in Swallow Task and Age on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Healthy Adult Males

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ABSTRACT

Effects of Alterations in Swallow Task and Age and on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Healthy Adult Males

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This study examined the effects of swallow task on swallow physiology, respiratory phase relationships, and oxygen saturation in healthy adult males. This study hoped to provide a building block to clinically relevant research with individuals with compromised swallowing and respiration.

Subjects included 40 healthy adult males with no history of swallowing disorders divided into four groups (20-30, 40-50, 60-70, and 80-90 years). Subjects submitted to a videofluoroscopic swallow study protocol of 27 swallows grouped into two tasks: (1) three single swallows of thin liquid barium and (2) three repetitions of eight consecutive, uninterrupted swallows of thin liquid barium. Order of the tasks were counterbalanced and randomly assigned.

The videofluorographic swallow study allowed for computation of durational measures for laryngeal elevation and closure. Use of respiratory inductive plethysmography allowed for analysis of the interruption and resumption of the respiratory cycle. Pulse oximetry allowed for assessment of oxygen saturation across the duration of the protocol.

Multiple repeated measures ANOVAs were completed and yielded the following statistically significant results: (1) a main effect of swallow task on duration of laryngeal elevation and closure, whereby durations are greater during consecutive swallows as compared to single bolus swallows, (2) a main effect of age on duration of both laryngeal

elevation and closure, whereby elevation and closure measures increased across the age groups, and (3) an interaction of age and swallow task on the durational increase in laryngeal elevation and closure, whereby increases were greater for older men (80-90) as compared to young (20-30) and middle aged (40-50) men. An increased tendency toward resumption of inspiration following consecutive swallows as compared to single swallows in healthy adult males across the age continuum was observed. Age had no impact on healthy adult males' propensities to return to inspiration following consecutive swallows or abilities to maintain stable oxygen saturation levels during the swallowing protocol.

Although the swallowing mechanism exhibited age related and task related fluctuations, overall swallow function and respiratory homeostasis remained uncompromised. The question remains if individuals with compromised swallowing or pulmonary function would demonstrate the same abilities.

DEDICATION

This work is dedicated to the multitude of patients for whom I have provided services over the course of my clinical practice. Thank you for allowing me into your lives and trusting me with your well being. It has been a privilege and an inspiration.

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Last, but certainly not least, is my beautiful daughter, Yanira. You have lit up my life in ways I never thought imaginable. I hope that by my completing this educational journey, you may someday be encouraged to find your passion and know that you can craft a life that can be fulfilling both personally and professionally. My Nira, always know that the title I am most proud of is that of your Mommy. I love you, my sweet baby girl.

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CHAPTER I.

INTRODUCTION

Voltaire (1694-1778), the famous writer and philosopher of the French Enlightenment, is quoted to have said “nothing would be more tiresome than eating and drinking if God had not made them a pleasure as well as a necessity”. While pleasure may be the impetus for many an enjoyable meal and drink, adequate nutrition and hydration is requisite for sustaining life. Maintenance of nutrition and hydration is accomplished in healthy humans via oral intake, a behavior with a level of neurophysiological complexity that is belied by its commonplace and often unnoticed occurrence. For most individuals the act of swallowing remains unremarkable until an issue arises, and the simple ability to meet one’s biological needs is suddenly compromised.

Initial studies of the anatomy and physiology of the swallow as well as the interconnection of swallowing and respiration began to surface primarily in the 1950s and 1960s in the work of Bosma and others (Bosma, 1953; Bosma, 1957; Doty & Bosma, 1956; Kawasaki and Ogura, 1968; Kawasaki et al., 1965; Odanaka, 1950(1); Odanaka 1950(2); Odanaka, 1954; Shelton et al., 1960; Sumi, 1963; Sumi, 1969). However, research in swallowing and swallowing disorders as we know it today began in earnest in the late 1970s and early 1980s (Blonsky et al., 1975; Logemann & Bytell, 1979; Logemann, 1983; Robbins et al., 1986; Veis & Logemann, 1985). It is the work of these pioneers that laid the foundation for the current research and clinical practice.

When considering the upper aerodigestive tract, it is imperative to consider it in terms of its physiological hierarchy in coordinating three critical functions: respiration, swallowing, and speech (Logemann, 1998). The act of swallowing must coordinated with respiration to provide protection from aspiration of foreign materials into the respiratory tract while avoiding excessive disturbance of the respiratory cycle. During swallowing, normal control of respiration is relinquished momentarily while the larynx is closed to prevent aspiration, creating an apneic interval (interval of respiratory cessation) of approximately one second (Martin-Harris, Logemann, Shaker, & Dodds, 1994; Preiksaitis & Mills, 1996; Shaker et al, 1990). Subsequently, the act of swallowing must also be coordinated with respiration in such a way as to avoid excessive disturbance of the respiratory cycle and disruption of respiratory homeostasis (Mathew, 1988).

As the anatomical and physiological interconnections between swallowing and respiration have been elucidated, researchers began to explore the impact of different bolus sizes, types, and presentation on the coordination of swallowing and respiration in healthy adults (Amri et al., 1984; Anderson et al. , 1995; Clark, 1920; Dick et al., 1993; Eckberg, 1982; German, et al.,1996; Kijima et al., 2000; Klahn & Perlman, 1999; Logemann et al., 1993; Martin-Harris et al.,1994; Nishino et al., 1985; Oku et al.,1993; Palmer & Hiiemae, 2003; Preiksaitis & Mills, 1996; Selley et al., 1989a; Shaker et al, 1990; Smith et al., 1989). At the other end of the age continuum, the relevance of synchrony of swallowing and breathing has been realized in the neonatal and preterm infant populations (Bamford et al., 1992; Bu'Lock et al., 1990; Daniels et al, 1988; Guilleminault & Coons, 1984; Lau, et al., 2003; Mathew et al., 1992; Mizuno & Ueda, 2003; Pauldetto, et al, 1986; Pierantoni et al., 1986; Selley et al., 1986; Stevenson & Allaire, 1991; Thoyre & Carlson, 2003; Weber et al., 1986; Yimms et al., 1993).

Alternatively, some researchers explored how the coupling of swallowing and respiration is impacted by a variety of disease processes and alterations in physiology, including stroke, cerebral palsy, and chronic obstructive pulmonary disease and found that disease process were frequently associated with increased variability in the coupling of swallowing and breathing (Hadjikoutis et al., 2000; Leslie et al., 2002; McPherson et al., 1992; Rempel & Moussavi, 2005; Schols et al., 1991; Selley et al., 1989b; Shaker et al., 1992). In a logical extension of studying the impact of swallowing on respiration, additional studies focused on the impact of swallowing on oxygen saturation in a variety of populations and revealed a potential for oxygen fluctuations in individuals with neurogenic and respiratory disorders (Rogers et al., 1993 Sellars et al., 1998 Tamura et al., 1999). The coupling of swallowing and breathing has compelled some researchers to investigate the appropriateness, or lack thereof, of the use of pulse oximetry as a diagnostic or screening tool for dysphagia at bedside (Chong et al., 2003; Lim et al., 2001; Sherman et al., 1999; Smith, Lee, O'Neill, & Connolly, 2000; Collins & Barkheit, 1997; Zaidi et al., 1995).

Understanding the nature of the coupling of respiration and swallowing in normal, non-disordered individuals across the age continuum is imperative if we wish to understand the impact of disordered swallowing on respiration and disordered respiration on swallowing.

With this in mind, this dissertation attempts to make a contribution to the body of data regarding swallowing and respiratory patterns across the age range.

This dissertation is designed to elucidate possible effects of age on the swallow physiology, respiratory phase relationships, and oxygen saturation of young adult to elderly non smoking males during the duration of multiple, consecutive, uninterrupted swallows versus single swallows. Four age groups of men will be utilized: (1) 20-30 years, (2) 40-50 years, (3) 60-70years, and (4) 80-90years. The study aims to address the following objectives:

(1) determine the impact of swallow task (single versus consecutive swallows) on measures of swallow physiology, temporal integration of swallowing with the respiratory cycle, and oxygen saturation in health adult men
(2) determine the impact of age on the aforementioned measures
(3) determine the possible interactions between swallow task and age and the interaction's impact on the aforementioned measures
(4) provide a stepping stone for clinically relevant research for patients with respiratory disorders and concomitant dysphagia

The present study is based on several unifying hypotheses:

(1) that the physiology of the normal oropharyngeal swallow in healthy adults is characterized by predictable alterations of physiology when presented with alterations in swallowing tasks;

(2) that the normal oropharyngeal swallow is intricately coordinated with respiration to allow for the prevention of aspiration while minimizing the impact of the apneic interval of the swallow on respiratory homeostasis;

(3) that healthy adults are capable of effective coordination of swallowing and breathing with minimal impact on respiratory homeostasis, but this coordination may decline or be altered with the aging process;

(4) that adults with less effective patterns of coordination of swallowing and breathing will be more likely to demonstrate signs of respiratory instability, such as alterations in oxygen saturation.

In summary, the significance of this study lies in its ability to elucidate patterns of coordination of swallowing and respiration during consecutive swallows in healthy adult males. The study may yield information regarding the impact, or lack thereof, of multiple consecutive swallows on oxygen saturation status in adult males, and the inclusion of multiple age groups in the subject population will allow for investigation of possible age effects. Lastly, this study may provide a stepping stone for clinically relevant research for patients with respiratory disorders and concomitant dysphagia.

Chapters I and II provide an overview of the literature pertaining to swallowing and respiration, in addition to variances in function secondary to different disease processes. Chapter III addresses the methodology and procedures utilized in this study. Chapter IV presents the statistical results, which are discussed at length in Chapter V.

CHAPTER II.

REVIEW OF THE LITERATURE

Historical Perspective

In 1920, the publication of Clark's article entitled "Deglutition Apnoea" marked the commencement of study of the relationship between swallowing and respiratory function. Studies completed in the 1950s and 1960s by Kawasaki and colleagues, Odanaka, and Sumi, expanded upon the notion of the interdependence of swallowing and respiration (Kawasaki and Ogura, 1968; Kawasaki, Ogura, and Takenouchi, 1965; Odanaka, 1950(1); Odanaka 1950(2); Odanaka, 1954; Sumi, 1963; Sumi, 1969). In the greater than 85 years following Clark's publication, investigators have found increasing support for the assertion that the swallowing and respiratory functions of the upper aerodigestive tract are anatomically, physiologically and neurophysiologically interdependent across the age continuum (Bamford, Taciak, and Gewolb, 1992; Bu'Lock, Woolridge, and Baum, 1990; Hirst, Ford, Gibson, and Wilson, 2002; Hiss, Treole, and Stuart, 2001; Kijima, Isono, and Nishino, 1999; Klahn and Pearlman, 1999; Martin-Harris, Logemann, Shaker, and Dodds, 1994; Martin-Harris, Brodsky, Price, Michel, and Walters, 2003; Mathew, 1988; McFarland and Lund, 1995; Nishino, Yonezawa, and Honda, 1985; Selley, Flack, Ellis, and Brooks, 1989; Smith, Wolkove, Colacone, and Kreisman, 1989; Storey, 1976; Wilson, Thach, Brouillette, and Abu-Osba, 1981).

It is critical to consider the upper aerodigestive tract in terms of its physiological hierarchy in coordinating three critical functions: respiration, swallowing and speech

(Logemann, 1998). The act of swallowing must be coordinated with respiration in such a way as to protect the airway but avoid excessive disturbance of the respiratory cycle and disruption of respiratory homeostasis (Mathew, 1988). Despite the multitude of studies supporting the interdependence between swallowing and respiration, "the basic physiologic relationships between breathing and swallowing remain poorly understood, and the impact of disordered deglutition on respiration is not clearly defined" (Martin-Harris, Logemann, Shaker, and Dodds, 1994, p. 714). The potential impact of disordered respiration on swallowing is still unclear.

Laryngeal Closure during Swallowing

While breathing requires a patent airway with an unobstructed larynx, swallowing requires laryngeal closure. During swallowing, normal control of respiration is relinquished momentarily while the larynx is closed, creating an apneic interval (interval of respiratory cessation). In humans, the apneic interval is approximately one second in duration for swallows of single boluses ranging in size from one to 20 ml (Martin-Harris et al., 1994; Preiksaitis & Mills, 1996; Shaker et al., 1990).

Closure of the airway during swallowing is necessary for the prevention of aspiration of foreign materials into the respiratory tract (Nishino, Yonezawa, and Honda, 1985). A multitude of research has demonstrated this phenomenon in humans as well as other mammals (Amri, Car, & Jean, 1984; Anderson, Dick, & Orem, 1995; Clark, 1920; Dick, Oku, Romaniuk, &Cherniack, 1993; Eckberg, 1982; German, Crompton, McClusky, and

Thexton (1996); Martin-Harris et al., 1994; Nishino, Yonezawa, & Honda, 1985; Oku, Dick, & Cherniack, 1993; Preiksaitis & Mills, 1996; Shaker et al, 1990). While it was once thought that human infants were capable of swallowing and breathing simultaneously, it is now generally accepted that breathing and swallowing are mutually exclusive tasks in infants, as in adults (Mathew, 1988).

Normal Physiological Prevention of Aspiration during Swallowing

Aspiration is prevented via a complex series of movements commenced after initiation of the pharyngeal swallow. During the act of swallowing, the larynx closes, beginning at the level of the true vocal folds and progressing supraglottally to closure of the false vocal folds, the anterior displacement of the arytenoids to the base of the epiglottis, stiffening of the aryepiglottic folds, and epiglottic inversion (Martin-Harris, et al., 1994, Shaker, et al., 1990; Eckberg, 1982). As closure of the larynx occurs, the hyoid bone and larynx elevate which contributes to closure of the larynx (Logemann, 1998). The hyolaryngeal structures also move anteriorly, contributing to contact of the arytenoids to the base of the epiglottis and opening of the relaxed upper esophageal sphincter (Logemann, 1998). Pressure created by tongue base retraction and anterior movement of the posterior pharyngeal wall, laryngeal closure, hyolaryngeal elevation and anterior movement, and upper esophageal sphincter relaxation and opening, allow for passage of the bolus through the pharynx and upper esophageal sphincter into the esophagus. Subsequently, aspiration of any portion of the bolus into the respiratory tract is prevented.

Bolus Volume and Repeated Swallow Effects on Laryngeal Closure

In a study investigating the temporal effects of bolus volume on duration of closure of the laryngeal vestibule, Logemann et al. (1993) found that the duration of laryngeal closure increased as bolus size increased (1, 5, 10, and 20ml liquid boluses). Studies by Shaker et al. (1990), Martin-Harris et al. (1994), Preiksatis and Mills (1996) revealed apneic intervals of approximately 1 second with single swallows of thin liquid boluses ranging from 1 to 20 ml in size. Prolonged periods of apnea and laryngeal excursion (defined as duration of laryngeal elevation) have been noted in large volume (20ml) swallows (Leslie et al., 1999) and large volume (100ml) repeated swallows from a straw (Martin-Harris et al., 1994).

A pilot of the current project attempted to explore the impact of single versus consecutive, uninterrupted swallows on swallow physiology of healthy 20-30 year old adult males. The same stimuli, design, procedures, and data reduction were utilized as those described later in this document. Statistically significant increases in duration of laryngeal vestibule closure and laryngeal elevation during consecutive swallows as compared to single swallows were consistent with the alterations in the apneic interval associated with larger volume swallows (Hiss et al., 2001; Leslie et al., 1999; Logemann et al., 1993; Martin-Harris et al., 1994). The greater variability noted in duration of laryngeal vestibule closure and elevation during consecutive versus single swallows was similar to findings by Martin-Harris, et al whereby large volume swallows were associated with increases in the duration of the apneic interval and extent of laryngeal excursion (1994).

Coordination of Swallowing and the Respiratory Cycle

A number of studies have investigated the coordination of the swallow with phases of the respiratory cycle. Most of these studies have been done with single boluses and saliva swallows. The predominant pattern which emerged from this research indicated that the pharyngeal swallow most frequently interrupts the expiratory phase of the respiratory cycle and is followed by exhalation in non impaired adults across the age span (Kijima, Isono, & Nishino, 2000; Klahn & Perlman, 1999; Martin-Harris et al., 1994; Nishino et al., 1985; Palmer & Hiiemae, 2003; Preiksaitis and Mills, 1996; Selley, Flack, Ellis, and Brooks, 1989a; Smith, Wolkove, Colacone, & Kreisman, 1989).

Different explanations have been posited for the coupling of the swallow with the expiratory cycle. Most commonly, it is presumed that the coupling of swallowing with expiration aids in clearance of the upper airway of any residue remaining after the swallow, thereby protecting the individual from aspiration of any residue (Hadjikoutis et al., 2000; Klahn & Perlman, 1999; Martin-Harris et al., 1994; Nishino et al., 1985; Palmer & Hiiemae, 2003; Selley et al., 1989a & b; Shaker et al., 1992; Smith et al., 1989). Gross et al. (2003) posit that “the preferential timing of the normal swallow with the exhalation phase is a mechanism that allows for stimulation of subglottic mechanoreceptors and generation of the Psub (positive subglottic air pressure)” that is theorized to be important for the neuroregulation of swallowing.

Variability in Coordination of Swallowing and the Respiratory Cycle in Adults without Swallowing, Neurogenic, or Respiratory Impairments

While expiration before and after the period of swallow apnea appears to be the most common pattern in non-impaired adults, alterations in this pattern have been noted. These alterations have been noted in tasks involving larger bolus volumes or material requiring mastication. In reference to respiratory cycle interruption, Preiksaitis and Mills (1996) observed an increased propensity to interrupt the inspiratory phase with a swallow during 20ml swallows from a cup or syringe. Conversely, Martin-Harris et al.'s (1994) study revealed that with exception of only two swallows by one subject, "the apneic pause interrupted exclusively the expiratory phase of respiration…regardless of bolus volume" (p. 720), and overall the apneic interval interrupted expiration 94-100% of all trials. In 2003, Martin-Harris et al. observed that during 5ml barium swallows, a pattern of interruption of the inspiratory phase of the respiratory cycle was noted on less than 20% of all swallow trials.

Regarding resumption of the respiratory cycle, Preiksaitis and Mills (1996) noted inspiration following 200ml drink and sandwich trials in 18-26% and 16% of swallows respectively, while inspiration followed single bolus swallows in less than 5% of trials. Martin-Harris et al. (1994) also noted a higher occurrence of post swallow inspiration with larger (100ml) liquid boluses than with smaller (3, 10, and 20 ml) liquid boluses.

Smith et al. (1989) noted irregular breathing patterns during more typical eating and drinking behavior. McFarland and Lund (1995) concluded that mastication impacts respiratory rhythm and may be related to longer periods of apnea and alterations in the depth and duration of inspiration. It is questionable if patterns observed during single bolus swallows reflect the actual coordination of respiration and swallowing utilized during regular eating and drinking (Preiksaitis & Mills, 1996).

In the aforementioned pilot of the current study, single and consecutive swallows interrupted the expiratory phase of the respiratory cycle on 95% of all trials. Single swallows were followed by expiration on 97% trials. However, a statistically significant difference was noted in resumption of the respiratory cycle following single versus consecutive swallows. While subjects resumed inspiration following single swallows on only 10% of all trials, subjects resumed inspiration following consecutive swallows on 25% of trials. This was similar to the findings of Martin-Harris et al. (1994) and Preiksaitis and Mills (1996), which demonstrated a higher occurrence of post swallow inspiration after large versus small liquid swallows.

Variability in Coordination of Swallowing and the Respiratory Cycle in Individuals with Neurogenic Impairments

The few studies completed on various patient populations have indicated increased variability in coordination of swallowing and respiration in individuals with neurogenic disorders. For example, children with cerebral palsy (McPherson, Kenny, Koheil, Bablich, Sochaniwskji, & Milner, 1992), young adults with cerebral palsy (Rempel & Moussavi, 2005), and neurologically impaired dysphagic patients (Hadjikoutis, Pickersgill, Dawson, and Wiles, 2000; Hirst et al., (1999); Leslie, Drinnan, Ford, & Wilson, 2002; Selley, Flack, Ellis, and Brooks, 1989b) have demonstrated an increased likelihood of post swallow inspiration.

Variability in Coordination of Swallowing and the Respiratory Cycle in Adults with Disrupted Respiratory Function

Shaker et al (1992) demonstrated significant differences in both interruption and resumption of the respiratory cycle during water swallows in individuals with COPD, both in exacerbated and basal conditions. Incidence of interruption of inspiration occurred on approximately 5% of 5ml water trials in patients with basal COPD. However, during exacerbation incidence of interruption of inspiration increased significantly to approximately 37%. The same trend was noted on resumption of the respiratory cycle following swallowing, whereby the incidence of inspiration resumption increased from 17% in the basal state to 42% in the exacerbated state.

Additionally, Shaker et al (1992) compared the interruption and resumption tendencies of elderly individuals to individuals with exacerbated and basal COPD. Individuals with basal and exacerbated COPD demonstrated a decreased tendency to interrupt inspiration (5% and 37% respectively) as compared to elderly individuals (55%). While the incidence of resumption of inspiration was roughly 17% for elderly, normal individuals and individuals with basal COPD, incidence of resumption of inspiration increased significantly to approximately 42% in individuals with exacerbated COPD.

A study by Kijima, et al (1999) demonstrated that manipulations of experimental conditions designed to mimic particular respiratory issues resulted in alteration of coordination of respiration and swallowing. Subjects wore facemasks coupled to a pneumotachograph during the duration of the study. Resistive loading, which was intended to mimic restrictive pulmonary diseases such as bronchitis, was applied by placing a 3 mm tube 16.5 cm long between the facemask and pneumotachograph, creating a total resistance of 180cmH2O/L/s. Elastic loading, which was intended to mimic diseases characterized by increased lung elasticity such as emphysema, was produced using a 16 L solid container with a valve allowing the subjects to breathe through an elastic load of 70cmH2O/L during inspiration.

The authors noted that during continuous infusion of water into the pharynx, swallows occurred during expiration in normal breathing conditions on approximately 60% of all trials. However, swallows occurred at the transition from inspiration to expiration on approximately 45% of all trials during conditions mimicking restrictive pulmonary diseases. The investigators also observed that swallows occurred between the expiration to inspiration transition on approximately 50% of all trials during conditions mimicking diseases characterized by increased lung elasticity.

A subsequent study by Kijima, Isono, & Nishino (2000) demonstrated again that the coordination of swallowing and respiration can be altered by manipulating conditions relating to pulmonary function. Subjects completed the swallow trials while wearing an extrathoracic plastic shell through which the authors were able to apply negative extrathoracic pressure. Conditions of increased lung volume in healthy adults resulted in a prolongation of the swallow response during single bolus tasks and a decrease in frequency of swallowing during continuous infusion tasks. Additionally, the altered lung volume condition resulted in a greater incidence of swallows occurring both during inspiration and between the expiration to inspiration transition during conditions of increased lung volume, as compared to the pattern of coupling with the expiratory phase, which was noted on approximately 55% of all trials in the control condition.

Oxygen Saturation

In addition to studying the temporal integration of the acts of swallowing with respiratory cycle, the apneic interval required for airway protection during the swallow has lead some researchers to question the possible impact of brief swallow related apneic intervals on oxygen saturation. Oxygen saturation (SaO2) is defined as the "percent of arterial hemoglobin saturated with oxygen" (Venes, 2005, p. 1944). Normal oxygen saturation levels are typically higher than 95%, though saturation may be lower in patients with severe respiratory disorders (Fearnley, 1995).

Oxygen saturation may be monitored noninvasively via a pulse oximeter, though it is measured most accurately via an arterial blood gas test. Pulse oximetry, which uses a finger or earlobe probe connected to a computerized processor unit, is considered a simple and noninvasive method to monitor oxygen saturation (Fearnley, 1995(2), Hill & Stoneham, 2000). While pulse oximetry provides an adequate estimation of oxygen saturation, readings may be impacted by a multitude of factors including peripheral vasoconstriction or the use of nail polish (Fearnley, 1995 1&2).

Oxygen Saturation during Swallowing

The majority of studies of oxygen saturation and swallowing have involved individuals with compromised swallowing function. There is a dearth of research investigating the possible fluctuations in oxygen saturation, or lack thereof, during swallowing in individuals without compromised swallowing function.

In the aforementioned pilot of the current study, no statistically significant changes in oxygen saturation were noted between the onset of either the single or consecutive swallow condition and the completion of the swallowing task. Additionally, no differences were noted at five-second intervals up to 60 seconds following the consecutive swallow task, with the exception of 20 and 25 seconds after the completion of the task. A statistically significant difference was noted between oxygen saturation at the onset of the consecutive swallow task and both 20 and 25 seconds after completion of the consecutive swallow task.

This was an unexpected result, as it was not expected that the duration of the apneic interval during normal swallowing behavior would be great enough to impact saturation in a healthy adult. Although the fluctuations in saturation were not clinically relevant (no subject's saturation dropped below 94%), the mere fact that any fluctuations in the saturation of normal, healthy, young adult males were noted is of interest. Certainly the results of this preliminary study require further investigation, as they demonstrate the possibility for fluctuations in oxygen saturation in healthy adults during swallowing tasks that more closely resemble typical drinking behavior, such as consecutive swallow tasks.

<u>Oxygen Saturation during Meals in Patients with COPD</u>

In a study by Schols et al., (1991) the effects of eating on transcutaneous oxygen saturation (SaO2) and transcutaneous carbon dioxide tension (PtCO2) in patients with chronic obstructive pulmonary disease (COPD) were investigated. A subgroup of their hypoxemic patients experienced significant meal related changes in SaO2, although the actual mechanism to explain the desaturation was unclear and the desaturations did not appear to be correlated with episodes of aspiration. One hypothesis presented was a decrease in SaO2 related to a decrease in minute ventilation resulting from apneic intervals associated with chewing and swallowing. However, the authors rejected this theory as the decrease in SaO2 was not accompanied by a concomitant increase in PtCO2.

Oxygen Saturation during Meals in Patients with Motor Impairments

Rogers, Arvedson, Msall, and Demerath (1993) investigated hypoxemia during oral feeds in children with cerebral palsy. In this study, upright oral feeding resulted in significant hypoxemia in all of the five subjects. In four of the five subjects, the alterations in SaO2 were not associated with episodes of aspiration. Consistent with the findings of Rogers et al., (1993) a study of eight individuals with severe motoric disabilities aged 14 to 28 years by Tamura, Shishikura, Mukai, and Kaneko (1999) revealed decreases in oxygen saturation during oral feedings. The authors noted that eating in the sitting position rather than the supine position resulted in the greatest saturation alterations.

In a study by Rogers, Msall, and Shucard (1993), hypoxemia during oral feedings was studied in three adults with neurological disabilities (cerebral palsy and multiple sclerosis). Pulse oximetry revealed desaturation of all three subjects during oral feeds, although it was unclear if these episodes of desaturations were associated with episodes of aspiration. Sellars, Dunnet, and Carter (1998) utilized videofluorography and pulse oximetry to assess six patients diagnosed with neurogenic dysphagia. While oxygen desaturation was not predictive of episodes of aspiration, alterations in oxygen saturation were noted during oral feeding.

Oxygen Saturation and Aspiration

There is increasing interest in the use of pulse oximetry as a tool for screening or evaluation of dysphagia, specifically the occurrence of aspiration. However, research has yielded variable results, and there is little solid evidence to support such a practice. Several preliminary studies support the use of pulse oximetry as a supplemental screening or evaluative device at bedside (Chong et al., 2003; Lim et al., 2001; Sherman et al., 1999; Smith, Lee, O'Neill, & Connolly, 2000; Collins & Barkheit, 1997; Zaidi et al., 1995). However, within these studies the predictive value of pulse oximetry for events of aspiration was limited. In all of the studies, there were individuals who aspirated as identified via videofluoroscopy or fiberoptic endoscopic examination of swallowing (FEES) yet did not demonstrate alterations in oxygen saturation. Conversely, there were individuals who demonstrated alterations in oxygen saturation in the absence of aspiration. Additionally, the studies varied in their operational definitions of significant saturation fluctuations, though all studies operationally defined significant fluctuation as either a 2% or 3% change in saturation.

Collins and Barkheit (1997) indicated that while pulse oximetry may be useful in identifying an episode of aspiration with some patients, interpretation of results may not be reliable with particular populations including the elderly, those with COPD, and smokers. In additional studies of aspiration and oxygen saturation, Colodny (2000), Higo, Tayama, Watanabe, and Nito (2003), Leder (1999), and Wang, Chang, Chen, and Hsiao (2005) all concluded that pulse oximetry was not reliable for the detection or prediction of aspiration. Despite the lack of validity of pulse oximetry to detect or predict aspiration, it is important to note that in all of the aforementioned studies, oxygen fluctuations during swallowing activities in individuals with dysphagia were noted but not well explained.

<u>Relevance of Oxygen Saturation Fluctuations</u>

Little may be concluded regarding the actual association between specific acts of the swallow, such as duration of laryngeal closure or the apneic period, and episodes of desaturation, nor does aspiration account for all episodes of oxygen saturation fluctuation. Perhaps the multiple apneic intervals associated with mealtime eating as compared to single swallows have a cumulative effect on oxygen saturation. One may question if a cumulative effect would be noted in normal nonhypoxemic adults, or if it would be confined to those with respiratory disorders or dysphagia.

Sufit (1993) brought questions regarding oxygen desaturation and swallowing to the forefront. Of the many issues he raised, the most obvious issue was the lack of normative data regarding the range of desaturations for disease free adults during swallowing. It is unclear if a healthy nonhypoxemic adult would experience desaturations during swallowing, possibly resulting from the apneic intervals associated with the swallow.

Age Effects on Swallowing and Respiration

Multiple studies have demonstrated physiological changes in swallow physiology associated with the normal aging process, such as an overall reduction or slowing in tongue movement during the oral phase of the swallow, reduced tongue base movement, delayed initiation of the pharyngeal swallow, and increased duration of the swallow (Jaradeh, 1994; Leslie, Drinnan, Ford, & Wilson, 2005; Logemann, 1990; Logemann, Pauloski, Rademaker, & Kharilas, 2002; McKee, Johnson, McBride, & Primrose, 1998; Robbins, Hamilton, Lof, &

Kempster, 1992; Sonies et al., 1984; Sonies et al., 1988; Tracy et al., 1989). In a study by Rademaker, Pauloski, Colangelo, and Logemann (1998) duration of cricopharyngeal sphincter opening increased with age in women, and multiple researchers have demonstrated increases in duration of laryngeal elevation, airway closure with age (Hiss et al., 2001; Rademaker et al., 1998; Ren et al., 1993; Seeley et al., 1989a; Tracy et al., 1989).

Recent studies have begun exploring the possibilities of age related changes in the relationship between swallowing and respiration. Hirst, Ford, Ginson, and Wilson (2002) studied respiratory alteration during single swallows and continuous drinking in older individuals with a mean age of 73. As bolus volume increased, the duration of the apneic interval increased; this result was consistent with findings of Martin-Harris et al. (1994) in younger individuals. While a predominant pattern of post swallow expiration following 5 ml boluses was noted on 91% of all trials, results following continuous swallows of 100ml via cup and straw were significantly different. Post swallow expiration was noted on 78.5% and 63.5% of the continuous drinking trials via cup and straw respectively. Additionally, a median fall of 2% in oxygen saturation levels was noted across swallow trials, which was statistically, though not clinically significant.

Hiss, Treole, and Stuart (2001) demonstrated similar results regarding the apneic intervals of elderly adults across saliva swallows and a variety of bolus volumes. Elderly adults demonstrated longer apneic intervals than both young and middle aged adults. Mean apneic intervals were .84 seconds and .92 seconds for young and middle aged individuals respectively, while elderly individuals exhibited an average apneic interval of 1.10 seconds. Additionally, the authors observed an effect of gender on the apneic interval, whereby women exhibited a statistically significant increase in the apneic interval as compared to men.

Regarding swallowing and respiration, the typical pattern of expiration – swallow – expiration was noted during 62% of all of Hiss, Treole, and Stuart's (2001) subjects' trials. Seventy-five percent and 86% of swallows interrupted or were followed by expiration. Following logistic regression, the authors concluded that age, gender, or bolus volume was not a valid predictor of the likelihood of a subject presenting with a pattern typical or atypical of expiration – swallow – expiration. Consistent with these findings, Martin-Harris et al. (2003) found no age effects regarding propensity to interrupt inspiration or expiration, nor did Leslie, Drinnan, Ford, and Wilson (2005) find an age effect regarding propensity to resume inspiration or expiration.

Conversely, Shaker et al. (1992) noted that elderly individuals were more likely to interrupt the inspiratory cycle when completing subconscious swallows as compared to their younger counterparts. Additionally, in a study of 53 individuals aged 71 to 81 years of age, Nilsson et al. (1996) noted that older adults resumed inspiration following swallowing 30% of swallows, as compared with only 10% by the younger subjects.

Colodny (2001) investigated age, gender, and disease effects on oxygen saturation. Subjects included healthy control subjects and residents from an area nursing home who were identified as dysphagic. A wide variety of disparate diagnoses were associated with the diagnoses of dysphagia, including stroke, dementia, COPD, and "other". Older individuals with dysphagia had lower saturation levels than younger individuals with dysphagia, although no age effect on oxygen saturation was noted in the individuals without dysphagia. Individuals with COPD and dysphagia had lower saturation levels than individuals with dysphagia and other disorders. The author concluded that the normal aging process does not significantly impact the relationship between swallowing and oxygen saturation. However, aging in conjunction with cerebrovascular accident or COPD may result in substantive alterations of oxygen saturation levels during swallowing.

Impact of Compromised Respiratory Function on Swallowing

Chronic Obstructive Pulmonary Disease (COPD)

According to the American Lung Association (2004), an estimated 11.2 million adults in the U.S. have been diagnosed with COPD. COPD is a common comorbidity in patients assessed for dysphagia (Martin-Harris, 2000). In a study by Mokhlesi et al. (2001), 17% of subjects with dysphagia were diagnosed with COPD as compared to only 4% of the control subjects. In a retrospective study of 78 males with a primary diagnosis of COPD who were referred for a videofluoroscopic evaluation of swallowing, nearly 85% exhibited some degree of dysphagia (Good-Fratturelli, Curlee, & Holle, 2000).

Exploration of actual alterations in swallow physiology associated with COPD is in its infancy. In a study of 25 patients with frequent and severe exacerbation of COPD, 17 elderly subjects were diagnosed with severe cricopharyngeal dysfunction (Stein et al., 1990). The authors concluded that frequent acute exacerbation of respiratory distress in patients with COPD warrants investigation of the swallow. Mokhlesi et al. (2002) revealed that individuals with COPD not in acute exacerbation demonstrated lower maximal laryngeal elevation and a greater tendency toward spontaneous protective swallowing maneuvers such as prolonged or early airway closure.

In a letter to the editor of Chest, Teramoto, Kume, and Ouchi (2002) utilized "a novel diagnostic approach" (p. 801), the swallow provocation test and the simple swallow provocation test, as a method for detecting swallowing disorders in patients with COPD. According to the authors, the swallowing provocation test (SPT) and the simple SPT (S-SPT) are variations of a protocol measuring the latency of induction of "the swallowing reflex…after 0.4 mL or 2 mL of distilled water injection into the suprapharynx" (p. 801). Using this protocol, 16.7% of their 28 patients with COPD demonstrated abnormal swallow function.

As noted previously, Shaker et al. (1992) demonstrated significant differences in both interruption and resumption of the respiratory cycle during water swallows when COPD was exacerbated. Additionally, the aforementioned studies by Kijima, Isono, & Nishino (1999, 2000) demonstrated that manipulations of experimental conditions designed to respiratory diseases characterized by increased lung elasticity, such as emphysema, resulted in alteration of the coordination of swallowing with the respiratory cycle, whereby there was an increase in occurrence of swallows occurring at the transition from expiration to inspiration.

Despite the work of a handful of investigators, our knowledge of the impact of COPD on swallowing is in its infancy. In Mokhlesi et al.'s (2002) aforementioned seminal work studying swallowing and COPD, the authors assert the need for research to investigate further the potential relationships among swallowing, swallowing dysfunction, and COPD. This need has been echoed by Teramoto, Kume, and Ouchi (2002) and Harding (2002). Elucidation of the possible relationship between COPD and dysphagia is necessary in order to provide the highest quality of care to patients with COPD diagnoses.

Smoking

The deleterious overall effects of cigarette smoking are well documented. Smoking increases the likelihood of lung, oral, pharyngeal, laryngeal, esophageal, pancreatic, uterine, bladder, and kidney cancer, COPD, coronary artery disease, cerebrovascular accident, peripheral vascular disease, fertility issues, and hip fracture (in women), and is associated with a greater decline of global cognitive function in elderly individuals without dementia (Novotny & Giovano, 1998; Ockene & Miller, 1997; Ott et al., 2004; U.S. Department of Health and Human Services, 1989).

The actual impact of smoking on the pulmonary function of an individual appears to be the result of multiple factors, including genotype, race, gender, age of smoking onset, and even diet (Chatila, Wynkoop, Vance, & Criner, 2004; Chen, Horne, & Dosman, 1991; Patel et al., 2004; Prescott et al., 1997; Tischler, Carey, Reed, & Fabsitz, 2002; Watson et al., 2002). There is the evidence that smokers who do not complain of or overtly demonstrate any symptoms of pulmonary implications may in fact have compromised pulmonary function. Multiple studies have demonstrated that smokers who are asymptomatic of any respiratory issues may demonstrate signs of COPD on spirometry measures, emphysema on computed tomography (CT) and spirometry, and cancer on CT (Diedrich et al., 2002; Henschke et al., 2001; Sashidar et al., 2002; Stratelis, Jakobsson, Molstad, & Zetterstom, 2004; Vrijhoef et al, 2003; Zielinski & Bedarneck, 2001). It is possible that asymptomatic smokers may demonstrate altered respiratory function in addition to symptomatic smokers known to have smoking induced respiratory sequelae.

In addition to the myriad of health concerns listed above, smoking has been found to alter the esophageal phase of the swallow. For example, Kahrilas and Gupta (1989) demonstrated alteration in saliva secretion and esophageal acid clearance in smokers as compared to non smokers. In 1998, Dua et al demonstrated alterations in the swallow physiology of smokers, whereby greater threshold volumes were required to elicit the pharyngo-upper esophageal reflex and pharyngeal swallow. These two studies have only begun to scratch the proverbial surface of possible smoking related effects on swallow physiology.

Given the impact of smoking on respiratory function, both for symptomatic and asymptomatic individuals, it is possible that such individuals may also experience alterations in respiratory function during swallowing. In a call to the community of pulmonary care physicians, Harding (2002) cited the dearth of studies investigating the potential impact of smoking on swallow function and the need to explore this relationship.

Purpose of the Present Study

The purpose of this study is to elucidate possible effects of swallow task and age on the swallow physiology, respiratory phase relationships, and oxygen saturation of young adult to elderly non smoking males. This study aims to provide information (1) for further clarification of normal swallow physiology and (2) for a basis of comparison across the age continuum.

This study will elucidate patterns of coordination of swallowing and respiration during consecutive swallows, which may be a closer approximation to natural eating and drinking behavior than the single swallows used in previous studies. The temporal integration of the swallow with the respiratory cycle has predominately been investigated using single boluses. Single boluses are not necessarily a good approximation of natural eating and drinking behavior. Subsequently, coordination of breathing and swallowing may differ substantially in normal swallowing behavior in comparison to that with single bolus swallows. Additionally, the study may yield information regarding the impact, or lack thereof, of multiple consecutive swallows on oxygen saturation status in adult males. The inclusion of multiple age groups in the subject population will allow for investigation of possible age effects. The results may provide a stepping stone for clinically relevant research for patients with dysphagia, respiratory disorders, or a combination thereof.

Experimental Questions

First, this study aims to determine the impact of age and smoking status on measures of swallow physiology over the course of multiple, consecutive, uninterrupted liquid swallows as compared to those measures during a single liquid bolus swallow. Specifically, the experimental questions are as follows:

(1) Do measures of (a) laryngeal closure and (b) laryngeal elevation differ significantly during the course of multiple, consecutive, uninterrupted liquid swallows versus single swallows? These measures have been selected as they represent airway closure which relates to the apneic interval of the swallow. It is hypothesized that a statistically significant difference in duration of laryngeal closure and elevation in the consecutive versus single swallow condition will be observed, whereby closure and elevation is longer in duration for consecutive versus single swallows.

(2) Are there significant differences in the aforementioned swallow physiology measures (laryngeal elevation and closure) under the two swallowing conditions (consecutive and single swallows) based on age (20-30 years, 40-50 years, 60-70 years, and 80+ years)? It is hypothesized that a significant age effect for the 80-90 year old group will be observed, whereby the durational increases in closure and

elevation secondary to swallow tasks (consecutive swallows) will be greater in the older subject populations.

Another area of interest addresses possible effects of age on changes in the temporal integration of swallowing with the respiratory cycle over the course of multiple, consecutive liquid swallows as compared to integration during a single liquid bolus swallow. Specifically, the experimental questions are as follows:

(3) Are there significant differences in (a) the propensity to interrupt either inspiration or expiration and (b) the propensity to return to either inspiration or expiration after the swallow during the course of multiple, consecutive, uninterrupted liquid swallows versus single swallows in men? It is hypothesized that there will be greater variability in the propensity to return to inspiration or expiration following consecutive swallows as compared to single swallows.

(4) Are there significant differences in the interruption and resumption of the respiratory cycle under the two swallowing conditions (consecutive and single swallows) in men based on age (20-30 years, 40-50 years, 60-70 years, and 80+ years)? It is hypothesized that a significant age effect will not be observed.

The final goal of the study is to determine if oxygen saturation is significantly impacted during the course of single or multiple, consecutive, uninterrupted liquid swallows. The specific experimental questions are:

(5) Are there significant differences in transcutaneous oxygen saturation (SaO2) from the onset of the apneic period to 60 seconds following completion of the swallow(s) during either single swallows or across the duration of multiple, consecutive, uninterrupted swallows? It is hypothesized that SaO2 fluctuations following either swallow task will be insignificant.

(6) Are there significant differences in SaO2 from the apneic interval to 60 seconds following completion of the swallow under the two swallowing conditions (consecutive and single swallows) based on age (20-30 years, 40-50 years, 60-70 years, and 80+ years)? It is hypothesized that an age effect on SaO2 levels following consecutive swallow tasks may exist for the 80-90 year group. It is hypothesized that the 80-90 year group may demonstrate greater SaO2 fluctuations following a consecutive swallowing task as compared to other age groups completing the task, but it is not anticipated that these fluctuations will be significant in terms of respiratory homeostasis, as demonstrated by levels of oxygen saturation approaching hypoxic levels.

CHAPTER III.

METHODS AND PROCEDURES

Subjects

A total of fifty men were scheduled to participate in this project after obtaining informed consent. Male subjects were chosen for ease of placement of the Respitrace coils. Ten non smoking males were recruited in each of the following age groups: 20-30 years (mean age of 26.8), 40-50 years (mean age of 44.8 years), 60-70 years (mean age of 65 years), and 80-90 years (mean age of 82.7 years). Subjects were recruited from a variety of sources, including the Northwestern University campus, local businesses, restaurants, and bars. Recruitment posters were posted as well (Appendices G-J). All of the subjects in the 80-90 year old group and eight out of 10 subjects in the 60-70 year old group were recruited from the Aging Research Registry provided by the Buehler Center on Aging in Chicago, IL (Appendix F). Subjects were recruited and included regardless of race or ethnicity.

Inclusion Criteria

In an effort to control for potential threats to internal validity, significant efforts were taken to create inclusion criteria that eliminated diseases, conditions, and behaviors that impact swallowing and/or respiratory function. Criteria for inclusion included good general health status and normal body habitus as defined by the Metropolitan Life Insurance Company standard height and weight chart (1999) in addition to negative history for any documented dysphagia or subjective complaints of swallowing difficulties, neurological disorders, oral/pharyngeal cancer, oral/pharyngeal surgery with the exception of standard dental work or tonsillectomy, head or neck injury, respiratory disorders including asthma, emphysema, or COPD, any type of illness or injury that interferes with comfortable nasal breathing, peripheral vascular disease, or use of medication known to impact swallow or pulmonary function. Information regarding these criteria was obtained via interview of the subject by the student investigator over the telephone when the potential subjects were solicited regarding the study.

Secondary to both the potential impact of smoking behavior on respiratory function and frequency of habitual and social smoking behavior in the general public, stringent guidelines were set regarding subject smoking history. Preference was given to appropriate subjects who reported no smoking history at any time. Potential subjects who indicated a history of smoking were probed further to determine both the extent and recency of any smoking behavior. Smoking behavior included smoking of any manufactured cigarettes (filtered, unfiltered, flavored, unflavored, light, extra light, or low tar), cigars, pipes, marijuana, or hand-rolled cigarettes.

Regarding extent of smoking history, great lengths were taken to exclude any individual whose prior smoking behavior may have an impact on current pulmonary function, despite a significant period of cessation. Smoking behavior was defined in pack-years. A pack-year was defined as the average number of packs of cigarettes smoked per day multiplied by the number of years of smoking (Frisch et al., 1999). Retrospective pack-year calculation, the common method for quantifying smoking behavior, is considered a valid method for estimating lifetime tobacco smoking (Bernaards et al., 2001).

The impact of smoking on pulmonary function is highly variable, as some smokers demonstrate profound respiratory involvement while others retain relatively normal respiratory function (Tischler, Carey, Reed, & Fabsitz, 2002). The actual impact of smoking on the pulmonary function of an individual appears to be the result of multiple factors, including genotype, race, gender, age of smoking onset, and even diet (Chatila, Wynkoop, Vance, & Criner, 2004; Chen, Horne, & Dosman, 1991; Patel et al., 2004; Prescott et al., 1997; Tischler, Carey, Reed, & Fabsitz, 2002; Watson et al., 2002). The earliest manifestations of smoking induced small airway changes have been noted with a smoking history of 10 or greater pack-years (Verbanck et al., 2004). Subsequently, any potential subject with a ten-pack year history of smoking, regardless of cessation history, was excluded immediately.

Subjects with a 10 pack-year history or less who were non smokers at the time of the study were probed further regarding their cessation history. Studies of the impact of smoking cessation on pulmonary function overwhelmingly point to significant, measurable improvement in pulmonary function within three to 24 months after cessation (Bake et al., 1977; Buist et al., 1976; Buist et al., 1979; Emmons et al., 1992; McCarthy et al., 1976; Swan et al., 1992) and a rate of respiratory decline equal to men who never smoked (Burchfiel et al., 1995). Older adults who ceased habitual smoking exhibited an overall risk of death equal to those who never smoked after 15 to 20 years of cessation (LaCroix & Omenn, 1992). Tables 1 and 2 outlined the criteria that were established for past habitual or social smoking behavior and the smoking histories.

Age Group	Smoking History of Any Kind	Period of Abstinence
20-30	None permitted	N/A
40-50	5 pack years or less	10 years or more
60-70	10 pack years or less	15 years or more
80-90	10 pack years or less	20 years or more

Table 1: Screening criteria for past habitual or social smoking behavior for participation in current study

Age Group	Number of Subjects Self Reporting a History of Smoking Behavior	Period of Abstinence
20-30	0	N/A
40-50	1 with a history of social smoking only	Greater than 12 years
60-70	0	N/A
80-90	2 with a brief period of social smoking during WWII	Greater than 60 years

Table 2: Final results of subject report of smoking histories of study participants

A total of 45 potential subjects in the 60-70 and 80-90 year age groups were identified as potential subjects from the Aging Research Registry provided by the Buehler Center on Aging and were solicited by phone. The resource list provided by the Buehler Center allowed for the student investigator to remove from the potential subject list all individuals with cardiac and pulmonary issues. A total of 18 subjects were recruited in this venue. Eight of the remaining 27 potential subjects from the registry did not meet the subject criteria. The remaining 19 potential subjects chose not to participate in the study, secondary to concerns about radiation exposure and/or ingesting barium, transportation issues, or general lack of interest.

In addition to the subjects recruited from the Aging Research Registry, 51 potential subjects were screened in person, on the phone, or via email communication. A total of 22 subjects were recruited in this venue. Of the 51 potential subjects screened, 29 did not meet the subject criteria, secondary to obesity, current social smoking, excessive pack year history, or short duration of smoking cessation.

Subjects who met the selection criteria were scheduled to participate in the study and gave informed consent (Appendices B, C, & E) in accordance with the policies and procedures set forth by the Northwestern University Institutional Review Board. This project was approved by the Northwestern University Institutional Review Board on two separate occasions (IRB Project #0328-056), as a new submission and as a renewal (Appendices A & D). Compensation of $20.00 in cash was provided.

Stimuli

Each subject was required to complete two tasks during a videofluoroscopic swallow study: (1) three comfortable single swallows of thin liquid barium from a cup (S) and (2) three repetitions of eight consecutive, uninterrupted swallows of thin liquid barium from a cup on one breath (C). Subjects were allowed to drink freely from cups containing a premeasured amount of barium in an effort to approximate their typical drinking behavior.

Subjects were instructed prior to initiation of the study regarding the procedure for the consecutive swallows. The two conditions (S and C) were counterbalanced and randomly assigned to the subjects to control for possible order or fatigue effects. Five subjects in each age group completed the single task first and the consecutive task second, while five subjects in each group complete the tasks in reverse order.

Design

A within and between group, mixed experimental design was utilized. The independent variables included: (1) swallow condition and (2) age. A repeated measures design was used for swallow condition, while a between groups design was utilized for age. Swallow condition had two levels: (1) three single swallows of thin liquid barium (S) and (2) three runs of eight consecutive, uninterrupted swallows of thin liquid barium (C). Age was comprised of four levels: (1) 20-30 years, (2) 40-50 years, (3) 60-70 years, and (4) 80+ years.

There were a total of five dependent variables: duration of laryngeal closure, duration of laryngeal elevation, interruption of the respiratory cycle at onset of swallow(s), resumption of respiratory cycle following completion of swallow(s), and oxygen saturation at onset and at every five seconds for 60 seconds after the apneic phase of the swallow(s). The dependent variables were operationally defined as follows:

(1) Duration of laryngeal vestibule closure is defined as the length of time in seconds that the laryngeal entrance between the arytenoid cartilage and the base of the epiglottis is viewed radiographically as closed in the lateral plane during the swallow.

(2) Duration of laryngeal elevation is defined as the length of time in seconds between the beginning of laryngeal ascent associated with the swallow (excluding pre elevation) to the time the larynx first returns to its resting position as defined radiographically.

(3) The interruption of the respiratory cycle at onset of swallow(s), is defined as the phase of the respiratory cycle interrupted by the apneic interval associated with a single swallow or eight consecutive swallows on one breath.

(4) The resumption of the respiratory cycle at onset of swallow(s), is defined as the phase of the respiratory cycle resumed immediately following the apneic interval associated with a single swallow or eight consecutive swallows on one breath.

(5) The SaO2 at the onset and every five seconds for 60 seconds post apneic phase of the swallow is defined as the measurement of transcutaneous oxygen saturation taken (a) at the onset of the apneic interval associated with a single swallow or eight consecutive swallows on one breath and (b) every five seconds for 60 seconds following return to either the expiratory or inspiratory phase of the respiratory cycle immediately after cessation of the apneic interval.

Procedures

Three types of data were collected during the study: (1) respiratory inductive plethysmographic data for a measurement of ribcage and abdominal displacement, (2) transcutaneous oxygen saturation data, and (3) videofluoroscopic recordings for temporal analysis of the swallow.

Respiratory Inductive Plethysmography

Respiratory inductive plethysmography (Respitrace, Respitrace systems, Ambulatory Monitoring, Ardsley, NY) was utilized to assess the respiratory cycle during the swallowing tasks via the monitoring of abdominal and ribcage displacement (Cohn et al, 1982). Two coils of Teflon coated wire (Respibands) encased in plastic bands were placed around the subject's body. One coil was positioned evenly around the ribcage just inferior to the armpits while the second coil was placed around the abdomen with the superior boundary of the coil placed just inferior to the 12^{th} rib. The elastic bands were connected to an oscillator module that detects frequency changes which were then converted to output voltage signals. Two signals were produced, ribcage and abdominal. These signals were recorded on a Linseis four channel recorder run at a paper speed of .5 cm/sec, providing a resolution of 2 seconds for each 1cm on the tracing.

Data gleaned from respiratory inductive plethysmography was reduced and analyzed for significant differences in the interruption and resumption of the respiratory cycle dependent on (1) swallowing condition (consecutive and single swallows) and (2) age (20-30 years, 40-50 years, 60-70 years, and 80+ years).

Transcutaneous Oxygen Saturation

An Ohmeda 3700 pulse oximeter was utilized to measure transcutaneous oxygen saturation. One of the subject's fingers was cleaned with alcohol to allow for optimal connection, and a probe was placed on the subject's non-dominant index finger. Any nail polish on the subject's fingernail was removed. Oxygen saturation measures were recorded at the onset and immediately following each swallow or sequence of swallows. Additionally oxygen saturation measures were manually recorded every 5 seconds for 60 seconds following completion of the final swallow. The latency of pulse oximeter response to oxygen saturation fluctuations is unclear. A study addressing the comparative latency of response using finger versus ear sensors indicate a mean delay for finger sensors as compared to ear sensors of 4.4 seconds (Broome, Harris & Reilly, 1992). In situations of mild hypothermia, the finger sensor was more susceptible to increased response latency than both forehead and ear sensors (MacLeod et al., 2005). However, these studies address comparative latencies among sensors, rather than the actual latency of the saturation fluctuation and its measurement. Given the possible latency between a potential fluctuation in saturation and reflection of that fluctuation on the pulse oximeter, measures were recorded for 60 seconds following completion of the consecutive swallow task in an effort to capture any potential fluctuation.

Data regarding oxygen saturation were analyzed for significant fluctuations in SaO_2 as compared to the subjects' baseline saturation measures from the apneic interval to 60 seconds following completion of the swallow dependent on (1) swallowing condition (consecutive and single swallows) and (2) age (20-30 years, 40-50 years, 60-70 years, and 80+ years).

Subject Positioning and Training

The subjects were trained to complete the multiple, consecutive swallow tasks prior to initiation of the study. After placement of the Respitrace coils and the oxygen saturation probe on the subject by the student investigator, the subject was placed in an upright, seated position in the radiographic equipment where he remained for the duration of the study. After correct placement of the subject was achieved as verified by the radiographic image, the subject remained in that position resting comfortably without talking or moving until the signals from the Respitrace and the pulse oximeter stabilized. Only after the signals from both the Respitrace and the signal for the pulse oximeter stabilized to allow for assessment of baseline were boluses provided.

Videofluoroscopic Swallow Studies

Data collection and reduction for the videofluoroscopic swallow studies followed the protocols outlined by Logemann (1993), and the studies were performed by a certified speech language pathologist in conjunction with a radiologic technician. Subjects were positioned to allow for a lateral radiographic view of the oral, pharyngeal and laryngeal regions. The boundaries for the radiographic view were as follows: the lips anteriorly, the cervical vertebrae posteriorly, the soft palate superiorly, and the bifurcation of the airway and esophagus inferiorly. The videofluoroscopic data was be recorded on ¾ inch videotape at 60 fields/second using a Sony Umatic videocassette recorder. A digital timing signal was imprinted on each frame of the tape at the top right corner of the video field. The digital timing signal on the radiographic videotape, along with manual time markings on the Respitrace, allowed for calculation of duration measures and for time linking data from the Respitrace. The entire sequence of all swallows, including subsequent swallows to clear residue, were recorded.

In both swallow conditions, the swallows consisted of room-temperature EZ-EM thin liquid barium. The same bolus viscosity was maintained for all swallows. Subjects were given cups containing a premeasured amount of barium. Subjects were given a cup containing 30 ml of barium for each single swallow and 200 ml for each consecutive swallow run. Volume estimates of amount of barium consumed were made following completion of the swallowing tasks by subtracting the amount of barium remaining in each cup from the initial premeasured amount of either 30 ml (single swallows) or 200 ml (consecutive swallows).

Temporal data obtained from videofluoroscopy was reduced and analyzed for significant differences in the duration of laryngeal elevation and closure dependent on (1) swallowing condition (consecutive and single swallows) and (2) age (20-30 years, 40-50 years, 60-70 years, and 80+ years).

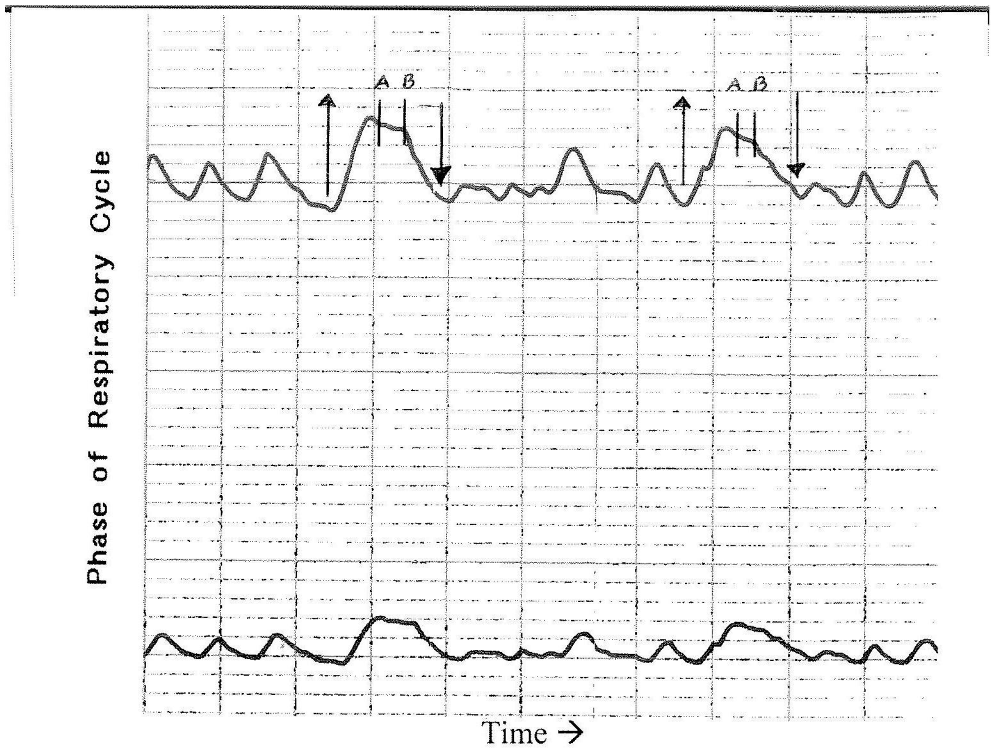
Data Reduction

Videofluoroscopic Data

Using frame-by-frame temporal analysis of the videofluoroscopic tape of each swallow, frames at which certain structural movements occurred were identified. Two temporal measurements were generated as dependent variables: (1) duration of laryngeal vestibule closure and (2) duration of laryngeal elevation. Duration of laryngeal vestibule closure was operationally defined as the length of time in seconds that the laryngeal entrance between the arytenoid cartilage and base of epiglottis was closed in the lateral plane during the swallow. Duration of laryngeal elevation was operationally defined as the length of time in seconds between the beginning of laryngeal ascent associated with the swallow (excluding pre elevation) to the time the larynx first returned to its resting position.

Respiratory Inductive Plethysmography Data

The Respitrace printouts were analyzed for interruption and resumption of the respiratory cycle prior to and following the swallow or swallows. Interruption of the respiratory cycle was operationally defined as the phase of the cycle (inspiration or expiration) that the apneic interval of the swallow interrupted as designated by the period of cessation of ribcage and abdominal movement. Resumption of the respiratory cycle was operationally defined as the phase of the respiratory cycle resumed (inspiration or expiration) immediately following the cessation of ribcage and abdominal movement associated with the apneic interval of the swallow.



(paper speed of .5 cm/sec, resolution of 2 seconds for each 1cm on the tracing)

Figure 1: Typical Respitrace print out of ribcage (upper line) and abdominal (lower line) movement during a single swallow. Upward arrows denote inhalation, while downward arrows denote exhalation. "A" represents onset of the apneic interval as the subject begins expiration. "B" represents end of apneic interval as subject returns to expiration.

<u>Transcutaneous Oxygen Saturation Data</u>

Transcutaneous oxygen saturation data were recorded directly from the pulse oximeter. No reduction was necessary.

Reliability

All data was reduced by the primary researcher. A second trained researcher was employed for interobserver reliability measures. Both intraobserver and interobserver reliability measures were obtained for 10% of all swallows. On those swallows randomly selected, temporal analysis of swallow and respiratory measures were recalculated. Both intra and interobserver reliability were completed blindly on a point by point basis. Acceptable temporal differences for swallow data were defined as timing measures that are within at least 6 frames (.06 seconds) of the original measure. Acceptable differences for the respiratory physiology data were defined as agreement on no less than nine of every ten measures. Discrepancies were discussed. When the primary researcher measurement was in question on a particular measure, all swallows for that subject were reassessed in regards to that particular measure. In lieu of formal statistical analyses to determine reliability agreements, the total number of data points in agreement or disagreement via point by point analysis was calculated as percentages of all reduced data. Inter- and intra-observer reliability of the temporal measures were .92 and .96 respectively. Thus, 92% and 96% of reduced temporal data were in agreement for inter- and intra-observer reliability respectively. Inter- and intraobserver reliability measurements for the analysis of the Respitrace printouts were 1.0. Thus, 100% of reduced respiratory data were in agreement for inter- and intra-observer reliability.

Statistical Analysis

All of the following statistical analyses were performed using SPSS, Standard Version 14.0 (SPSS, 2007). The level of significance for all analyses was set at $p<0.05$. Basic descriptive statistics (mean, standard deviation, and skewness) were calculated for every variable.

Videofluoroscopic Data

Each subject's temporal measures were averaged across both single and consecutive tasks to provide one average measurement for laryngeal elevation and closure in both single and consecutive tasks for each subject. To determine if there were significant (1) overall main effects of swallow condition (single versus consecutive swallows) on temporal measures of laryngeal elevation and laryngeal closure, (2) overall main effects of age on either temporal measure, and/or (3) interactions between swallow condition and age, a 2 way ANOVA was employed. The 2 x 4 ANOVA consisted of 2 levels of swallow condition and 4 levels of age. Appropriate follow up statistics were conducted when significant main effects or interactions were noted.

Respiratory Inductive Plethysmography Data

To determine the effects of age and smoking status on interruption or resumption of the respiratory cycle in relation to the swallow, the nominal data were transformed into ratio data. Each interruption and resumption for each swallow trial was considered one opportunity to interrupt or resume inspiration. Using this model, the proportion of times the individual interrupted or resumed inspiration was 0 (0 out of 3 times), .33 (1 out of 3 times),

.67 (2 out of 3 times), or 1 (3 out of 3 times). It was anticipated that a 2 way ANOVA would be employed to determine if there was significant (1) overall main effects of swallow condition (single versus consecutive swallows) on interruption or resumption of the respiratory cycle, (2) overall main effects of age on interruption or resumption of the respiratory cycle, and/or (3) interactions between swallow condition and age. The 2 x 4 ANOVA would have consisted of 2 levels of swallow condition and 4 levels of age, and appropriate follow up statistics would have been conducted when significant main effects or interactions were noted. However, secondary to the almost complete lack of variability of the data set for resumption of the respiratory cycle following single swallows, descriptive statistics and 1 way ANOVA were utilized.

Transcutaneous Oxygen Saturation Data

To determine if there were significant (1) overall main effects of age on oxygen saturation, (2) overall main effects of time on oxygen saturation, and/or (3) interactions between age and time, a 2 way ANOVA was employed for both the single and consecutive swallow conditions. The 4x14 ANOVA consisted of 4 levels of age and 14 levels of time (14 time points at which oxygen saturation was measured). Appropriate follow up statistics were conducted when significant main effects or interactions were noted.

CHAPTER IV.

RESULTS

Results of the current study will be addressed in the following manner. First, ANOVA assumptions will be addressed. Second, for each of the data types (videofluoroscopic data, respiratory inductive plethysmography data, and transcutaneous oxygen saturation data), main effects of swallow condition (single versus consecutive swallows) and age (20-30 years, 40-50 years, 60-70 years, and 80-90 years) as well as any interactions will be addressed. Last, analysis of average bolus volume as well as qualitative observations (residue, penetration, and aspiration) will follow.

ANOVA Assumptions

To verify that ANOVA assumptions were not violated, the data were assessed for normality, linearity, and unequal population variances. For normality, frequency histograms were plotted and the samples were not obviously skewed, with the exception of a slight positive skew in averages of laryngeal elevation. Scatterplots used to assess assumptions of linearity indicated a linear relationship between the dependent variables and age. Levene's Test for Equality of Variance indicated that the variances were not statistically significant. Given the linearity of the data, equal population variances, and balanced sample sizes, it was determined that the ANOVA would be robust enough to counter the slight positive skew noted in averages of laryngeal elevation.

Videofluoroscopic Data

Laryngeal Elevation

Descriptive statistics for laryngeal elevation revealed an observable increase in mean overall duration as well as variability of laryngeal elevation in the consecutive swallow versus single swallow tasks across all age groups. Additionally, the means and standard deviations for both single and consecutive swallow tasks were observed to be greatest with the oldest subject population (Tables 3 and 4).

Age	Mean Duration Laryngeal Elevation (s)	Standard Deviation
20-30	1.1167	.30369
40-50	1.0847	.22263
60-70	1.0570	.26216
80-90	1.3170	.32108

Table 3: Summary table of mean durations (in seconds) and standard deviations of laryngeal elevation during single swallow tasks by age group

Age	Mean Duration Laryngeal Elevation (s)	Standard Deviation
20-30	8.4183	.98751
40-50	9.1940	2.15025
60-70	11.3483	2.30184
80-90	12.0890	3.31745

Table 4: Summary table of mean durations (in seconds) and standard deviations of laryngeal elevation during consecutive swallow tasks by age group

Results of a 2 way ANOVA indicated significant (1) overall main effects of swallow condition (single versus consecutive swallows) on temporal measures of laryngeal elevation,

(2) overall main effects of age on temporal measures of laryngeal elevation, and (3) an interaction between swallow condition and age on temporal measures of laryngeal elevation.

Examination of the significant main effect of swallow task on laryngeal elevation [$F_{3,36}$= 626.49; p=0.001)] indicated that laryngeal elevation was greater in duration for consecutive swallows as compared to single swallows. Mean duration of laryngeal elevation for single swallows was 1.14 s (sd= .29), while mean duration of laryngeal elevation for consecutive swallows was 10.26 s (sd= 2.72). It was observed that the standard deviation of laryngeal elevation was much larger in the consecutive versus the single swallow condition.

Examination of the significant main effect of age on laryngeal elevation [$F_{3,36}$= 5.62; p=0.003] indicated that laryngeal elevation was greater in duration in older subjects as compared to younger subjects. Mean durations of laryngeal elevation in seconds for each age group were as follows (Table 5).

Age	Mean Duration Laryngeal Elevation (s)	Standard Deviation
20-30	4.77	.38
40-50	5.14	.38
60-70	6.20	.38
80-90	6.70	.38

Table 5: Summary table of mean durations (in seconds) and standard deviations of laryngeal elevation by age group collapsed across task (single versus consecutive)

A significant interaction between task and age was noted [$F_{3,36}$ = 5.29; p=0.004]. Follow up tests on the interaction (Tukey HSD) revealed statistically significant differences in duration of laryngeal elevation between 20-30 year olds and 80-90 year olds (p=.005) as well as 40-50 year olds and 80-90 year olds (p=.03). The interaction was investigated using paired t-tests comparing laryngeal elevation during single and consecutive swallow tasks for each age group. Differences were significant for each age group (Table 6). As demonstrated in the graph below (Figure 2), the difference between laryngeal elevation in single versus consecutive swallows appears to be proportionally larger for 60-70 and 80-90 years olds as compared to 20-30 and 40-50 year olds.

Age	t	df	*P* value
20-30	22.85	9	.0001
40-50	11.97	9	.0001
60-70	14.05	9	.0001
80-90	10.64	9	.0001

Table 6: Summary table of paired sample tests of durations of laryngeal elevation by age group for single versus consecutive tasks

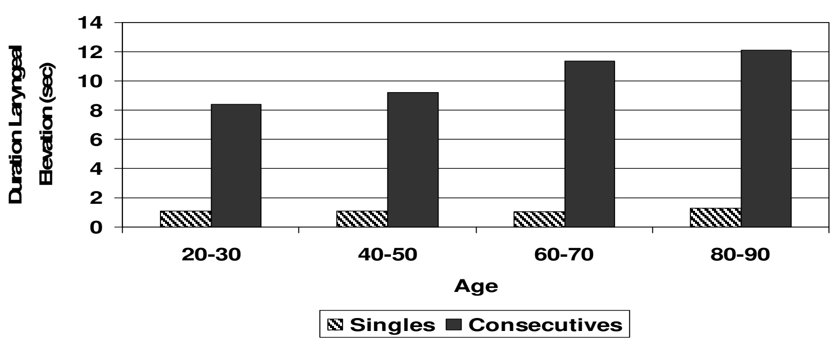


Figure 2: Mean durations of laryngeal elevation by age group for single versus consecutive tasks

Laryngeal Closure

As with laryngeal elevation measures, descriptive statistics for laryngeal closure revealed an observable increase in mean overall duration as well as variability of laryngeal closure in consecutive swallow tasks versus single swallows across all age groups. Additionally, the means for the single swallow task and both the means and standard deviations for the consecutive swallow tasks were observed to be greatest with the oldest subject population (Tables 7 and 8).

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	.4417	.06777
40-50	.6633	.18194
60-70	.6547	.19347
80-90	.7827	.17068

Table 7: Summary table of mean durations (in seconds) and standard deviations of laryngeal closure during single swallow tasks by age group

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	7.9657	1.10042
40-50	8.8297	2.07192
60-70	10.9323	2.35641
80-90	11.0290	2.78215

Table 8: Summary table of mean durations (in seconds) and standard deviations of laryngeal closure during consecutive swallow tasks by age group

Results of a 2 way ANOVA indicated significant (1) overall main effects of swallow condition (single versus consecutive swallows) on temporal measures of laryngeal closure, (2) overall main effects of age on temporal measures of laryngeal closure, and (3) an interaction between swallow condition and age on temporal measures of laryngeal closure.

Examination of the main effect of swallow task (singles versus consecutives) on laryngeal closure [$F_{1,36}$= 700.58; p=0.001)] indicated that laryngeal closure was greater in duration for consecutive swallows as compared to singles. Mean duration of laryngeal closure for single swallows was .636 s (sd=.03), while mean duration of laryngeal closure for consecutive swallows was 9.69 s (sd=.34). It was observed that the standard deviation of laryngeal closure was larger in the consecutive versus the single swallow condition.

Examination of the main effect of age on laryngeal closure [$F_{3,36}$ = 5.71; p=0.003)] indicated that laryngeal closure was greater in duration in older subjects as compared to younger subjects. Mean durations of laryngeal closure in seconds for each age group were as follows (Table 9).

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	4.20	.35
40-50	4.75	.35
60-70	5.79	.35
80-90	5.91	.35

Table 9: Summary table of mean durations (in seconds) and standard deviations of laryngeal closure by age group collapsed across task (single versus consecutive)

A significant interaction between task and age was noted [$F_{3,36}$= 4.31; p=0.011)]. Follow up tests on the interaction (Tukey HSD) revealed statistically significant differences in duration of laryngeal closure between 20-30 year olds and 60-70 year olds (p=.013) as well as between 20-30 year olds and 80-90 year olds (p=.007). The interaction was investigated using paired t-tests comparing laryngeal closure during single and consecutive swallow tasks for each age group. Differences were significant for each age group (Table 10). As demonstrated in the graph below (Figure 3), the difference between laryngeal closure in single versus consecutive swallows appears to be proportionally larger for 60-70 and 80-90 years olds as compared to 20-30 and 40-50 year olds.

Age	t	df	*P* value
20-30	22.85	9	.0001
40-50	11.97	9	.0001
60-70	14.05	9	.0001
80-90	10.64	9	.0001

Table 10: Summary table of paired sample tests of durations of laryngeal closure by age group for single versus consecutive tasks

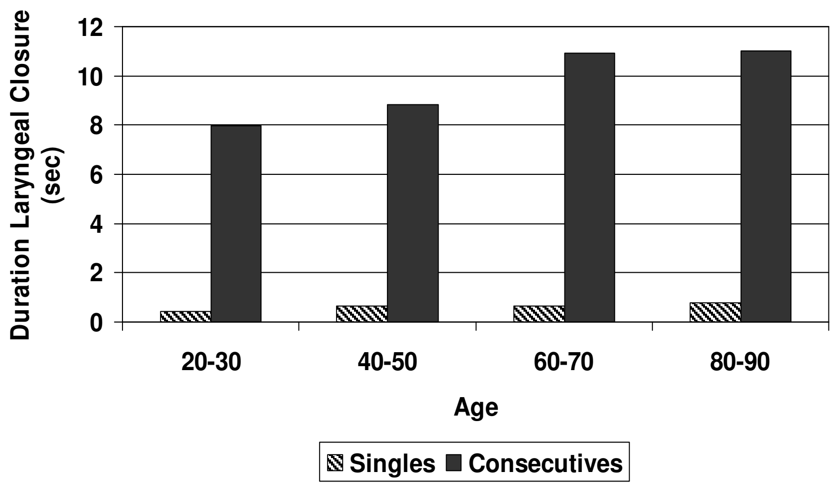


Figure 3: Mean durations of laryngeal closure by age group for single versus consecutive tasks

Respiratory Inductive Plethysmography Data

Interruption of the Respiratory Cycle

No variability was noted for interruption of the respiratory cycle on single and consecutive swallow tasks. For both single and consecutive swallows, all swallows interrupted the expiratory cycle in both conditions across all age groups.

Resumption of the Respiratory Cycle

Upon observation of the data in its raw, nonparametric form, a trend toward increased frequency of return to inspiration following consecutive swallows as compared to single swallows was noted. Additionally, the oldest subject group (80-90) demonstrated the greatest tendency to return to inspiration following consecutive swallows as compared to the other age groups. (Table 11, Figure 4). With the exception of one subject in the 20-30 age group, subjects always returned to expiration following single swallows.

Age	Return to expiration post singles (#occurrences)	% return to expiration post singles	Return to expiration post consecutives (#occurrences)	% return to expiration post consecutives
20-30	29	96.7%	24	80%
40-50	30	100%	25	83.3%
60-70	30	100%	24	80%
80-90	30	100%	15	50%

Table 11: Summary table of frequency of return to expiration following single versus consecutive swallow tasks by age group using raw, nonparametric data

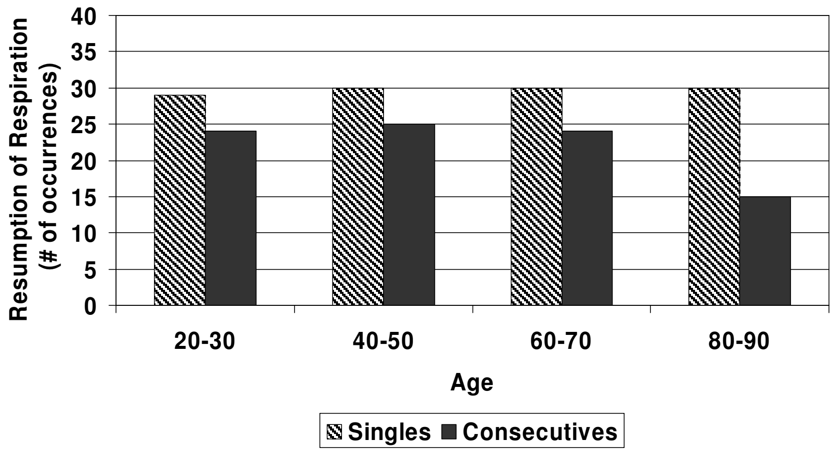


Figure 4: Return to expiration following single versus consecutive swallow tasks by age group using raw, nonparametric data

As indicated previously, the nonparametric data were transformed to ratio data in the following manner. Each interruption and resumption for each swallow trial was considered one opportunity to interrupt or resume expiration. Using this model, the proportion of times the individual interrupts or resumes expiration will be 0 (0 out of 3 times), .33 (1 out of 3 times), .67 (2 out of 3 times), or 1 (3 out of 3 times).

Descriptive statistics revealed an observable decrease in mean overall likelihood of a subject returning to expiration post consecutive swallows as compared to single swallows as well as an increase in variability across all age groups. Additionally, the mean overall likelihood of a subject returning to expiration post consecutive swallows was smallest in the oldest subject population, while variability was highest in the oldest subjects (Tables 12 and 13).

Age	Proportion (# of occurances/3) of Return to Expiration	Standard Deviation
20-30	.97	.10
40-50	1.0	.00
60-70	1.0	.00
80-90	1.0	.00

Table 12: Summary table of proportion (# of occurances/3) of overall likelihood to return to expiration following single swallow task by age group

Age	Proportion (# of occurances/3) Return to Expiration	Standard Deviation
20-30	.77	.35
40-50	.83	.32
60-70	.80	.42
80-90	.50	.45

Table 13: Summary table of proportion (# of occurances/3) of overall likelihood to return to expiration following consecutive swallow task by age group

Given the almost complete lack of variability in the mean overall likelihood to return to expiration following single swallow task by age group, a 2 way ANOVA could not be employed to analyze for a significant main effect of swallowing task on resumption of the respiratory cycle. However, the descriptive statistics in Tables 12 and 13 clearly demonstrate a greater incidence of inspiration following consecutive swallows than that of single swallows, though the overall tendency was to resume expiration regardless of the swallow task.

In the single swallow condition, the mean subject resumption of expiration was .99 (sd=.05). In other words, subjects resumed expiration following single swallows 2.94 to 3 times out of 3 trials. In the consecutive swallow condition, the mean subject resumption of expiration was .73 (sd=.40). In this case, subjects resumed expiration following consecutive swallows 2.01 to 2.37 times out of 3 trials.

Given that a 2 way ANOVA could not be completed, the statistical significance, or lack thereof, of an interaction between age and swallow task on return to expiration could not be determined. However, as Figure 5 illustrates, there appears to be an interaction between age and swallow task, whereby resumption of expiration appears to be significantly less frequent in the consecutive versus single swallow task for 80-90 years olds as compared to the other age groups.

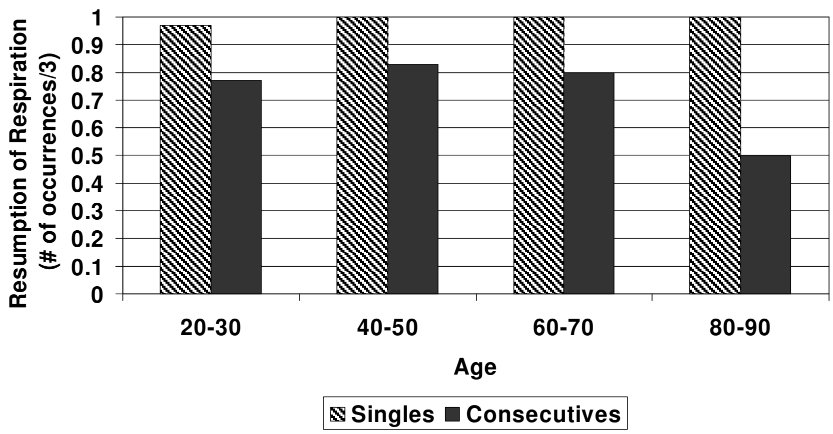


Figure 5: Proportion (# of occurances/3) of overall likelihood to return to expiration following single versus consecutive swallow tasks by age group

Results of a 1 way ANOVA of return to expiration following consecutive swallows across age groups revealed no significant effect of age [$F_{3,36}$= 1.55; p=.219)] were noted.

Transcutaneous Oxygen Saturation Data

Transcutaneous Oxygen Saturation Pre and Post Single Swallows

Descriptive statistics did not reveal any observable alterations in mean oxygen saturation at the onset of the single swallow as compared to the end of the single swallow or any other time point measured. The table in Appendix N provides mean oxygen saturation levels and standard deviations at onset of single swallow (sonsetavg), end of single swallow (sEndavg), and every five seconds thereafter for a total of 60 seconds (s5avg, s10avg, s15avg, s20avg, s25avg, s30avg, s35avg, s40avg, s45avg, s50avg, s55avg, s60avg). Mean saturations for the 20-30 age group are not included in the table in Appendix N, as the pilot study protocol when the age group was run only included pre and post single swallow oxygen saturation measures. Mean oxygen saturation for 20-30 year olds pre and post single swallows was 97.2 (sd= 1.9) and 97.5 (sd=1.82) respectively.

Results of a 2 way ANOVA did not reveal significant (1) overall main effects of age on oxygen saturation, (2) overall main effects of time on oxygen saturation, and/or (3) interaction between age and time. There were no main effects for age [$F_{2,27}$= 2.52; p=.1)]. No overall main effect of time on oxygen saturation at the onset of the single swallow as compared to the end of the single swallow was noted [$F_{13,36}$= .95; p=.5)] There was no significant difference in oxygen saturation at the onset of the single swallow task as compared to the end of the single swallow task (Table 14). Additionally, differences in oxygen saturation from the onset of the single swallow task and 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, and 60 seconds after the single swallows were not significant (Table 14). No interaction [$F_{26,27}$= .915; p=.59)] was noted.

Comparison	*p* value
Onset – immediately post swallow	.765
Onset – 5 sec post swallow	.614
Onset – 10 sec post swallow	.780
Onset – 15 sec post swallow	.506
Onset – 20 sec post swallow	.815
Onset – 25 sec post swallow	.382
Onset – 30 sec post swallow	.481
Onset – 35 sec post swallow	.510
Onset – 40 sec post swallow	.710
Onset – 45 sec post swallow	.700
Onset – 50 sec post swallow	.529
Onset – 55 sec post swallow	.432
Onset – 60 sec post swallow	.352

Table 14: Summary table for comparisons of oxygen saturation at onset of the single swallows to multiple time points post single swallows, collapsed across age groups

Transcutaneous Oxygen Saturation Pre and Post Consecutive Swallows

Descriptive statistics did not reveal any meaningful alterations in mean oxygen saturation at the onset of consecutive swallows as compared to the end of consecutive swallows or any other time point measured. Appendix O provides mean oxygen saturation levels and standard deviations at onset of consecutive swallows (consetavg), end of consecutive swallows (cEndavg), and every five seconds thereafter for a total of 60 seconds (c5avg, c10avg, c15avg, c20avg, c25avg, c30avg, c35avg, c40avg, c45avg, c50avg, c55avg, c60avg). Unlike data for the single swallows, mean saturations for the 20-30 age group are included in the table in Appendix O.

Results of a 2 way ANOVA did not reveal significant (1) overall main effects of age on oxygen saturation, (2) overall main effects of time on oxygen saturation, and/or (3) interaction between age and time. No overall main effect of time pre or post single swallows on oxygen saturation was noted [F(.99; df=13; p=.47)] . There was no significant difference in oxygen saturation at the onset of the consecutive swallow task as compared to the end of the consecutive swallow task (Table 15). Additionally, differences in oxygen saturation from the onset of the consecutive swallow task and 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, and 60 seconds after the consecutive swallows were not significant (Table 15). There were no main effects for age [F(1.82; df=3; p=.16)] or interaction [F(1.01; df=39; p=.46)] noted. Figure 6 illustrates the relative stability of mean oxygen saturations pre and post single and consecutive swallows and at the multiple time points thereafter collapsed across age.

Comparison	*p* value
Onset – immediately post swallow	.772
Onset – 5 sec post swallow	.104
Onset – 10 sec post swallow	.627
Onset – 15 sec post swallow	.943
Onset – 20 sec post swallow	.330
Onset – 25 sec post swallow	.130
Onset – 30 sec post swallow	.063
Onset – 35 sec post swallow	.132
Onset – 40 sec post swallow	.221
Onset – 45 sec post swallow	.761
Onset – 50 sec post swallow	1.00
Onset – 55 sec post swallow	.940
Onset – 60 sec post swallow	.936

Table 15: Summary table for comparisons of oxygen saturation at onset of consecutive swallows to multiple time points post consecutive swallows, collapsed across age groups

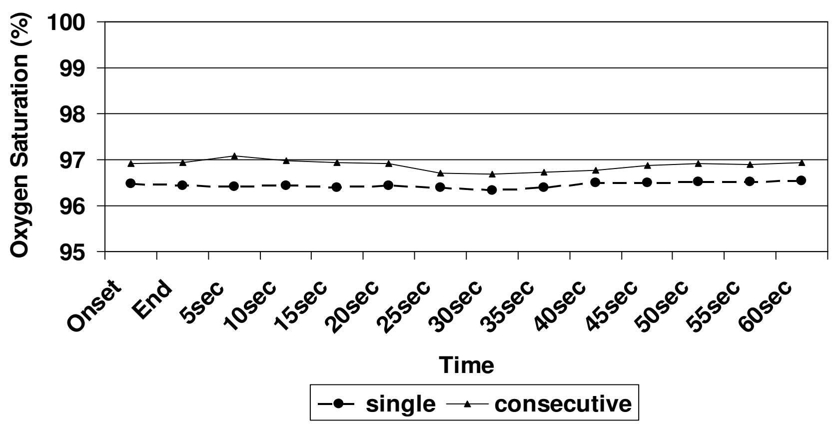


Figure 6: Mean oxygen saturation at multiple time points pre and post single and consecutive swallow tasks collapsed across age

Despite the lack of significant interaction between age and measurement of oxygen saturation across time, the potential for older adults to demonstrate greater susceptibility to oxygen saturation changes over time following consecutive swallows was a specific focus in this study. Additionally, when the pilot data were run on 20-30 year old males, a statistically significant difference between oxygen saturation pre consecutive swallow run and at 20 and 25 seconds post was observed. To clarify the previous findings in light of the additional subject groups, repeated measure ANOVAs were performed for each age group. For all but the 20-30 year group, no significant differences in oxygen saturation from the onset of the single swallows and 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, and 60 seconds after the swallows were noted (Tables 16, 17, and 18). For the 20-30 year age group, the difference in oxygen saturation at the onset of the consecutive swallows as compared to oxygen saturation at 20 and 25 seconds after the consecutive swallows were both significant (20 seconds, p=.018; 25 seconds, p=.029, Table 19).

Comparison	*p* value
Onset – immediately post swallow	.541
Onset – 5 sec post swallow	.299
Onset – 10 sec post swallow	.191
Onset – 15 sec post swallow	.191
Onset – 20 sec post swallow	.341
Onset – 25 sec post swallow	.906
Onset – 30 sec post swallow	.832
Onset – 35 sec post swallow	.705
Onset – 40 sec post swallow	1.00
Onset – 45 sec post swallow	.751
Onset – 50 sec post swallow	.604
Onset – 55 sec post swallow	.576
Onset – 60 sec post swallow	.462

Table 16: Summary table for comparisons of oxygen saturation at onset of consecutive swallows to multiple time points post consecutive swallows, 40-50 year olds

Comparison	*p* value
Onset – immediately post swallow	.210
Onset – 5 sec post swallow	.237
Onset – 10 sec post swallow	.909
Onset – 15 sec post swallow	.546
Onset – 20 sec post swallow	.794
Onset – 25 sec post swallow	.448
Onset – 30 sec post swallow	.545
Onset – 35 sec post swallow	.823
Onset – 40 sec post swallow	.853
Onset – 45 sec post swallow	.879
Onset – 50 sec post swallow	.743
Onset – 55 sec post swallow	.814
Onset – 60 sec post swallow	1.00

Table 17: Summary table for comparisons of oxygen saturation at onset of consecutive swallows to multiple time points post consecutive swallows, 60-70 year olds

Comparison	*p* value
Onset – immediately post swallow	.853
Onset – 5 sec post swallow	1.00
Onset – 10 sec post swallow	.840
Onset – 15 sec post swallow	.534
Onset – 20 sec post swallow	.775
Onset – 25 sec post swallow	.348
Onset – 30 sec post swallow	.185
Onset – 35 sec post swallow	.122
Onset – 40 sec post swallow	.274
Onset – 45 sec post swallow	.531
Onset – 50 sec post swallow	.653
Onset – 55 sec post swallow	.722
Onset – 60 sec post swallow	.722

Table 18: Summary table for comparisons of oxygen saturation at onset of consecutive swallows to multiple time points post consecutive swallows, 80-90 year olds

Comparison	*p* value
Onset – immediately post swallow	.520
Onset – 5 sec post swallow	.309
Onset – 10 sec post swallow	.859
Onset – 15 sec post swallow	.545
Onset – 20 sec post swallow	.018*
Onset – 25 sec post swallow	.029*
Onset – 30 sec post swallow	.111
Onset – 35 sec post swallow	.269
Onset – 40 sec post swallow	.138
Onset – 45 sec post swallow	.726
Onset – 50 sec post swallow	.758
Onset – 55 sec post swallow	.394
Onset – 60 sec post swallow	1.00

* significant at the .05 level

Table 19: Summary table for comparisons of oxygen saturation at onset of consecutive swallows to multiple time points post consecutive swallows, 20-30 year olds

<u>Average Bolus Volume</u>

Although bolus volume was not a dependent measure in this design, average bolus volume measures were recorded for each swallow tasks for each subject. Given that, in an effort to create a more lifelike swallowing task, bolus volume was not controlled, and increases in bolus volume are known to increase durational measures of laryngeal elevation and closure, analyses were conducted to determine if any significant differences existed in average bolus sizes.

With the exception of the oldest subject group, descriptive statistics did not reveal any observable differences between mean bolus volume during single versus consecutive swallows for each age group, or collapsed across ages (Table 20).

Age	Bolus Vol (ml) Singles	Bolus Vol (ml) Consecutives
20-30	10.60 (sd+/-5.72)	13.09 (sd=2.43)
40-50	11.88 (sd+/-4.33)	13.18 (sd=2.84)
60-70	10.72 (sd+/-1.77)	10.71 (sd=2.43)
80-90	10.22 (sd+/-3.78)	14.18 (sd=3.18)
Collapsed	10.86 (sd+/-4.04)	12.79 (sd2.93)

Table 20: Summary table mean bolus volumes (ml) for single versus consecutive swallow tasks by age group and collapsed across age groups

A significant difference in the estimated bolus volume per swallow [t(2.71; df=39; p=.01)] between the single versus consecutive swallow conditions was noted. As indicated in Table 20, mean bolus volume for each single swallow was 10.86ml (sd=4.04). Mean bolus volume for each swallow within each consecutive swallow run was 12.79 ml (sd=2.93).

Paired sample t-tests comparing average bolus volumes in the single versus consecutive conditions for each age group revealed statistically significant differences for only the oldest age group (Table 21).

Age	t	df	*P* value
20-30	1.27	9	.23
40-50	1.24	9	.25
60-70	.01	9	.99
80-90	2.41	9	.04*

* significant at the .05 level

Table 21: Summary table of paired sample tests of bolus volume by age group for single versus consecutive tasks

ANCOVA

As stated previously, paired sample t-tests comparing average bolus volumes in the single versus consecutive conditions for each age group revealed statistically significant differences for only the oldest age group (Table 21). To rule out the possibility that increased bolus size, rather than age, accounted for increases in laryngeal elevation and closure measures, multiple one way ANCOVAs were performed on the durational measures with bolus volume utilized as a covariate.

The original statistical results outlined previously held, indicating that the apparent main effect of age on durational measures on laryngeal elevation and closure was not due to the fact that the older subjects' boluses were significantly larger (Tables 22-25).

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	1.12	.086
40-50	1.064	.087
60-70	1.06	.086
80-90	1.33*	1.155

* significant at the .05 level

Table 22: Summary table of adjusted mean durations (in seconds) and standard deviations of laryngeal elevation during single swallow tasks by age group

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	8.376	.741
40-50	9.139	.742
60-70	11.641*	.797
80-90	11.893*	.766

* significant at the .05 level

Table 23: Summary table of adjusted mean durations (in seconds) and standard deviations of laryngeal elevation during consecutive swallow tasks by age group

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	.443	.051
40-50	.658	.052
60-70	.655*	.051
80-90	.786*	.052

* significant at the .05 level

Table 24: Summary table of adjusted mean durations (in seconds) and standard deviations of laryngeal closure during single swallow tasks by age group

Age	Mean Duration Laryngeal Closure (s)	Standard Deviation
20-30	7.928	.688
40-50	8.782	.689
60-70	10.857*	.711
80-90	11.190*	.739

* significant at the .05 level

Table 25: Summary table of adjusted mean durations (in seconds) and standard deviations of laryngeal closure during consecutive swallow tasks by age group

Qualitative Observations

General qualitative observations were made regarding incidence of penetration and aspiration as well as pharyngeal residue remaining after each swallow task for each subject in each age group. Penetration is typically operationally defined as entry of any portion of the test bolus into the laryngeal vestibule above the level of the true vocal folds. Aspiration is typically operationally defined as entry of any portion of the test bolus below the level of the true vocal folds. Pharyngeal residue is typically operationalized as a portion of the test bolus remaining in the pharynx following completion of the swallow.

Table 26 and Figure 7 illustrate observations made regarding penetration during single and consecutive swallows. Penetration was observed in all but the 40-50 age group during single swallows, and in all age groups during the consecutive swallows. Incidence of penetration increased with age during the consecutive swallow task. Amount of bolus observed to penetrate was between trace (less than 1% of test bolus) and 2% for single swallows. Amounts increased to between trace and 5% during consecutive swallows. The episodes of 5% of bolus penetration occurred only in the 80-90 age group. No subject aspirated during any single swallow.

Age	Singles	Consecutives
20-30	3%	13.33%
40-50	0%	16%
60-70	3%	20%
80-90	5%	16.7%

Table 26: Summary table % occurrence of penetration during single and consecutive swallow tasks by age group

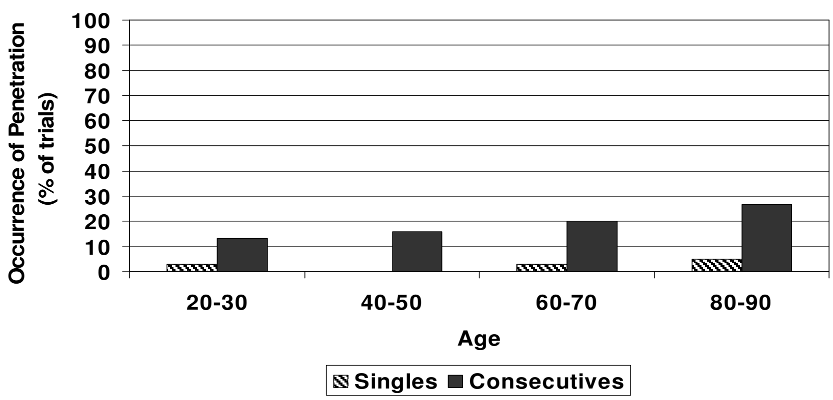


Figure 7: Occurrence of penetration (%) during single and consecutive swallow tasks for each age group

Residue was largely unremarkable on single swallows across age groups and judged to be clinically within normal limits. Incidence and amount of pharyngeal residue increased following consecutive swallows, particularly in the 60-70 and 80-90 age groups. Subjects in the 20-30 and 40-50 age groups exhibited no more that 0-3% residue following consecutive swallows. 60-70 years old and 80-90 year olds exhibited an average range of 3-5% residue following consecutive swallows.

CHAPTER V.

DISCUSSION

Summary of Results

This cross sectional descriptive study examined the effects of alterations in swallow task (single versus consecutive swallows) on swallow physiology, respiratory phase relationships, and oxygen saturation in healthy adult males across the age continuum (20-30 years, 40-50 years, 60-70 years, and 80-90 years). In doing so, this study hoped to provide a critical building block to clinically relevant research with individuals with compromised swallowing and respiration.

Forty healthy adult males participated in this study, with 10 subjects per age group: 20-30 years, 40-50 years, 60-70 years, and 80-90 years. After being screened and providing consent, subjects completed a videofluorographic swallow study while respiratory events and oxygen saturation were monitored using respiratory inductive plethysmography and pulse oximetry. Videofluoroscopy is considered the "gold standard" in the field of speech language pathology for evaluation of swallow physiology, and is commonly utilized for both clinical and research purposes. Completion of the videofluorographic swallow study allowed for computation of durational measures for laryngeal elevation and closure. Use of respiratory inductive plethysmography is one of a multitude of respiratory measures commonly used in research protocols, and use of the Respitrace allowed for analysis of the interruption and resumption of the respiratory cycle during single and consecutive swallowing tasks. Pulse oximetry is commonly used in a myriad of medical and research settings, and is the standard noninvasive method for assessing oxygen saturation.

The protocol included a total 27 swallows grouped into two different tasks: (1) three comfortable single swallows of thin liquid from a cup and (2) three repetitions of eight consecutive, uninterrupted swallows of thin liquid from a cup. During completion of the task, each subject remained seated with fabric covered coils (Respibands) placed around his chest and abdomen and a pulse oximetry probe placed on his index finger of the non-dominant hand.

Following completion of the protocol, the temporal data (laryngeal elevation and closure) and respiratory inductive plethysmography were reduced. The oxygen saturation data did not require reduction. All data were analyzed to determine whether differences in swallow physiology, respiratory phase relationships, and oxygen saturation in healthy adult males existed secondary to age and/or swallow task (singles versus consecutives).

Videofluoroscopic Data

Statistically significant main effects of swallow task (single versus consecutive) and age (20-30 years, 40-50 years, 60-70 years, and 80-90 years) on temporal measures of laryngeal vestibule closure and laryngeal elevation, as well as interactions were noted.

The findings of the main effect of task on durational measures of laryngeal elevation and closure not only are intuitive, but are supported by prior research. Certainly, one would expect a task requiring eight swallow to take longer than a task requiring only one swallow. Subsequently, the statistically significant increases in duration of laryngeal vestibule closure and laryngeal elevation during consecutive swallows as compared to single swallows were as expected. Additionally, these alterations were consistent with the alterations in the apneic interval associated with larger volume swallows or repeated swallows from a straw (Hiss et al., 2001; Leslie et al., 1999; Logemann et al., 1993; Martin-Harris et al., 1994).

The findings of the main effect of age on durational measures of laryngeal elevation and closure are consistent with prior research. (Hiss et al., 2001; Rademaker et al., 1998; Ren et al., 1993; Seeley et al., 1989a; Tracy et al., 1989). Hiss et al.'s (2001) research indicates that young men exhibit a swallow apnea duration (SAD) of .74 to .80, depending on bolus volume (10-20ml), while elderly men demonstrate an SAD of .96 to 1.0 across the same bolus range.

The significant interaction between task and age on durational measures was anticipated. While durational measures increased for all subjects in consecutive swallow versus single swallow tasks, the durational increase in laryngeal elevation and closure are greater for older men (80-90 years) as compared to young (20-30) and middle aged (40-50 year old) men. This is consistent with age and bolus volume interaction on laryngeal elevation and closure in women (Rademaker et al, 1998).

In summary, based on this study we may conclude that in healthy males across the age span, the apneic interval of the swallow, a consequence of laryngeal vestibule closure, is increased in duration on consecutive swallows as compared to single swallows. There is greater variability in the duration of the apneic interval on consecutive swallows versus single swallows. Additionally, the durational increase in laryngeal elevation and closure are greater for older men (80-90 years) as compared to young (20-30) and middle aged (40-50 year old) men.

Respiratory Inductive Plethysmography

Both single and consecutive swallows were found to interrupt the expiratory phase of the respiratory cycle on 100% of all trials across all ages. Single swallows were followed by a return to expiration on 99% of all trials; the only exception to this was one subject in the 20-30 age group. This overwhelmingly consistent pattern of interruption and resumption of the expiratory phase is consistent with prior research (Martin-Harris et al., 1994; Preiksaitis & Mills, 1996; Nishino et al., 1985; and Selley et al., 1989a).

An increased tendency toward resumption of inspiration following consecutive swallows as compared to single swallows in healthy adult males across the age continuum was observed. This appears to be similar to the findings of both Martin et al., 1994 and Preiksaitis and Mills, 1996, which demonstrated a higher occurrence of post swallow inspiration after large versus small liquid swallows.

Age had no impact on healthy adult males' propensities to return to inspiration following consecutive swallows during the swallowing protocol. This is consistent with the work of Hiss et al. (2001), Martin et al. (2003), Leslie et al. (2005), Selley (1989a) who all observed no significant age effect regarding propensity to return to inspiration or expiration.

In summary, based on this study we may conclude that in healthy males across the age span, there is an increased likelihood of post swallow inspiration following consecutive swallows as compared to single swallows, and age does not play a role in a subject's likelihood to return to inspiration or expiration.

Transcutaneous Oxygen Saturation

No statistically significant changes in oxygen saturation were noted between the onset of either the single or consecutive swallow condition and the completion of the swallowing task regardless of subject age. Additionally, no statistically significant differences were noted at five-second intervals up to 60 seconds following the single or consecutive swallow task regardless of subject age.

Following completion of the pilot study that led to development of this research project, a statistically significant difference was noted between oxygen saturation at the onset of the consecutive swallow task and both 20 and 25 seconds after completion of the consecutive swallow task in the 20-30 year old subjects. To further explore this finding in light of the statistical results revealed with this repeated measures ANOVA, paired t-tests were performed for the consecutive swallow task for each age group. All results were insignificant, with the exception of the difference between saturation from onset to 20 and 25 second post consecutive swallow in the 20-30 year old subjects only. This result was considered to be spurious, as it is inconsistent not only with the findings of the other subject groups but also with what is known regarding oxygen saturation in humans. A healthy, saturated adult not subjected to large temperature fluctuations, would be likely to remain saturated unless he or she was subjected to substantial exercise or other physiological stressors. It is not expected that the duration of the apneic interval during normal swallowing behavior would be result in exertion significant enough to impact saturation in a healthy adult.

In summary, the study demonstrated that healthy adult males across the age continuum are capable of tolerating increased apneic durations associated with consecutive swallows without significant fluctuations in oxygen saturation.

Average Bolus Volume and ANCOVA

Although a statistically significant difference in bolus volume per swallow was noted and attributed to the 80-90 year old group in subsequent analysis, this result should be taken with caution. It is important to note that these measures were merely bolus volume estimates (completed as delineated in the procedures detailing the videofluoroscopic swallow study) made by the student investigator at the end of the study protocol. Completion of the protocol took place in a busy outpatient radiology department, which required quick movement of the subjects and the student investigator out of the room upon completion of the protocol. For example, on an occasion when three subjects (one 60-70 year old and two 80-90 year olds) completed the protocol, the student investigator was required to complete the subsequent bolus volume estimates in another radiology suite. This result was considered to be the result of investigator error.

However, to rule out the possibility that increased bolus size, rather than age, accounted for increases in laryngeal elevation and closure measures, multiple one way ANCOVAs were performed on the durational measures with bolus volume utilized as a covariate. The original results held, indicating that when bolus volume was taken into consideration, durational measures of laryngeal elevation and closure were still significantly longer in the older subject population.

Qualitative Observations

Frequency of penetration of the test bolus into the larynx above the level of the true vocal folds was observed to increase in consecutive versus single swallow tasks for all age groups and with age in both swallow tasks. This is consistent with the research of Daniels et al. (2004), Frederick et al. (1996), and Robbins et al. (1999) which have demonstrated increased occurrence of penetration across a variety of swallow tasks with age. No aspiration was observed. It is questionable how the potential for increased penetration during consecutive swallows and the increased propensity of post consecutive swallow inspiration may intersect to create an environment where certain individuals may be more likely to aspirate material that penetrates the larynx during a consecutive swallow run.

Clinical Implications

Several findings of the present study have significant clinical implications. First, the duration of laryngeal elevation and closure are greater during consecutive swallows as compared to single bolus swallows, thereby increasing the apneic interval during the consecutive swallow. Additionally, the durational increase in laryngeal elevation and closure are greater for older men (80-90 years) as compared to young (20-30) and middle aged (40-50 year old) men. Second, regardless of swallowing task, duration of both laryngeal elevation and closure appear to increase with age. Third, healthy adult males across the age continuum are capable of tolerating increased apneic durations associated with consecutive swallows without significant fluctuations in oxygen saturation. Fourth, healthy adult males across the age continuum demonstrate an increased tendency toward resumption of inspiration following consecutive swallows as compared to single swallows. Fifth, the frequency and amount of penetration of the bolus was greater during a series of consecutive swallows when compared to single swallows across all ages. However, older adults (80-90 years) exhibited the greatest tendency and amount of penetration during consecutive swallows. Sixth, despite the changes in the duration of the apneic interval and the increased propensity to return to inspiration rather than expiration following consecutive swallows, males demonstrate remarkable ability to maintain respiratory homeostasis across the lifespan. Lastly, despite the fact that healthy men across the age continuum demonstrate the ability to maintain respiratory homeostasis, the question remains if individuals with compromised swallowing or pulmonary function would demonstrate the same abilities.

As demonstrated by the findings enumerated above, the healthy adult male, regardless of age, does not exhibit difficulty in maintaining respiratory homeostasis, despite completion of swallow tasks designed to tax the synchrony of swallowing and breathing. However, in a clinical setting, when dealing with individuals with dysphagia, respiratory diseases, or a combination thereof, the impact of a taxing swallow task may be different.

It is important to recall that altering a swallow task, such as increasing the number of swallows completed consecutively (as in this protocol), results in a cascade of events that may or may not eventually impact respiratory homeostasis. Duration of seconds of laryngeal closure, which in this study increased with consecutive swallows and age, is directly related to the duration of the apneic interval. In this study, healthy adult males were capable of tolerating the increases in the apneic interval associated with task and age, as demonstrated by the insignificance of the changes in oxygen saturation. However, it is conceivable that an individual with a comprised respiratory system and baseline reduction in oxygen saturation may not demonstrate the same resiliency, and may require clinical intervention despite the lack of neurologically associated dysphagia.

As noted previously, an increase in return to inspiration following consecutive swallows was observed with age. Additionally, the subjects demonstrated a greater tendency and amount of residue following consecutive swallows with age. While this did not result in episodes of aspiration in the subject population, it is conceivable that an individual with dysphagia who experiences penetration, aspiration, and/or residue during a single swallow may be at much greater risk of aspiration if they inspire following completion of consecutive swallows. In this case, knowledge of this increased propensity to inspire following consecutive swallows may result in recommendations to complete swallowing tasks with single swallows and/or use a maneuver such as the supraglottic swallow (which ends with a cough to clear the airway) to force expiration instead of inspiration following a swallow.

Lastly, the question remains as to how respiratory disease and dysphagia might coalesce to significantly reduce not only swallow efficacy but the efficacy of maneuvers typically employed with patients with dysphagia. A patient with dysphagia but no respiratory compromise might be capable of effectively performing a supraglottic swallow maneuver, which requires a prolongation of the apneic interval and cough subsequent to swallowing. However, it is possible that an individual with dysphagia and COPD may not be capable of handling such a demand in terms of synchronization of the respiratory cycle and impact of oxygen saturation.

Study Limitations

Limitations Related to Subject Sample or Sampling Methods

Multiple studies of the oropharyngeal swallow in both young adult men and women in their early to late 20s have yielded similar homogenous results in regards to swallow duration measures (Perlman, Shultz, and VanDeale, 1993; Shaker et al., 1993; Rademaker, Pauloski, Colangelo, and Logemann, 1998; Robbins, Hamilton, Lof, and Kempster, 1992). Additionally, we know that the normal aging process brings anticipated changes in swallow function, particularly increased duration of laryngeal elevation, airway closure, and cricopharyngeal sphincter opening (Rademaker, Pauloski, Colangelo, and Logemann, 1998). Although the student investigator made every possible attempt to create a homogenous subject sampling at each age group, it is possible that internal threats to validity existed within the samples themselves. Additionally, it is important to bear in mind that the normative values generated in this study represent group averages of performance, and do not represent any individual subject's performance.

Given the relatively small sample size per age group (10 in each age category), limitations exist in the ability to extend the results of the study to all members of the age group. Additionally, the vast majority of 40 subjects (90%) were caucasian. Two individuals in the 20-30 year old group were Hispanic, and one subject in the 60-70 and 80-90 year old groups was African American. It is important to note that determination of race was made by the student investigator and not directly asked of any subject; it is possible that greater diversity in the subject pool existed, but was not noticed by the student investigator. Given the apparent racial and ethnic homogeneity of the subject sample, extension of these results to other races and ethnicities must be done with caution.

Increasingly the entire biomedical community is acknowledging the fact that gender-based differences exist in normal physiology, disease processes, and response to a myriad of medical interventions. Moreover, investigators have noted gender based differences in swallowing function and gender based differences in age related changes in the swallow (Hiss et al., 2001; Logemann et al., 2002; Robbins et al., 1992) . Given that only males were utilized in this study, extension of results to females must be done with caution.

All subjects were screened by the student investigator only. No process was in place for assessment of the student investigator's reliability. When subjects were screened by the student investigator, assessment of the subjects' candidacy to participate was based on the subject's self report of any exclusionary criteria. Although the student investigator attempted to assure each subject's comprehension of all the exclusionary criteria, it is conceivable that a subject may not have understood some of the illness or diagnostic categories mentioned or that the subject was not entirely aware of his health status. Additionally, it is possible that subjects were not screened for disease processes that as yet are unknown to have an impact on swallow function.

The reliability of subject self report regarding smoking status may be scrutinized; it is conceivable that some subjects may have had a vested interest in potentially under-reporting prior smoking behavior, over-reporting their cessation history, or misrepresenting their history of smoking illegal substances. Additionally, no control was in place for subject exposure to second-hand smoke. As research increasingly demonstrates, second-hand smoke may have significant deleterious effects. It is possible that a subject may have alterations in respiratory function secondary to second-hand smoke exposure, yet was included in the study.

Lastly, the time between completion of the subject intake questionnaire and completion of the study averaged nine days, with a range of two to 32 days. It is conceivable that a subject might have had a change in health status between the time of intake and study completion but failed to notify the student investigator.

Limitations Related to Subject Recruitment

In addition to exploring the impact of age and swallow task on swallow physiology, respiratory phase relationships, and oxygen saturation in healthy adult males, this study initially intended to elucidate the potential effects of smoking on swallow and respiration as well. Originally, two additional groups, smokers in the 20-30 age group and 60-70 age group were to be included. However, significant issues prevented accrual of subjects needed in both age groups.

In the 20-30 year age group, the one pack-year history requirement proved to be a stumbling block. While multiple individuals with a history significant for social smoking were identified, males with true pack-year history were difficult to obtain. While in-person solicitations by the student researcher in local bars and the posting of advertisements in locations holding meetings with groups of individuals known for increased smoking behavior (such as Alcoholics Anonymous) yielded potential subjects, these subjects proved highly unreliable, frequently failing to follow through with scheduling or failing to arrive at the hospital on the day of the study. In all, only two subjects in the group actually completed the protocol, and eventually the age group was eliminated from the study.

In the 60-70 year old group, the criteria of no cardiopulmonary issues and normal body habitus proved to be an accrual issue. In-person solicitations and posting of advertisements were performed as mentioned for the 20-30 year old group. The student investigator observed that 60-70 year old individuals who currently smoke and have a 10 pack-year or more history of smoking typically exhibited a multitude of cardiac, pulmonary, or weight issues that excluded them from participation. Ultimately, no subjects were accrued for this category, and the age group was eliminated from the study.

Limitations Related to the Design of the Swallow Tasks

Despite attempts to induce "normal" swallowing behavior by utilizing consecutive swallows, the task and the environment were not similar to a typical drinking scenario. It is possible that in a more realistic setting, a subject would have chosen to complete fewer or more swallows in a consecutive swallow run. Several subjects commented on the taste of the barium, which may have impacted their willingness to take typical sized sips. The consecutive swallow runs were completed one after the other, with three runs in total. It is possible that natural drinking behavior might include a run of consecutive swallows, followed by a series of sips before another run of consecutive swallows. Perhaps an interspersing of single and consecutive tasks and allowing the subject to take as few or as many sips as desired in a consecutive run may mimic typical swallowing behavior more closely.

Limitations Related to Instrumentation or Instrumentation Utilization

The Respitrace system used in the study required coupling to a multichannel paper recorder. Newer models of Respitrace and other similar systems now utilize computer technology to record and process the respiratory data, as well as other measures such as oxygen saturation. In this study, respiratory data were manually time-locked with the videofluoroscopic data and the oxygen saturation data by the student investigator. Oxygen saturation was manually recorded by the student investigator. With the manual time-locking of the respiratory data and the manual recording of the oxygen saturation data, there was a greater potential for investigator error.

Respitrace bands and pulse oximetry probes were placed on all subjects by the student investigator. No additional judges were involved in the placement process and no verification was made, other than by the student investigator, regarding proper position of the bands and probes. Although signals for all bands and probes were verified by the student investigator prior to proceeding with the study, a method for verification of placement might reduce potential for error.

In a study of the efficacy of various methods of respiratory monitoring, Tarrant et al (1997) advocate for the possible inclusion of additional respiratory monitoring beyond respiratory inductive plethysmography devices such as Respitrace. A comparison of monitoring of respiratory measures for swallowing indicated that swallowing events may be more difficult to observe on Respitrace alone, secondary to Respitrace's susceptibility to movement artifact (Tarrant et al., 1997). Addition of nasal airflow monitoring via nasal cannula may improve the overall interpretation of results (Tarrant et al., 1997).

Regarding the use of pulse oximetry, studies have reported the potential for error in reliability and validity of the signals produced. Potential for motion artifact, delay in signal processing, and variability in pulse oximeter reliability exists whenever transcutaneous pulse oximetry is utilized (Bonhorst et al., 2000; Fearnley, 1995 (1&2); Hay et al., 2002; Hill, 2000; Tobin et al., 2002). Additionally, although the procedures allowed for recording of oxygen saturation for 60 seconds after the swallows, it is possible that alterations in saturation occurred outside of the 60 second window.

Recommendations for Future Research

It is imperative for research into swallow physiology and its coupling with the respiratory system continue and expand, as it is our only means of elucidating patterns of the interrelationship of swallowing and breathing in normal healthy individuals, across the life cycle, and in cases of dysphagia or respiratory compromise. Effort should be made to attempt to re-create swallowing tasks that are most like normal eating and drinking behavior.

Creating an assessment environment that most mimics typical eating and drinking behavior is a challenge for every practicing researcher and clinician. However, when swallowing tasks utilized in assessment do not replicate mealtime behavior, little extension may be made of the data collected in an artificial environment.

Lifespan Studies

Continued study of the coupling of swallowing with the respiratory cycle as well as any possible impact on respiratory physiology measures must be conducted across the life span continuum. This extends from healthy term infants to the elderly. Additionally, females must be included in every segment of study and comparisons must be made to determine when gender based differences begin to occur.

Knowledge of normal development and change in the interdependence of swallowing and respiration require researchers to compare normative date with populations manifesting a variety of disorders or disease processes across the age continuum. For example, despite the fact that the rate of premature births continues to increase yearly (Hamilton, et al, 2003) and transition from tube to bottle or breast feeds proves difficult for many preterm infants (Lau, et al, 2003; Shaker, 1999; Thoyre, 2003), there is a paucity of data regarding the sequence and timing of development of suck swallow breathe synchrony and the efficacy of alterations (such as rate of flow or position) made to allegedly facilitate oral feeding in the preterm infant. There are a lack of policies for initiation of oral feedings and evidence-based standards regarding transition (Bakewell-Sachs & Blackburn, 2003; Siddell & Froman, 1994). At best, the major decisions of when and how to initiate oral feedings are based on the clinical judgment of a seasoned professional. At worst, the decisions may be based on cost containing and early discharge imperatives. Overall, there is a need to track the maturational changes in the preterm infant swallow and respiration and understand when the preterm mechanism attains a level of functioning equivalent to term infants.

A few small studies have explored the impact of neuromuscular disorders such as cerebral palsy on the coordination of swallowing and breathing in children and adolescents (McPherson, Kenny, Koheil, Bablich, Sochaniwskji, & Milner, 1992). However, no developmental studies on nonimpaired children and adolescents have been completed. Again, overall patterns of maturation of the synchrony of swallowing and breathing across childhood and adolescence must be elucidated in order to have a firm basis of comparison in different groups with disordered physiology.

Additionally, any patterns of age based alterations in the coupling of swallowing and respiration must be clearly elucidated in order for practitioners to appropriately identify dysphagia as compared to normal patterns of aging. Erroneous identification of the normal aging process versus disorders has fiscal and ethical ramifications. Moreover, knowing the changes to expect in swallow function across the age span allows for the provision of appropriate health education for our aging population, which may impact quality of life.

Disease and Disorder Studies

In an effort to best serve our patients, we must have empirical data regarding the impact of various disease processes and disorders on the coordination of swallowing and breathing. In the pediatric and adult dysphagic population, studies must be completed on individuals who have experienced strokes, traumatic head injury, and a wide variety of neuromuscular disorders. Though much is already known regarding the typical physiological implications of the diseases and disorders on swallow physiology and the subsequent risk or lack thereof of aspiration, it is unclear if alterations in the coupling of swallow and breathing may in fact be exacerbating dysphagia. It is possible that such knowledge would allow for better service provision for these patient groups, which might reduce their risk of aspiration and improve their oral maintenance of nutrition and hydration, safety when eating and drinking, and overall quality of life.

There is increasing opinion in the speech language pathology community that patients with chronic respiratory issues often display dysphagic behavior in the absence of any neurophysiological or structural deficits associated with swallowing. It is imperative that we have a clear understanding of the impact of a variety of respiratory disorders on the ability to synchronize swallowing with the respiratory cycle as well as the impact of the overall “work” of eating and drinking on respiratory physiology. It is possible that speech language pathologists may become more common collaborators in the care of patients with respiratory issues and may serve to increase patients’ abilities to maintain nutrition and hydration safely, improve overall quality of life, and decrease the exacerbation of respiratory issues.

Smoking Studies

The Center for Disease Control (2004) estimates that 22.5% of all adults in the United States smoke cigarettes. Cigarette smoking accounts for 440,000 deaths annually in the United States as well as a myriad of health complications (Center for Disease Control, 2002; Center for Disease Control, 2003; deMarco et al., 2004; Dockery et al., 1998; Higgins et al., 1993; Jimenez-Ruiz et al., 2004; Ockene & Miller, 1997; Novotny & Giovano, 1998; Shin et al., 2003; U.S. Department of Health and Human Services, 1989). Additionally, smoking has been shown to alter swallow physiology (Dua et al, 1998; Kahrilas and Gupta, 1989).

Given the evidence on smoking's impact on respiratory function, particularly COPD (deMarco et al., 2004; Dockery et al., 1998; Higgins et al., 1993; Jimenez-Ruiz et al., 2004; Novotny & Giovino, 1998; Shin et al., 2003), as well as alteration of respiratory measures in asymptomatic smokers (Diedrich et al., 2002; Henschke et al., 2001; Sashidar et al., 2002; Stratelis, Jakobsson, Molstad, & Zetterstom, 2004; Vrijhoef et al, 2003; Zielinski & Bedarneck, 2001), it is conceivable that smokers may demonstrate altered coupling of swallowing and respiration and/or increased impact of swallowing tasks on respiratory physiology measures. Investigation of this potential relationship is a public health concern for smokers as well as nonsmokers exposed to second-hand smoke.

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APPENDICES

APPENDIX A.

Initial IRB Approval (exp. 3/07)

May 10,2006

Jerilyn Logemann, PhD
Communication Sciences and Disorders
2240 Campus Drive
Frances Searle Building, Room 3-334
Evanston Campus
IRB Project Number: 0328-056
Meeting Date: 3/23/2006
Study Sites: Northwestern Memorial Hospital

Project Title: Effects of Age and Smoking on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males, Supported by: NIH/NCI P01 CA 40007 OTHER

Submission Accession Number:
200603-0250 **Submission(s)**
Considered: New Project
Recruitment Material Flyers/Posters

Status: APPROVED **Project Expiration: 3/22/2007**

Full Institutional Review Board approval has now been granted for your submission referenced above for a one year period ending 3/22/2007. IRB approval includes approval of the protocol, HIPAA Compliance and consent forms(s) listed below.

Version Date: 04/30/2006 Main Consent Form
Version Date: 03/14/2006 HIPAA Authorization Form

IRB approval is granted with the understanding that the investigator will:

- Change neither the procedures nor the consent form without prior IRB review and approval of those changes.
  Proposed changes must be submitted via the IRB Revisions Submission Form found on the OPRS website.
- Report any serious adverse events (SAEs) involving an NU subject to the IRB within 5 days.
- Report any unanticipated problems involving risks to subjects or adverse events (AEs) to the IRB within 30 days.
- Submit a periodic review (PR) to the IRB 6 weeks prior to the expiration of this approval. If renewal is not obtained by the indicated expiration date, the project will be closed.
- Send a copy of the final approved consent form and a copy of this approval letter to the Office of Sponsored Research (OSR) if this is a sponsored project. Additionally, OSR must be contacted if any amendments are made to this project that may affect the award.

Sincerely,

CC: kaplan@cdnet.cod.edu

This Institution has an approved Federalvvide Assurance with the Department of Health and Human Services: Assurance ID# FWA00001549. For more information regarding OPRS submissions and guidelines, please consult wvvw.northwestern.edu/research/OPRS/irb.

APPENDIX B.

Initial Subject Consent Form (exp. 3/07)

Northwestern University Medical School
The Department of Communication Sciences and Disorders
Consent Form

Title of Study:	Effects of Age and Smoking on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males
Principal Investigator:	Jeri A. Logemann, Ph.D.
Student Investigator:	Stacy L. Kaplan, M.S.
Funded by:	The Department of Communication Sciences and Disorders

Introduction. You are being asked to take part in a research study looking at age and smoking status on the coordination of swallowing and breathing. The purpose of this study is to determine if age and/or smoking changes swallowing patterns, breathing patterns, and the amount of oxygen in the blood. You have been asked to take part in this study because you are a healthy male over 20 years of age.

Procedures. As a subject in this study, you have been asked to come to the Radiology Department at Northwestern Memorial Hospital. You are being asked to undergo a type of x-ray swallow study. This is a technique for making x-ray videotapes of swallows. You will be asked to swallow apple flavored barium liquid a total of 27 times, with rest periods as needed. Barium is used because it is visible on x-rays. During this test you will perform the following swallows, taking a comfortable size sip from a cup: (1) 3 single swallows of liquid barium and (2) 3 sets of 8 consecutive swallows of liquid barium on one breath for each set. It will take about 8 seconds to do 8 swallows on one breath. In order to monitor movements associated with breathing, you will be asked to wear a thin t-shirt to allow for placement of plastic bands around your chest and waist. To monitor oxygen in your blood, you will be asked to wear a probe on your left index finger. The bands and probe will remain on your body for the whole study. Your participation in this study will last approximately 10 minutes, with two and a half minutes of total x-ray exposure.

Risks. The x-ray involves radiation. The area of x-ray exposure will be to the head and neck. Lead shielding will be used to protect below the waist. The total dose of research radiation you will receive is equal to that of 11 days of background radiation. Background radiation is the radiation you receive from daily living. The barium to be swallowed may have an unpleasant taste and/or texture and may cause constipation. The bands and probe may be mildly irritating to your skin, and may restrict your movement during the duration of the study.

Reproductive Health. The area of x-ray exposure will be to the head and neck regions only. The effects of radiation from the x-ray swallow study on human sperm cannot be predicted. However, lead shielding below the waist will be used to provide additional protection to reproductive organs. This shielding will be used regardless of age. The risks of reproductive damage are considered low as long as adequate lead shielding is used appropriately in regions that may be exposed to radiation or effects.

Benefits. You will not benefit from this research study. The information gained from this study will be used in scientific research to expand the knowledge of swallowing. An understanding of swallowing and how it can be altered may aid in development of more effective treatment of others with swallowing disorders.

Alternative. You do not have to take part in this research study.

Confidentiality. Involvement in this research study may result in loss of privacy, since persons other than the investigator(s) might view your study records. Unless required by law, the following people can review your study records: study investigators, members of the investigator's staff, and the Northwestern University Institutional Review Board. They are required to keep your personal information confidential. Results of this study may be used for publication or presentation at scientific meetings. If your individual results are discussed, your identity will be protected by using a study code number rather than you name or identifying information. Records of your participation in this study will be kept confidential at Northwestern University. All research materials will be held in the strictest of confidence until the study is completed, at which point all research material, including videotaped records, will be destroyed. The results of your study will be collected in a centralized computer at the Northwestern University Swallow Physiology Laboratory, Evanston, Illinois. Your records will be identified by numeric code and will be stored Northwestern University Swallow Physiology Laboratory, Evanston, Illinois.

Financial Information. You will be paid $20.00 cash for your participation in this study. The payment will be given to you after you have completed the study. Should you withdraw prior to completion of the study, you will still be paid $20.00. You will not be required to pay for any aspect of the study.

Research Related Injuries. In the event of injury or illness as a result of study medications, devices, or procedures, you should seek medical treatment through your physician or treatment center of choice. You should promptly notify the project director in the event of any illness or injury. Payment for this treatment will be your responsibility.

The Office for the Protection of Research Subjects of Northwestern University, at telephone number (312) 503-9338, can provide further information about rights as a research subject and is where any research-related injury should be reported. Further information regarding this study may be obtained from the project director, Dr. Logemann, at telephone number (847) 491- 2490. For problems arising on evening or weekends, you may call the student investigator at (773) 248-2773.

Subject Rights. Your participation in this study is voluntary, and you are free to withdraw at any time. Your decision regarding whether or not to participate or your decision to withdraw will not affect your present or future relations with Northwestern University or the staff at this institution. Withdrawal will not in any way affect the nature of treatment otherwise available to you.

CONSENT

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions. If I have additional questions, I have been told whom to call. I

agree to participate in the research study described above. A copy of this consent form will be provided to me after I sign it.

Northwestern University
Institutional Review Board
IRB L
#: 0328-056
APPROVED: 5-10-2006

APPENDIX C.

Initial HIPAA Form (exp. 3/07)

Northwestern University
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: Effects of Age and Smoking on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males

Principal Investigator: Jeri A. Logemann, Ph.D.
The Department of Communication Sciences and Disorders
2240 Campus Drive
Evanston, Il 60208
Frances Searle Building 3-219
(847)491-2490

You have agreed to participate in the research Study mentioned above and have signed a separate informed consent that explained the procedures of the research Study and the confidentiality of your personal health information. This authorization form gives more detailed information about the following:

- What personal health information about you will be collected in this Study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access your personal health information during the Study
- Your right to withdraw your authorization (approval) for any future use of your personal health information

You are also allowing Northwestern University and the researcher to disclose that personal health information to outside organizations or people involved with the processing of this Study, as described in the separate informed consent form.

What personal information is collected and used in this Study, and might also be shared (disclosed)?

The following personal contact and personal health information will be collected, used for this research Study and may be disclosed or released during your involvement with this research Study:
Name
Address
Telephone number
Medical history
Allergies
Current and past medications or therapies

Other tests and procedures that will be performed in the Study
include:

Videofluorographic swallow study
Monitoring of oxygen saturation via pulse oximeter during completion of the videofluorographic swallow study
Monitoring of respiratory cycle via use of Respitrace® bands on abdomen and rib cage during completion of the videofluorographic swallow study

Why is **your personal information being used?**

Your personal contact information is important for Northwestern University research team to contact you during the Study. Your personal health information (including the results of tests and procedures) is being collected during this research Study for purposes of the Study. The Principal Investigator will not use the results of these tests and procedures to treat you. You will be encouraged to contact your physician to seek out a proper referral for further assessment or treatment, should any abnormal test result which may impact your health be revealed during your participation in the study.

Who within Northwestern University may use or disclose your personal health information?

The following individuals and organizations within Northwestern University may use or disclose your personal health information for this research project:

The Principal Investigator and the Investigator's Study team (other University staff associated with the Study)
The Northwestern University Institutional Review Boards (the committees charged with overseeing research on human subjects)
The Northwestern University Office for the Protection of Research Subjects (the office which monitors research studies)
Authorized members of the Northwestern University workforce who may need to access your information in the performance of their duties (for example: to make sure the research is being done correctly).

Who outside of Northwestern University might receive your personal health information?

As part of the Study the Principal Investigator, Study team and others listed above, may disclose your personal health information, including the results of the research Study tests and procedures to the following:

Study monitors and auditors who are responsible for overseeing the quality and integrity of the Study

The personal information of yours that is disclosed in connection with the Study may no longer be protected by the federal privacy protection regulations.

In records and information disclosed outside of Northwestern University, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research Study.

How long will Northwestern University be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific Study does not expire. This information may be maintained in a research repository (database). However, Northwestern University may not reuse or re-disclose your personal health information collected in this Study for another purpose other than the research Study described in this document unless it obtains permission to do so from the Northwestern University Institutional Review Board.

Will you be able to access your records?

Results of all tests and procedures done solely for this research Study and not as part of your regular care will not be included in your medical record. You will be able to request access to your medical record when the Study is completed.

During your participation in this Study, you will not be able to access the medical records that have been created as a result of your participation in the Study. This will be done to prevent the knowledge of Study results from affecting the reliability of the Study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any Study information that is part of that medical record when the Study is over or earlier, if possible. The investigator is not required to release to you information in the research records.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research Study may still use your personal information that was collected prior to your withdrawal of permission if that information is necessary to the integrity of the Study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research Study.

You are not required to sign this authorization. If you decide not to sign the authorization:

It will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you may not be allowed to participate in the research Study.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this Study.

By signing this document you are permitting your doctors and other health care providers to disclose your personal health infonnation to Northwestern University and permitting Northwestern University to use and disclose personal health information collected about you for research purposes as described above.

Northwestern University
Institutional Review Board
#: 0328-056
APPROVED: 5-10-2006

APPENDIX D.

IRB Renewal Approval (exp. 3/08)

March 26, 2007

Jerilyn Logemann, PhD Communication Sciences and Disorders Frances Searle Building, 3-358 Evanston Campus

IRB Project Number: 0328-056
Meeting Date: 3/19/2007
Approval Period: **3/23/2007 - 3/22/2008**
Study Sites: Northwestern University, Northwestern Memorial Hospital

Project Title: Effects of Age and Smoking on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males NIH/NCI P01 CA 40007

Submission Accession Number:
200701-0255 **Submission(s)**
Considered: Periodic Review

Status: APPROVED Project Expiration: 3/22/2008

Full Institutional Review Board approval has now been granted for your submission referenced above for a one year period ending 3/22/2008. IRB approval includes approval of the protocol and consent forms(s) listed below. Version Date: 03/22/2007

IRB approval is granted with the understanding that the investigator will:

- Change neither the procedures nor the consent form without prior IRB review and approval of those changes.
  Proposed changes must be submitted via the IRB Revisions Submission Form found on the OPRS website.
- Report any serious adverse events (SAEs) involving an NU subject to the IRB within 5 days.
- Report any unanticipated problems involving risks to subjects or adverse events (AEs) to the IRB within 30 days.
- Submit a periodic review (PR) to the IRB 6 weeks prior to the expiration of this approval. If renewal is not obtained by the indicated expiration date, the project will be closed.
- Send a copy of the final approved consent form and a copy of this approval letter to the Office of Sponsored Research (OSR) if this is a sponsored project. Additionally, OSR must be contacted if any amendments are made to this project that may affect the award.

Sincere

Debra Gibson TicY, BS, CCRC
IRB Manager, Expedited/Continuing Reviews

APPENDIX E.

Combined Subject Consent and HIPAA Form (exp. 3/08)

Northwestern University
The Department of Communication Sciences and Disorders

CONSENT FORM AND A UTHORIZA TION FOR RESEARCH

Title: Effects of Age and Smoking on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males

Principal Investigator: Jeri A. Logemann, Ph.D.

Supported by [or Funded by]: The Department of Communication Sciences and Disorders

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we (i.e., Northwestern University or the Rehabilitation Institute of Chicago) would like to use information about you and your health.

What is the reason for doing this study?

You are being asked to take part in a research study looking at age and smoking status on the coordination of swallowing and breathing. The purpose of this study is to determine if age and/or smoking changes swallowing patterns, breathing patterns, and the amount of oxygen in the blood. You have been asked to take part in this study because you are a healthy male over 20 years of age.

What you will do if you choose to be in this study?

As a subject in this study, you have been asked to come to the Radiology Department at Northwestern Memorial Hospital. You are being asked to undergo a type of x-ray swallow study. This is a technique for making x-ray videotapes of swallows. You will be asked to swallow apple flavored barium liquid a total of 27 times, with rest periods as needed. Barium is used because it is visible on x-rays. During this test you will perform the following swallows, taking a comfortable size sip from a cup: (1)3 single swallows of liquid barium and (2) 3 sets of 8 consecutive swallows of liquid barium on one breath for each set. It will take about 8 seconds to do 8 swallows on one breath. In order to monitor movements associated with breathing, you will be asked to wear a thin t-shirt to allow for placement of plastic bands around your chest and waist. To monitor oxygen in your blood, you will be asked to wear a probe on your left index finger. The bands and probe will remain on your body for the whole study. Your participation in this study will last approximately 10 minutes, with two and a half minutes of total x-ray exposure.

What are some of the risks and discomforts that may happen to people who are in this study?

Taking part in this study may involve the following risks. The x-ray involves radiation. The area of x-ray exposure will be to the head and neck. Lead shielding will be used to protect below the waist. The total dose of research radiation you will receive is equal to that of 11 days of background radiation. Background radiation is the radiation you receive from daily living. The barium to be swallowed may have an unpleasant taste and/or texture and may cause constipation. The bands and
probe may be mildly irritating to your skin, and may restrict your movement during the duration of the study.

What do I need to know about reproductive health/sexual activity if I am in this study?

The area of x-ray exposure will be to the head and neck regions only. The effects of radiation from the x-ray swallow study on human sperm cannot be predicted. However, lead shielding below the waist will be used to provide additional protection to reproductive organs. This shielding will be used regardless of age. The risks of reproductive damage are considered low as long as adequate lead shielding is used appropriately in regions that may be exposed to radiation or effects.

What are some of the benefits that are likely to come from my being in this study?

You are not likely to have any direct benefit from being in this research study. The information gained from this study will be used in scientific research to expand the knowledge of swallowing. An understanding of swallowing and how it can be altered may aid in development of more effective treatment of others with swallowing disorders.

Are there any financial costs to being in this study?

There will be no costs to you for being in this study. You will get $20.00 for taking part in this research study. It will be paid in cash. If you withdraw from the study, you will still be paid $20.00.

What should I do if I am injured as a result of being in this study?

In the event of injury or illness as a result of study medications, devices, or procedures, you should seek medical treatment through your physician or treatment center of choice. You should promptly notify the project director in the event of any illness or injury. Payment for this treatment will be your responsibility.

<u>If I have questions or concerns about this research study, whom can I call?</u>

You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. Dr.Logemann is the person in charge of this research study. You can call him/her at (847) 491 2490, Monday-Friday from 9-5. You can also call the student investigator, Stacy Kaplan, at (773) 447 0627, 24 hours a day with questions about this research study.

<u>What are my rights as a research subject?</u>

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment to which you are otherwise entitled.
If you want to speak with someone <u>who is not</u> directly involved in this research, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at 312-503-9338.

<u>What about my confidentiality and privacy rights?</u>

We are committed to respect your privacy and to keep your personal information confidential.

In order for us to do this research, and for you to be in this study, we will need to collect information about you, including your contact information (name, address, e-mail, telephone number) as well as other personal health information about you or from your medical records. You have the right to decide if we can use and share your health information for this research. However, we will not be able to include you in this study unless you give the Principal Investigator and his/her research team permission to use and share your personal health information.

Your health information we may use or share for this research includes:
> Name
> Address
> Telephone number
> Medical history
> Allergies
> Current and past medications or therapies

If you sign this document, you are giving permission to the following groups of people to give information about you (described above) to the researchers for this study:

> The Principal Investigator and the Investigator's Study team (other University staff associated with the Study)

Once we have the health information listed above, we may share it with :

> Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office of Research, and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),

> Study monitors and auditors who make sure that the study is being done properly,

In all disclosures outside of Northwestern University, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

Please note that:

> You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.

> You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to: Jeri A. Logemann, Ph.D., Northwestern University, The Department of Communication Sciences and Disorders, 2240 Campus Drive, Frances Searle Bldg. 3-219, Evanston, IL 60208.

Unless you revoke your consent, it will not expire.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it. A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company

Northwestern **University**
Institutional Review Board 1RB #:
Approved to consent subjects
through: *0*^

APPENDIX F.

Buehler Center on Aging Research Registry Permission Letter

Date: November 30, 2005

To: Institutional Review Board Members

From: Celia Berdes, PhD
Aging Research Registry
Buehler Center on Aging

Subject: Permission to Access the Aging Research Registry

This memo is to certify that the Buehler Center on Aging gives permission to the investigators of the following research project to request and use the Aging Research Registry to recruit subjects for their study. This memo is written to meet the requirements of the IRB application, section 15.4.

Project Title: "Effects of Age and Smoking Status on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Adult Males."

Principal Investigator: Stacy Kaplan, doctoral candidate, Communication Sciences and Disorders; Jerilynn Logemann, PhD, advisor

Sincerely,

Celia Berdes, PhD
750 N Lake Shore Drive, Suite 601
Chicago, 1L 60611-2611

APPENDIX G.

Volunteer and Recruitment Poster (General 20-80+)

NU/Department of Speech Pathology

Male Volunteers Needed for a Research Study

Males Ages 20-80+

You can earn $20 by participating in an x-ray study investigating swallowing and breathing in healthy adult males.

- **Subjects must be in good general health and have no history of swallowing disorders, head or neck cancer, oral/pharyngeal surgery, or respiratory diseases including asthma and must be of normal weight for height.**
- **The study will take place at Northwestern Memorial Hospital in Chicago (parking arrangements will be made if needed).**

Interested?? Please call Stacy at (773) 447-0627!

APPENDIX H.

Volunteer and Recruitment Poster (General 40-80+)

NU/Department of Speech Pathology

Male Volunteers Needed for a Research Study

Males Ages 40-80+

You can earn $20 by participating in an x-ray study investigating swallowing and breathing in healthy adult males.

- **Subjects must be in good general health and have no history of swallowing disorders, head or neck cancer, oral/pharyngeal surgery, or respiratory diseases including asthma and must be of normal weight for height.**
- **The study will take place at Northwestern Memorial Hospital in Chicago (parking arrangements will be made if needed).**

<u>Interested?? Please call Stacy at (773) 447-0627!</u>

APPENDIX I.

Volunteer and Recruitment Poster (Smoker 20-30+)

NU/Department of Speech Pathology

DO YOU SMOKE?
Males Needed for a Research Study

Males Ages 20-30

You can earn $20 by participating in an x-ray study investigating swallowing and breathing in healthy adult males.

- **Subjects must be in good general health and have no history of swallowing disorders, head or neck cancer, oral/pharyngeal surgery, or respiratory diseases including asthma and must be of normal weight for height.**
- **The study will take place at Northwestern Memorial Hospital in Chicago (parking arrangements will be made if needed).**

Interested?? Please call Stacy at (773) 447-0627!

APPENDIX J.

Volunteer and Recruitment Poster (Smoker 60-70)

NU/Department of Speech Pathology

DO YOU SMOKE?
Males Needed for a Research Study

Males Ages 60-70

You can earn $20 by participating in an x-ray study investigating swallowing and breathing in healthy adult males.

- **Subjects must be in good general health and have no history of swallowing disorders, head or neck cancer, oral/pharyngeal surgery, or respiratory diseases including asthma and must be of normal weight for height.**

- **The study will take place at Northwestern Memorial Hospital in Chicago (parking arrangements will be made if needed).**

Interested?? Please call Stacy at (773) 447-0627!

APPENDIX K.

Oxygen Saturation Data Form

Sequence of Presentation

S→C **C→S**

O2 Stats

Single Swallows:

#	Onset	End	5	10	15	20	25	30	35	40	45	50	55	60	+/-
1															
2															
3															

Consecutives:

#	Onset	End	5	10	15	20	25	30	35	40	45	50	55	60	+/-
1															
2															
3															

APPENDIX L.

Respiratory Cycle Data Reduction Form

<u>Swallow:</u> S1 S2 S3 C1 C2 C3

*Respitrace output placed here

<u>Interrupt: I E Resume: I E</u>

Legend: I=Inspiration, E=Expiration

Summary of Respitrace Data

Assigned Values:

Inspiration (I) = 1   Expiration (E) = 2

S1

Interrupt: ____ = ____

Resume: ____ = ____

S2

Interrupt: ____ = ____

Resume: ____ = ____

S3

Interrupt: ____ = ____

Resume: ____ = ____

C1

Interrupt: ____ = ____

Resume: ____ = ____

C2

Interrupt: ____ = ____

Resume: ____ = ____

C3

Interrupt: ____ = ____

Resume: ____ = ____

APPENDIX M.

Temporal Measures Data Reduction Form

VFSS Temporal Data

Swallow Type: Singles / Consecutives Condition: S→C / C→S

1) Beg. laryn. elevation __ __ : __ __ __ __ : __ __ __ __ : __ __

2) Laryn. return to rest __ __ : __ __ __ __ : __ __ __ __ : __ __

3) First laryn closure for __ __ : __ __ __ __ : __ __ __ __ : __ __

4) Last laryn. closure __ __ : __ __ __ __ : __ __ __ __ : __ __

Calculations

Duration laryn. elevation (2-1): _______ _______ _______

Duration laryn. closure (4-3): _______ _______ _______

Misc.

Spontaneous posture/maneuver? Y / N If yes →

Motility D/O? Y /N If yes →

Aspiration/Penetration? Y / N When? Before / During / After
% Bolus: _____ Cough? Y / N

Oral Residue? (% & location): _____________; Pharyngeal Residue? (% & location): _________

APPENDIX N.

Summary Table of Mean SaO2:
pre and post single swallow task and every 5 sec thereafter for 60 sec by age group

Descriptive Statistics

	Age	Mean	Std. Deviation	N
sonsetavg	2	96.9333	1.59320	10
	3	96.7333	1.88431	10
	4	95.7333	1.23528	10
	Total	96.4667	1.62735	30
sEndavg	2	96.9000	1.55595	10
	3	96.8333	2.00770	10
	4	95.6000	1.36807	10
	Total	96.4444	1.71836	30
s5avg	2	96.8000	1.53317	10
	3	96.9333	1.84458	10
	4	95.5333	1.24920	10
	Total	96.4222	1.63752	30
s10avg	2	96.9667	1.44402	10
	3	96.7000	1.88856	10
	4	95.6333	1.30951	10
	Total	96.4333	1.62157	30
s15avg	2	97.0000	1.44016	10
	3	96.8000	1.83384	10
	4	95.4000	1.14180	10
	Total	96.4000	1.61743	30
s20avg	2	96.9667	1.51902	10
	3	96.9333	1.81761	10
	4	95.4333	1.49938	10
	Total	96.4444	1.72281	30
s25avg	2	96.9333	1.47238	10
	3	96.8333	1.77951	10
	4	95.3667	1.57488	10
	Total	96.3778	1.71925	30
s30avg	2	97.0333	1.46102	10
	3	96.8000	1.99506	10
	4	95.1667	2.38436	10
	Total	96.3333	2.09176	30
s35avg	2	97.0000	1.44871	10
	3	96.7000	2.13986	10
	4	95.5000	1.50923	10
	Total	96.4000	1.79271	30
s40avg	2	97.0667	1.56189	10
	3	96.8667	1.79299	10
	4	95.5667	1.51576	10
	Total	96.5000	1.71035	30
s45avg	2	97.0667	1.48074	10
	3	96.8667	1.87380	10
	4	95.5667	1.44059	10
	Total	96.5000	1.69459	30
s50avg	2	97.1000	1.49938	10
	3	96.8667	1.91936	10
	4	95.6000	1.45551	10
	Total	96.5222	1.71691	30
s55avg	2	97.1000	1.49938	10
	3	96.8667	1.91936	10
	4	95.6333	1.40062	10
	Total	96.5333	1.69651	30
s60avg	2	97.1000	1.49938	10
	3	96.9000	1.85958	10
	4	95.6333	1.40062	10
	Total	96.5444	1.67808	30

APPENDIX O.

Summary Table of Mean SaO2:
Pre and post consecutive swallow task and every 5 sec thereafter for 60 sec by age group

Descriptive Statistics

	Age	Mean	Std. Deviation	N
Consetavg	1	97.4333	1.69276	10
	2	97.4667	1.38956	10
	3	96.7667	2.15481	10
	4	96.0000	1.95631	10
	Total	96.9167	1.85170	40
CEndavg	1	97.3333	1.81217	10
	2	97.3667	1.21157	10
	3	97.0333	1.84223	10
	4	96.0333	1.74589	10
	Total	96.9417	1.69781	40
C5avg	1	97.5667	1.67811	10
	2	97.6333	1.14881	10
	3	97.1000	1.62580	10
	4	96.0000	1.82574	10
	Total	97.0750	1.66493	40
C10avg	1	97.4000	1.59320	10
	2	97.7000	1.09375	10
	3	96.7333	1.85126	10
	4	96.0333	1.63639	10
	Total	96.9667	1.64135	40
C15avg	1	97.3000	1.72455	10
	2	97.7000	1.09375	10
	3	96.5667	2.00031	10
	4	96.1333	1.54120	10
	Total	96.9250	1.67857	40
C20avg	1	97.0333	1.70294	10
	2	127.6000	95.13354	10
	3	96.6667	1.65552	10
	4	95.9333	1.63903	10
	Total	104.3083	47.70854	40
C25avg	1	97.1333	1.77221	10
	2	97.5000	1.18894	10
	3	96.5333	1.87380	10
	4	95.6333	1.82878	10
	Total	96.7000	1.77318	40
C30avg	1	97.2333	1.69276	10
	2	97.4333	1.25757	10
	3	96.6333	1.90807	10
	4	95.4333	2.04909	10
	Total	96.6833	1.85968	40
C35avg	1	97.3000	1.66630	10
	2	97.5333	1.12437	10
	3	96.8000	1.94492	10
	4	95.2667	2.05961	10
	Total	96.7250	1.89299	40
C40avg	1	97.2667	1.62390	10
	2	97.4667	1.07955	10
	3	96.8000	1.82709	10
	4	95.5667	2.03700	10
	Total	96.7750	1.77893	40
C45avg	1	97.4000	1.70547	10
	2	97.5333	1.11333	10
	3	96.8000	1.79299	10
	4	95.8000	1.85392	10
	Total	96.8833	1.72389	40
C50avg	1	97.4000	1.69093	10
	2	97.5667	1.11167	10
	3	96.8333	1.87413	10
	4	95.8667	1.73703	10
	Total	96.9167	1.70428	40
C55avg	1	97.3333	1.66296	10
	2	97.5667	1.12272	10
	3	96.8333	1.70873	10
	4	95.9000	1.67811	10
	Total	96.9083	1.63472	40
C60avg	1	97.4333	1.74306	10
	2	97.6000	1.11996	10
	3	96.7667	1.79883	10
	4	95.9000	1.67811	10
	Total	96.9250	1.68703	40

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Education

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Ph.D. in Speech and Language Pathology, 2007
Dissertation: Effects of Alterations in Swallow Task and Age and on Swallow Physiology, Respiratory Phase Relationships, and Oxygen Saturation in Healthy Adult Males
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M.S., Speech and Hearing Sciences, 1994
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Professional Experience

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Michael Reese Hospital and Medical Center, Chicago, IL
Speech Language Pathologist, 1996-1998

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State or National Presentations

95% Female: Exploring the Impact of Gender on the Professions (American Speech Language Hearing Association National Conference, 11/02)

Extending Services with SLPAs (Illinois Speech Language Hearing Association Annual Conference, 2/02)

SLPA Instruction and Training (American Speech Language Hearing Association National Conference, 11/01)

Role, Training, and Supervision of SLPAs (Illinois Speech Language Hearing Association, 2/01)

Advanced Topics in Dysphagia (South Dakota Speech Language Hearing Association, 4/00)