Use Authorization

In presenting this dissertation in partial fulfillment of the requirements for an advanced degree at Idaho State University, I agree that the Library shall make it freely available for inspection. I further state that permission to download and/or print my dissertation for scholarly purposes may be granted by the Dean of the Graduate School, Dean of my academic division, or by the University Librarian. It is understood that any copying or publication of this dissertation for financial gain shall not be allowed without my written permission.

Signature _____

Date _____

Tongue Strengthening Efficacy of the Slurp Swallow Exercise in Individuals with Tongue Thrust

Dylan M. Wake

A thesis

submitted in partial fulfillment

of the requirements for the degree of

Master of Science in the Department of Communication Sciences & Disorders

Idaho State University

May 2017

Committee Approval

To the Graduate Faculty:

The members of the committee appointed to examine the thesis of Dylan Wake find it satisfactory and recommend that it be accepted.

J. Anthony Seikel, PhD.
Major Advisor

Joni G. Loftin, MSR-CCC-SLP, COM
Committee Member

Bryant M. Gee, PhD, OTR/L, BCP
Graduate Faculty Representative

Human Subjects Committee Approval

October 24, 2016

Dylan Wake
Comm Sci Disorders/Deaf Educ
MS 8116

RE: regarding study number IRB-FY2017-49: Tongue Strengthening Efficacy of the Slurp swallow Exercise in Individuals with Tongue Thrust

Mr. Wake:

Thank you for your responses from a previous full-board review of the study listed above. These responses are eligible for expedited review under FDA and OHRP (DHHS) guidelines. This is to confirm that I have approved your application.

Notify the HSC of any adverse events. Serious, unexpected adverse events must be reported in writing within 10 business days.

You may conduct your study as described in your application effective immediately. The study is subject to renewal on or before Oct 24, 2017, unless closed before that date.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review. Contact Tom Bailey (208-282-2179; email humsubj@isu.edu) if you have any questions or require further information.

Sincerely,

Ralph Baergen, PhD, MPH, CIP
Human Subjects Chair

Acknowledgments

I want to express my gratitude for the members of my Thesis committee, Dr. Seikel, Joni Loftin, and Dr. Gee. Thank you for your time, guidance, and support. I am also grateful for the academic and clinical faculty at ISU who have contributed to the many educational opportunities foundational to the writing of this Thesis. Thank you.

I especially want to thank my Thesis Advisor Dr. Seikel. I am extremely grateful for your willingness to take me on as a Thesis Student. From start to finish you have been unfailingly enthusiastic, encouraging, and supportive. I am grateful to have learned so much with your guidance and from your expertise.

I want to express my gratitude for my cohort. I have immensely enjoyed your comradery, support, and kindness, particularly through hard times. I am glad to have known every one of you. These past years, and consequently this Thesis, would have been much more grueling without such a wonderful cohort. Thank you for everything.

Most of all I want to thank my wonderful and beautiful wife Diana, and my children Ammon, and Beckham. I could not have done this without you. Your boundless support as I've gone through grad school and worked on this Thesis has been overwhelming. As I have had to dedicate time away from home working on this project I cannot express enough my appreciation for your understanding, kindness, and support. I love you. Thank you for all you have done in helping me complete this Thesis.

Table of Contents

List of Figures

List of Tables

Abstract

Tongue Thrust is considered an Orofacial Myofunctional Disorder with several negative implications. Various treatment approaches have been studied generally and found efficacious; however, efficacy studies on specific treatment techniques are scant. Previous studies have provided preliminary evidence that the slurp swallow exercise may increase tongue strength in individuals with tongue thrust. The purpose of this study is to add to the existing evidence base to better ascertain if a 10 session intensive treatment program including 50 repetitions of the slurp swallow exercise is effective in increasing tongue strength in individuals with tongue thrust. Furthermore, this study analyzes an aggregate group of 17 subjects from previous studies to examine the efficacy of this exercise. Results of both the current study and aggregate group reveal that the slurp swallow exercise increases both tongue tip and dorsum strength in individuals with tongue thrust.

Chapter 1 - Review of the Literature

Introduction

Deglutition is defined as the transportation of food, liquid, and secretions from the oral cavity to the stomach (Arvedson & Brodsky, 2002; Dodds, 1989). Normal deglutition is important for the maintenance of adequate nutrition and hydration (Logemann, 1998). Furthermore, normal deglutition function provides protection for the respiratory system (Matsuo & Palmer, 2008; Miller, 1982).

Impairment of deglutition is known as oropharyngeal dysphagia (OPD). Dysphagia can have adverse effects on a person's quality of life due to its impact on nutrition, hydration and respiratory protection (Logemann, 1998; Matsuo & Palmer, 2008; Steele & Cichero, 2014). A common component of dysphagia treatment is isometric resistance exercise that targets increasing lingual muscular strength.

Tongue thrust is an Orofacial Myofunctional Disorder (OMD) that has been linked with signs of OPD and is also commonly treated through the use of isometric exercises targeting muscle training and control (Hanson, 1988; Hanson & Mason, 2003; Holzer, 2011). The purpose of this study is to examine whether the slurp swallow exercise effectively increases lingual strength in individuals with tongue thrust.

Normal Deglutition

Deglutition is often described in terms of phases that characterize the general location of the bolus relative to anatomical structures. Dodds, Stewart, and Logemann (1990) describe four phases of deglutition: oral preparatory, oral, pharyngeal, and esophageal. Leopold and Kagel (1997) describe five phases of deglutition, including an anticipatory phase occurring before the oral preparatory phase. This anticipatory phase

accounts for visual and olfactory perceptual components which stimulate salivation, as well as cognitive information that affects oral motor activity prior to feeding.

The oral preparatory phase involves preparation of food or liquid for swallowing. Once food or liquid has been introduced into the mouth, contraction of the orbicularis oris muscle initiates strong labial seal to prevent the spilling of food or liquid from the oral cavity. During this phase, the velum is depressed to allow for nasal breathing. The tongue is active throughout the oral preparatory phase, maintaining food in the oral cavity, and transferring it to the occlusal surfaces of the teeth for mastication. During mastication, the tongue mixes food with saliva to assist the formation of a cohesive bolus. Contraction of the buccinator and risorius muscles prevent food from spilling into the lateral sulcus. Once food has been triturated to a desirable consistency, the tongue gathers it into a cohesive bolus before initiating the oral phase of deglutition (Dodds et al., 1990; Leopold & Kagel, 1997; Logemann, 1998; Matsuo & Palmer, 2009; Seikel et al., 2010).

The oral phase involves posterior propulsion of the bolus towards the oropharynx by the tongue. During this phase labial seal is maintained by continued contraction of the orbicularis oris muscle. The velum remains depressed, allowing for continued nasal breathing. The tongue forms a seal against the alveolar ridge and a groove along the midline of the tongue allows the bolus to move posteriorly as the tongue moves in a stripping or rolling motion, squeezing the bolus posteriorly towards the facial pillars. When the bolus passes the anterior faucial pillars, the pharyngeal phase of deglutition is triggered. The duration of the oral phase is typically between 1 and 1.5 seconds and may increase slightly with bolus viscosity, as greater lingual pressure is required to transport

the bolus posteriorly (Dodds et al., 1990; Logemann, 1998; Seikel et al., 2010; van den Engel-Hoek et al., 2012).

The pharyngeal phase involves both propulsion of the bolus to the upper esophageal sphincter (UES) and protection of the airway. It is triggered as the bolus passes the anterior faucial pillars. As the pharyngeal phase is triggered, the velum elevates, separating the oropharynx from the nasopharynx, preventing material from entering the nasal cavity. Contraction of several suprahyoid muscles elevate the hyoid bone and the larynx, and pull them forward anteriorly. In quick succession the true vocal folds adduct, contraction of the aryepiglottic muscles cause the false vocal folds to constrict, and the epiglottis inverts. This closure of the laryngeal vestibule prevents material from entering the airway. The cricopharyngeus muscle relaxes due to inhibition of the recurrent laryngeal branch of the vagus nerve. Relaxation of cricopharyngeus, coupled with hyolaryngeal excursion and pressure from the descending bolus, open the UES. Ramping of the tongue and subsequent tongue base retraction assist in propelling the bolus inferiorly. Sequential contraction of the pharyngeal constrictor muscles from superior to inferior assist in the propulsion of the bolus to the UES. From its trigger to the passage of the bolus through the UES, the pharyngeal phase typically lasts less than a second (Logemann, 1998; Matsuo & Palmer, 2008; Seikel et al., 2010).

The esophageal phase involves the transportation of the bolus through the esophagus to the stomach. Duration of the esophageal phase ranges between 8 and 20 seconds. A combination of peristalsis and gravity transport the bolus inferiorly through the esophagus. Relaxation and the opening of the lower esophageal sphincter (LES) allow

the bolus to pass into the stomach (Logemann, 1998; Matsuo & Palmer, 2008; Seikel et al., 2010).

Several anatomical structures are involved in the process of deglutition including the jaw, teeth, pharynx, and larynx (van den Engel-Hoek et al., 2012). The tongue is particularly important for normal deglutition. Tongue movement is essential for bolus manipulation and its propulsion towards the oropharynx (Logemann 1998; Stierwalt & Youmanns, 2006). Both the central and peripheral nervous systems are involved throughout the process of deglutition. Jean (2001) describes deglutition as being controlled and organized by a central pattern generator (CPG) located in the medulla oblongata. The CPG consists of various subsystems: an afferent system for sensory input, an efferent system of output to motor neurons, and an organizing system which programs swallowing patterns (Jean, 2001).

Anatomical structures necessary for normal deglutition begin to develop prenatally and continue to develop through infancy and childhood (Delaney & Arvedson, 2008). Matsuo and Palmer (2008) note several anatomical differences between infants and adults pertinent to deglutition. In infants both the hyoid bone and larynx are higher in the neck, the hard palate is flatter than in adults, and the epiglottis is in contact with the soft palate. During development these distinctions are lost as structures become larger and move farther apart. Neurological development important for deglutition begins prenatally. Myelination of the brainstem occurs between 18-24 weeks' gestation. Several cranial nerves involved in deglutition, including VII, IX, and XII begin myelination between 20-24 weeks' gestation, and the neuronal network that controls the pharyngeal

phase of swallowing has been found to be functional in fetuses (Delaney & Arvedson, 2008).

Infants exhibit a sucking reflex involving tongue protrusion and retraction in a piston-like motion. Pumping action of the tongue initiates flow of milk from the breast while feeding. Deglutition is typically triggered after four or five repetitions of this pumping action. This pattern of deglutition is referred to as visceral or infantile swallowing and is characterized by forward movement of the tongue. Development of dentition blocks anterior protrusion of the tongue during deglutition and leads to the development of somatic or mature swallowing (Horn, Künhanst, Axmann-Krcmar, & Göz, 2004; Peng, Jost-Brinkmann, Yoshida, Miethke, & Lin, 2003; Seikel, King, & Drumright, 2010).

Oropharyngeal Dysphagia

Logemann (1998) defines dysphagia as difficulty moving food from the mouth to the stomach. When discussing dysphagia, Leopold and Kagel (1997) include impairment of pre-oral factors such as state of hunger, texture of the food, ambiance, emotional state, use of utensils, and posture. Impairment of these factors will negatively impact deglutition, particularly in special populations such as individuals with Parkinson's disease, Huntington's disease, and dementia of the Alzheimer's type.

Dysphagia presents across all age groups and a variety of etiologies. Congenital abnormality, cerebrovascular accident (CVA), neurodegenerative disease, traumatic brain injury, and tumor can all impair normal deglutition (Martino et al., 2005; Logemann, 1998; Palmer, Drennan, & Baba, 2000). Impaired deglutition can significantly affect a person's general health and quality of life. Additionally, it can lead to weight loss

because of its impact on nutrition and hydration. Dysphagia presents with significant risks to airway protection during feeding, and may lead to penetration or aspiration of material into the airway (Logemann, 1998; Matsuo & Palmer, 2008; Steele & Cichero, 2014).

Symptoms of dysphagia include coughing or choking while swallowing, food sticking in the throat, gurgly voice, drooling, changes in diet, and recurrent pneumonia. Non-invasive screening procedures are used to identify patients with signs of dysphagia for more in-depth assessment (Logemann, Veis, & Colangeo, 1999; Palmer, Drennan, & Baba, 2000). Recent studies have shown correlation between tongue weakness and dysphagia, suggesting tongue weakness may serve as a diagnostic indicator for swallowing impairment (Maeda & Akagi, 2015; Stierwalt & Youmans, 2006; Yoshida et al., 2006).

Treatment for dysphagia includes a wide variety of strategies. Texture modification of foods and liquids is a common intervention for dysphagia. Thin liquids may be artificially thickened to reduce the risk of aspiration or penetration. Thicker liquids and solid food may require increased lingual strength for propulsion towards the oropharynx (Steele et al., 2015). Postural adjustment during feeding and swallowing is another common intervention for dysphagia. Head turns and chin tucks may help compensate for muscle weakness and decrease the risk of aspiration (Palmer, Drennan, & Baba, 2000). Recent literature has discussed the importance of tongue strength in deglutition. Several range of motion resistance exercises have been studied including the supraglottic swallow, effortful swallow, Mendelsohn maneuver, Masako maneuver, and Shaker exercise. While these exercises are useful for strengthening laryngeal

musculature, they are not intended to improve the oral stage of deglutition. High resistance or isometric exercises target increased muscular strength, as opposed to low resistance exercises that target muscular endurance. Isometric type exercises targeting increased lingual strength have demonstrated improved swallowing function (Clark & Shelton, 2014; Doeltgen, Witte, Gumbley, & Huckabee, 2009; Kraaijenga et al., 2015; Logemann, 2005).

Clark and Shelton (2014) conducted a study examining the influence of high effort sips from small diameter straws on linguapalatal pressure during deglutition. They also examined training effects of effortful swallows preceded by maximum effort lingual presses against the palate compared to effortful swallows in isolation. Both linguapalatal pressure during deglutition and maximum isometric pressure (MIP) of lingual presses against the palate were measured in 40 adult subjects prior to and following 4 weeks of training. Increased linguapalatal pressure and MIP were noted following the training period.

Carroll et at. (2008) conducted a study with 18 adult subjects with head and neck squamous cell carcinoma. Half of the subjects received swallowing therapy prior to chemotherapy radiation, the others received swallowing therapy post-chemotherapy radiation. Videofluoroscopy was used to measure treatment outcomes. Epiglottis inversion and tongue base retraction were found to be significantly better in the subjects which had received swallowing therapy before chemotherapy radiation.

Orofacial Myofunctional Disorders

Orofacial Myofunctional Disorders (OMDs) are conditions or behaviors in oral structure and musculature that negatively impact oral posture and function (de Felício &

Ferreira, 2007; Mason, 2008). OMDs include habitually deviant labial and lingual postures at rest, during deglutition, and during speech. Specific examples of OMDs include tongue thrust, forward tongue posture, lip incompetence, open mouth rest posture, thumb and finger sucking, bruxism, and biting habits involving lips, fingers, tongue and cheeks (de Felício & Ferreira, 2007; Hale et al., 1992; Mason, 2008). OMDs may negatively impact dentition, deglutition, respiration, and articulation (de Felício & Ferreira, 2007; Hanson & Mason, 2003).

OMDs may be diagnosed by a wide variety of professionals. Dentists and orthodontists are typically involved when OMDs interfere with dentition and alignment of the mandible. Physicians may be involved when blocked airway due to allergies or enlarged tonsils or adenoids are areas of concern. Speech-language Pathologists (SLPs) are involved when OMDs affect speech, rest posture, or swallowing. Treatment may involve awareness training of mouth and facial muscles, awareness training of mouth and tongue postures, muscle strength and coordination, improving speech patterns, and swallowing therapy (American Speech-Language and Hearing Association [ASHA], 2015).

Tongue Thrust

Tongue thrust is an OMD characterized by forward tongue posture at rest and anterior thrusting or protrusion beyond the teeth during deglutition (ASHA, 2015; Hanson, 1972; Hanson & Barrett, 1988). Tongue thrust is sometimes referred to as retained infantile swallowing, and has been described as a normal developmental stage (Peng et al., 2003). Children replace an anterior seal between the tongue and dentition with a superior seal between the tongue and the palate (Hanson, 1988). The forward rest

posture associated with tongue thrust exerts pressure against the teeth which may cause dental malocclusions and other dentofacial abnormalities. Incisor protrusion and anterior open bite have been associated with tongue thrust. Forward tongue posture associated with tongue thrust may additionally cause palatal vaulting and speech problems (Mason & Proffit, 1973; Peng, Jost-Brinkman, Yoshida, Chou, & Lin, 2004; Rampp & Pannbacker, 1978; Seikel et al., 2010).

Both the oral preparatory and oral stages of deglutition are negatively impacted by tongue thrust. Anterior protrusion of the tongue may begin before the presentation of the food or liquid. Because mouth breathing is common among individuals with tongue thrust, labial seal is often diminished or absent during deglutition. Bolus formation may also be impacted by anterior tongue protrusion during swallowing (Hanson & Mason, 2003).

In a study that examined normative swallowing data from 387 subjects, Holzer (2011) found that presence of tongue thrust predicted presence of signs and symptoms of OPD. Results of this study indicate relationships between timing, masseter contraction, tongue strength, posture, tongue protrusion, and coughing after deglutition in individuals with tongue thrust and oropharyngeal dysphagia. Holzer concludes that untreated tongue thrust increases later risk of OPD. Evers (2013) conducted a study with 11 subjects with tongue thrust between the ages of 7 and 51. Data from this study were compared to normative data (Holzer) and significant differences were found between tongue, lip, masseter strength, and oropharyngeal transit time. Particular differences were noted in masseter contraction and force. Evers concluded that individuals with tongue thrust exhibit typical indicators of OPD.

Assessment of tongue thrust.

Assessment of tongue thrust includes examination and observation of oral structures at rest and their function, such as tongue protrusion during deglutition (Hanson, 1988; Pierce, 1986). Hanson recommends examining structures before examining function. Lips should be observed for symmetry at rest. Dentition should be examined thoroughly and any deviations or malocclusions noted. Both the upper labial frenulum and lingual frenulum should be examined for abnormality and potential restriction of upper lip and tongue movement should be noted. The tongue should be examined performing both superior-inferior, and lateral movements.

Assessment of function should include observation of the client eating and drinking. Open mouth posture during chewing should be noted. It should also be noted if the client attempts to gather food by tongue thrusting motion in anticipation of deglutition. During drinking it is common for individuals with tongue thrust to exhibit groping movements with their tongue as a cup is brought to the lips. Significant movement of the lips during cup drinking, and licking of the lips afterwards are characteristics of tongue thrust. A client's speech should be observed and any tongue contact with the anterior teeth should be noted for all lingua-alveolar sounds (Hanson, 1988). Protocols are often used to create a systematic approach to assessment. The Idaho State University Tongue Thrust Protocol (ISUTTP) includes a detailed case history as well as a comprehensive examination of oral mechanism and function.

Treatment of tongue thrust.

Orofacial myofunctional therapy (OMT) aims to develop and strengthen both structural and functional deficits such as lip incompetency and tongue thrust during

deglutition. Therapy goals include teaching correct resting tongue posture and increasing muscular control during deglutition. Treatment for tongue thrust can be broken into three phases: training, strengthening, and maintaining muscle patterns (Hanson, 1988; Hanson & Mason, 2003). Therapy generally includes strengthening exercises that target muscle tone of the tongue, lips, and face. Elimination of negative oral habits as well as habituating proper patterns of chewing and deglutition are also targeted through OMT (Benkert, 1997).

Pierce (1993) developed the exercise program *Swallow Right* for tongue thrust correction, which targets both resting posture and swallowing patterns. *Swallow Right* teaches correct tongue position by emphasizing placement of the tongue tip on the "spot" posterior to the incisal papilla. Proper swallowing patterns are taught using a variety of exercises. One such exercise is the slurp swallow. This exercise targets proper tongue placement during deglutition and emphasizes avoiding lingual contact with the teeth throughout the process.

Efficacy of tongue thrust treatment.

Several studies have examined the efficacy of tongue thrust therapy. Christensen and Hanson (1981) conducted a study examining both the effectiveness of therapy for correcting tongue thrust, and consequent correction of frontal lisp. Subjects of this study included 10 kindergarteners that were divided into two treatment groups. One group received only articulation therapy for 14 weeks, while the other group received therapy targeting tongue thrust for six weeks and alternating articulation therapy and tongue thrust therapy for eight weeks. The authors found that subjects in the group receiving tongue thrust therapy made significantly more progress in remediating tongue thrust

patterns. Remediation of tongue thrust was not noted for the group receiving only articulation therapy.

Adrianopoulos and Hanson (1987) conducted a study examining tongue thrust therapy and the stability of orthodontic overjet correction in individuals with class II malocclusions. A therapy group consisted of 17 subjects who had received therapy for tongue thrust. Another 17 subjects were included in a non-therapy group, who had worn orthodontic appliances. At the time of the study 17.6% of the therapy subjects and 70.6% of the non-therapy subjects were currently exhibiting tongue thrust. Analysis of the results indicated mean overjet relapse to be greater in the non-therapy group, with a significant inverse relationship between tongue thrust therapy and overjet relapse.

Smithpeter and Covell (2010) conducted a study examining the effectiveness of OMT on retention of anterior open bite with orthodontic treatment. In this study, the experimental group of 27 subjects received both OMT and orthodontic treatment. The control group included 49 subjects with history of orthodontic treatment and relapse of anterior open bite. Analysis of the results indicated a significantly lower mean relapse of overbite in the experimental group compared with the control group, indicating that OMT and orthodontic treatment were more effective than orthodontic treatment alone.

Alexandria Buchanan (2007) conducted a study to determine whether the slurp swallow exercise increases tongue strength in individuals with tongue thrust. Buchanan's study included four subjects between the ages of 8 and 12 exhibiting signs of tongue thrust. Subjects received ten treatment sessions of intensive practice consisting of 50 repetitions of the slurp swallow exercise. Baseline and treatment data for tongue strength were collected using the Iowa Oral Performance Instrument (IOPI) which has been

widely used to obtain normative data for tongue strength and function (Robbins, Levine, Wood, Roecker, & Luschei, 1995). Increased tongue strength was noted for three of the four subjects. The author cited motivation as a likely factor influencing the outcomes of the study.

Durrant (2013) replicated Buchanan's study (2011) with an additional four subjects between the ages of 6 and 10 exhibiting signs of tongue thrust. Increased tongue strength was noted in all four subjects, supporting the finding of Buchanan's study. Torrey (2013) also replicated Buchanan's study with four subjects ages 7-33. Three out of four subjects demonstrated increases in tongue strength, further supporting previous findings. Krause (2014) also replicated Buchanan's study with a single subject and similar results.

The purpose of this study is to replicate and expand upon these previous studies by adding to the existing evidence base. This study seeks to further investigate the efficacy of the slurp swallow exercise in increasing tongue strength in individuals with tongue thrust. Increasing the the overall sample size of individuals exhibiting increased tongue strength as result of this exercise will help clarify its treatment efficacy and inform future intervention for individuals with tongue thrust.

Chapter 2 – Methodology

The purpose of this study is to replicate and expand upon the previous studies conducted by Buchannan (2007), Durrant (2013), Torrey (2013), and Krause (2014) to ascertain whether a treatment regimen using the slurp swallow exercise will increase measures of tongue strength in individuals with tongue thrust. This study specifically examines whether 10 intensive treatment sessions will yield increased measures of tongue tip and dorsum strength. Furthermore, this study examines the aggregate data of the previous studies with this current study in a group analysis.

Participants

Inclusion criteria for this study include a diagnosis of tongue thrust, and no prior therapy or treatment for tongue thrust or OPD. Subjects were screened using the ISUTTP to confirm the presence of tongue thrust. Additional inclusion criteria include visible tongue protrusion during swallowing, and one of the following additional indicators of tongue thrust: groping movements of labial musculature during cup drinking, anterior spillage of food or liquid during deglutition, excessive residue in the oral cavity following deglutition, or lack of masseter contraction.

Subject 1.

Subject 1 was a 23-year-old female with typical cognitive development. The subject's orthodontist suspected her as having tongue thrust, but she never received therapy. The ISUTTP history indicated a habit of mouth breathing confirmed through clinician observation. The oral mechanism examination revealed an open bite and overt tongue protrusion beyond dentition during swallowing trials with liquid and solid boluses. Groping movements with the lips were noted during cup drinking.

Subject 2.

Subject 2 was a 21-year-old male with typical cognitive development. The subject reported a habit of forward tongue rest posture. The subject's orthodontist suspected him as having tongue thrust, but he did not receive therapy. The ISUTTP history indicated a family history of tongue thrust, as well as family history of dental problems and mouth breathing. The history also indicated a childhood habit of digit sucking as well as an ongoing habit of mouth breathing. The oral mechanism examination revealed a Class II malocclusion and anterior bite and overjet. During liquid swallowing trials overt tongue protrusion beyond dentition was noted along with spillage. Excessive residue was noted during solid bolus swallowing trials.

Subject 3.

Subject 3 was a 19-year-old female with typical cognitive development. The subject reported her mother having suspected her as having tongue thrust, but she never received therapy. The ISUTTP history indicated a family history of tongue thrust. Additionally, the protocol indicated a childhood habit of digit sucking. Mouth breathing was also indicated and observed through clinician observation. The oral mechanism examination revealed anterior bite and overjet along with palatal vaulting. During swallowing trials weak masseter contraction was noted and overt tongue protrusion beyond dentition was noted for both liquid and solid boluses.

Subject 4.

Subject 4 was a 22-year old female with typical cognitive development. The subject reported having a forward tongue resting posture. The ISUTTP indicated childhood habits of cheek biting and an ongoing habit of mouth breathing. Lip movement

was noted during a dry swallow trial. The oral mechanism examination revealed a Class II malocclusion. During liquid bolus swallowing trials the subject exhibited difficulty with water retention on the tongue with an open mouth. Overt tongue protrusion beyond dentition was noted. Poor solid bolus cohesion was noted after mastication and excessive residue was noted following deglutition.

Instrumentation

ISUTTP.

The ISUTTP was used to assess subjects for the presence of tongue thrust (see Appendix A). This protocol includes a detailed case history and a comprehensive examination of oral mechanism and function.

The case history includes an inventory of early feeding behaviors, history of negative oral habits such as digit sucking and prolonged pacifier or bottle use, and family history of swallowing. Other behaviors commonly indicative of or related to tongue thrust are also included, such as mouth breathing, allergies, structural and anatomic issues, and medical history.

Following the case history, the oral mechanism was examined at rest. Symmetry and tone of facial features were observed and noted. Resting posture of both both the lips and tongue were examined in relation to dentition. Dentition was examined for malocclusion and signs of open bite, and the palate was examined for presence of vaulting, velar function, and signs of submucosa cleft. The tongue was examined to determine potential size abnormality, and evaluate the frenulum for adequate length. Respiratory support was evaluated by clinician observation.

The ISUTTP concludes with an assessment of swallowing function. Subjects were observed swallowing both thin liquid and solid boluses with three trails of each consistency. Masseter contraction, lip tension, bolus formation, and overt signs of tongue thrust were noted.

IOPI.

The Iowa Oral Performance Instrument (Breakthrough Inc., Oakdale, IA; Model 1.5) is a digital manometer commonly used to quantify lingual strength. This device has been used in various studies to obtain normative data for tongue strength and function (Robbins et al., 1995). The IOPI measures lingual force exerted against a small air-filled bulb situated between the tongue and palate. A digital reading of pressure is provided in kilopascals (kPa). Subjects are instructed to push against the bulb as hard as they can. Proper placement is monitored to ensure continuity between subjects and calibration is performed prior to each use.

Procedures

A description of the study and research procedures, and an informed consent letter (see Appendix B) were distributed to participants prior to the initiation of the study. Signed consent letters were collected prior to the first meeting with study subjects. During the first meeting with subjects, information in the consent form was discussed and questions taken from participants. The ISUTTP was administered to subjects to confirm the presence of tongue thrust. Confirmation of tongue thrust required both observation of tongue protrusion during swallowing and at least of of the following: excessive labial musculature, spillage of food or liquid during, lack of masseter contraction or significant residue in mouth after swallow.

Baseline.

Subjects were familiarized with the IOPI and practice using the bulb while it is disconnected from the device. Once subject understanding of the device and measurement task was evident, the bulb was connected to the device and three separate maximum effort measures of lingual force are taken with the bulb first placed on the tongue tip, and then on the dorsum of the tongue.

Control measures were taken along with baseline data. Lip strength, measured as labial force by the IOPI, and maximum phonation time for the /ɑ/ vowel were used as control measures as they will presumably not be affected by lingual exercise. Baseline data were taken over the course of three separate sessions.

Treatment.

Prior to each session of treatment, measures of lingual pressure were taken using the IOPI, with three measurements each for both tongue tip, and tongue dorsum. Control measures were also taken for labial pressure and maximum phonation time for the /ɑ/ vowel.

The treatment proper consisted of 50 repetitions of the slurp swallow exercise from the *Swallow Right* program (Pierce, 1993). Clinician feedback was provided for each repetition of the exercise to ensure continuity and proper execution. The directions for the slurp swallow exercise as described in the *Swallow Right* program are as follows:

1. Put your tongue tip up on the spot.
2. Bite your back teeth together. They should fit together like a puzzle.
3. Keep your lips wide apart, like a clown smiling.
4. Slurp!

5. Swallow.

"The spot" described in the *Swallow Right* program refers to the alveolar ridge, and is

taught to subjects. A small amount of water was sprayed onto the subject's tongues between repetitions of the slurp swallow exercise. Following the repetitions of the exercise, measures of lingual pressure for tongue tip and tongue dorsum were taken again, along with the control measures.

Each subject participated in a total of 10 treatment sessions, twice a week over five weeks. On non-treatment days subjects independently completed 50 repetitions of the slurp swallow exercise as part of a home treatment program. Subjects were given a form each week to track compliance. Four weeks' post-treatment retention data was taken over three sessions.

Design and Analysis

This study utilizes a quasi-multiple baseline across behaviors model, replicated across subjects. The independent variable is participation in ten intensive treatment sessions utilizing 50 repetitions of the slurp swallow exercise. The dependent variables are the measures of lingual force across baseline and treatment sessions. Differences between these measurements were compared against the control measures of labial force and maximum phonation time for the /ɑ/ vowel. Treatment effects were determined by comparison of these data.

Data from each treatment session was plotted on line graphs for each subject. The three repetitions of each lingual pressure measurement were averaged for each data point. Each variable's statistical significance was determined for each subject using the two

standard deviation band method (Nourbakhsh & Ottenbacher, 1994). The standard deviation of the baseline data for each subject was calculated using nine baseline trials for each measure of lingual pressure. Bands were created at two standard deviations above and below the mean. Treatment points falling outside of these bands suggest a statistically significant treatment effect.

Chapter 3 – Results

The purpose of this study is to replicate and expand upon the previous studies conducted by Buchannan (2007), Durrant (2013), Torrey (2013), and Krause (2014) to ascertain whether a treatment regimen using the slurp swallow exercise will increase measures of tongue strength in individuals with tongue thrust. Baseline measures of tongue tip and dorsum strength were collected using the IOPI prior to treatment for each subject. Control measures of lip strength were also collected with the IOPI along with maximum phonation time of a sustained /ɑ/ vowel. All measures were taken over three sessions prior to initiation of treatment. Nine trials were taken for each baseline and control measure and averaged for each data point. All subjects demonstrated significant treatment gains in measures of tongue tip strength and tongue dorsum strength over the course of treatment as shown in Table 1.

Table 1

Baseline and Retention IOPI Measurements for Tongue Tip and Dorsum Strength (force in kPa)

	Tongue Tip		Tongue Dorsum	
Subjects	Baseline	Retention	Baseline	Retention
1	31.89	38	27	34.33
2	36.33	49.89	43.78	58.56
3	33.44	39.89	30.89	37.11
4	28	36.78	29.33	42.67

Note. Baseline and retention data points represent the average of nine maximum effort trials. Retention data was collected four weeks' post-treatment.

Subject 1

Subject 1 participated in 10 treatment sessions, twice a week over five weeks and reported 80% compliance with the home treatment program. Baseline tongue tip strength was measured at 31.89 kPa, and baseline tongue dorsum strength was measured at 27 kPa.

Over the intervention period, measures of tongue tip and dorsum strength increased compared to baseline (see Table 2). Trend lines in Figures 1 and 2 show positive increases in tongue tip strength pre- and post-treatment with gains retained four weeks post intervention. Both pre- and post-treatment tongue tip strength measures fall above the two standard deviation band following the fifth treatment session.

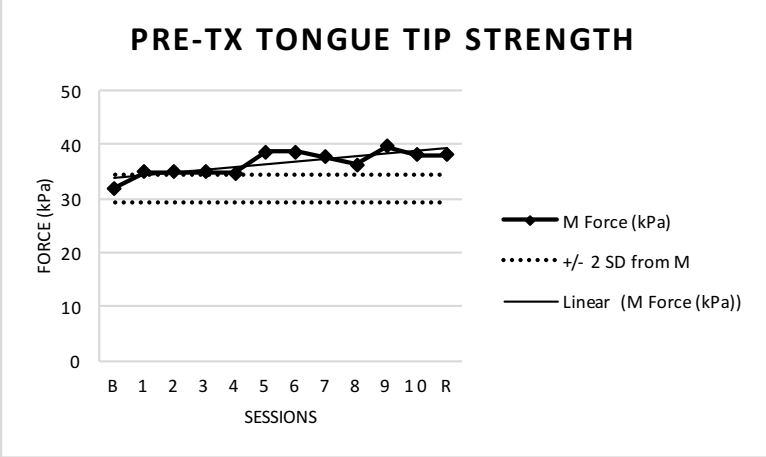

Figure 1. Subject 1 IOPI Measurements for Pre-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

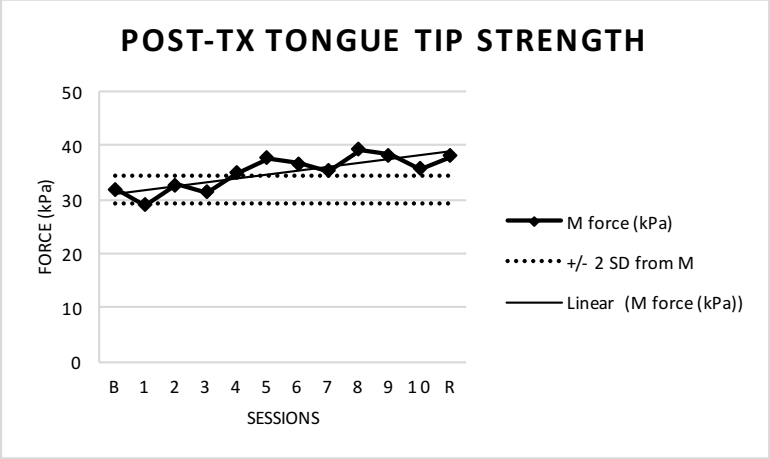

Figure 2. Subject 1 IOPI Measurements for Post-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

Table 2

Subject 1 IOPI Measurements for Tongue Tip and Dorsum Strength (force in kPa)

	Pre-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	30	31.67	34	31.89	28	28	25.33	27
1	36	35	34	35	25	27	30	27.33
2	31	40	34	35	29	31	28	29.33
3	37	34	34	35	28	25	28	27
4	32	35	37	34.67	29	30	26	28.33
5	34	44	38	38.67	29	34	32	31.67
6	37	40	39	38.67	31	28	29	29.33
7	39	37	37	37.67	29	30	32	30.33
8	35	36	38	36.33	34	35	30	33
9	44	39	36	39.67	30	35	34	33
10	39	36	39	38	37	34	31	34
R	37.33	37.33	39.33	38	33.33	34.67	35	34.33

	Post-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	30	31.67	34	31.89	28	28	25.33	27
1	27	30	30	29	27	24	24	25
2	33	31	34	32.67	25	32	28	28.33
3	31	31	32	31.33	25	27	21	24.33
4	36	34	35	35	31	26	26	27.67
5	35	38	40	37.67	36	30	32	32.67
6	35	40	35	36.67	32	33	35	33.33
7	39	32	35	35.33	28	33	30	30.33
8	36	40	42	39.33	32	33	30	31.67
9	38	40	37	38.33	31	33	28	30.67
10	33	37	37	35.67	35	33	32	33.33
R	37.33	37.33	39.33	38	33.33	34.67	35	34.33

Note. Tx = 50 repetitions of the slurp-swallow exercise. IOPI measurements were taken pre- and post-treatment each session. B = Baseline. R = Retention.

Measures of tongue dorsum strength also increased compared to baseline across the intervention period. Trend lines in Figures 3 and 4 show positive increases in tongue dorsum strength pre- and post-treatment. Measures of pre- and post-treatment tongue dorsum strength fall above the two standard deviation band at the end of intervention with gains retained four weeks post intervention.

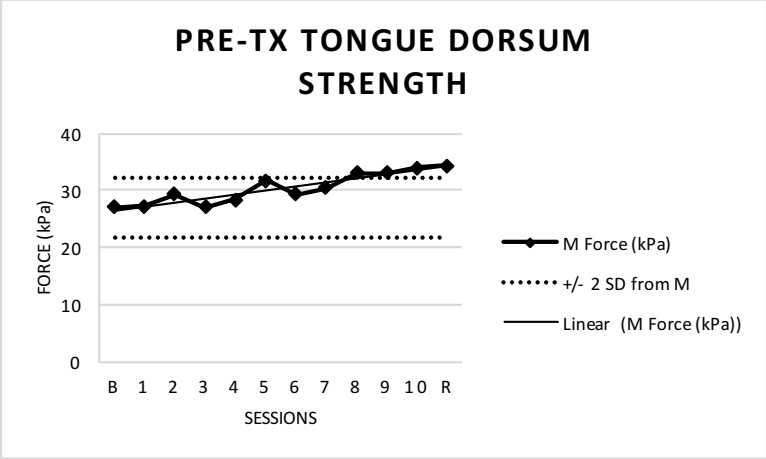

Figure 3. Subject 1 IOPI Measurements for Pre-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

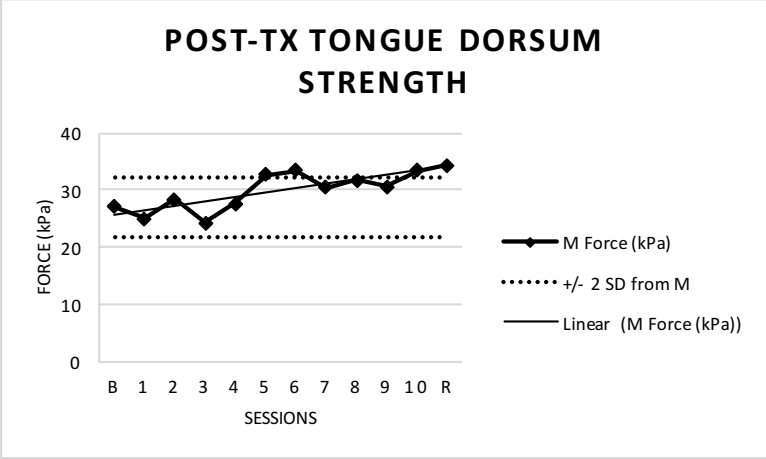

Figure 4. Subject 1 IOPI Measurements for Post-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

Figures 5 and 6 show measurements for lip strength over the course of intervention. Both pre- and post-treatment measures show all measures falling within the two standard deviation band. Additionally, Figures 7 and 8 show measurements for maximum phonation time of the /ɑ/ vowel over treatment. All measures both pre-and post-treatment fall within the two standard deviation band, indicating that the demonstrated treatments effects are attributable to the intervention and not extraneous variables.

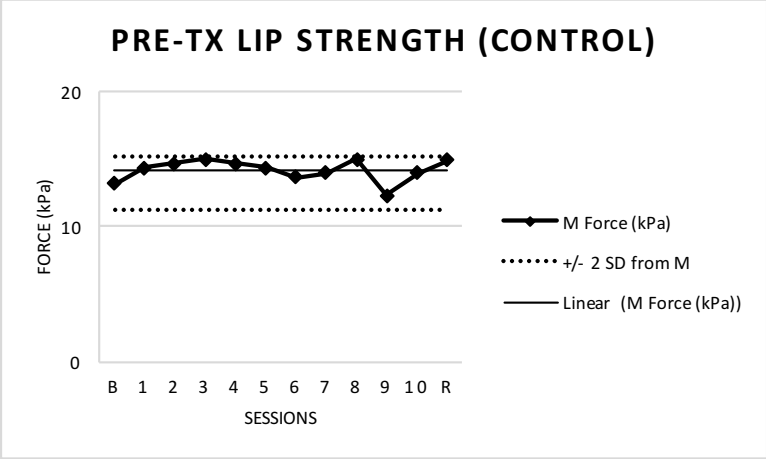

Figure 5. Subject 1 IOPI Measurements for Pre-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

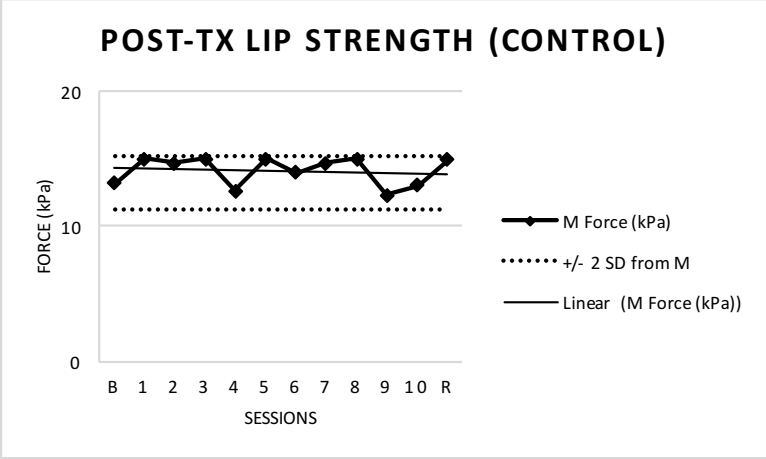

Figure 6. Subject 1 IOPI Measurements for Post-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

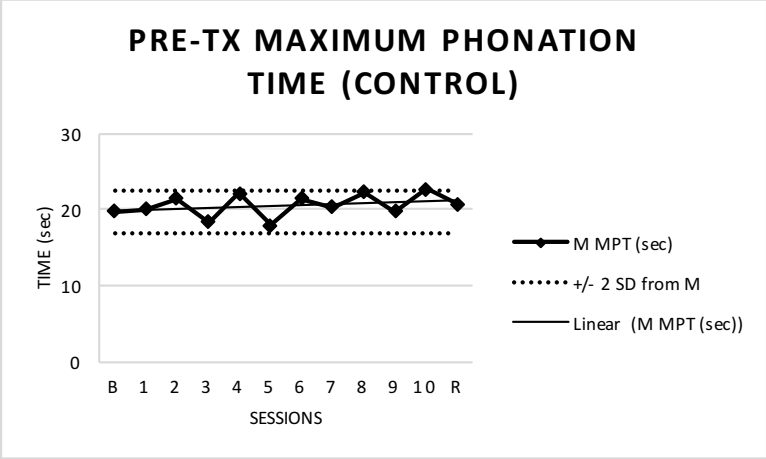

Figure 7. Subject 1 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

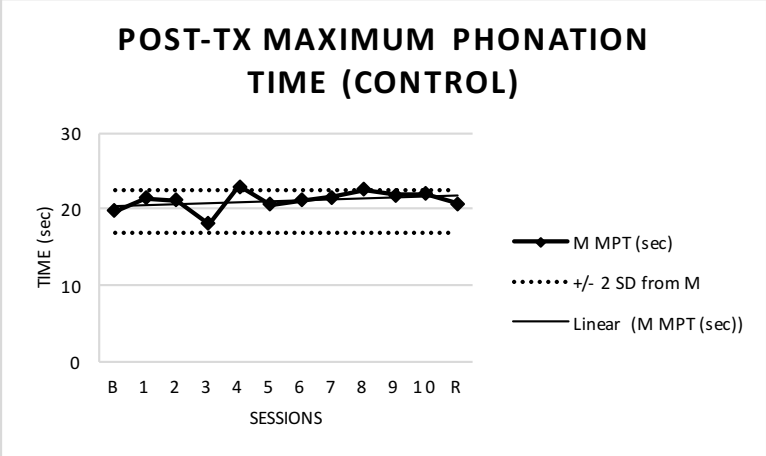

Figure 8. Subject 1 Measurements for Post-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

Subject 2

Subject 2 participated in 10 treatment sessions, twice a week over five weeks and reported 80% compliance with the home treatment program. Baseline tongue tip strength was measured at 36.33 kPa, and baseline tongue dorsum strength was measured at 43.78 kPa.

Over the course of intervention, measures of tongue tip strength increased compared to baseline (see Table 3). Figures 9 and 10 show positive trend lines for tongue tip strength pre- and post-treatment. Measures of both pre- and post-treatment tongue tip strength fall above the two standard deviation band after three sessions, demonstrating significant treatment effect with gains retained four weeks post intervention.

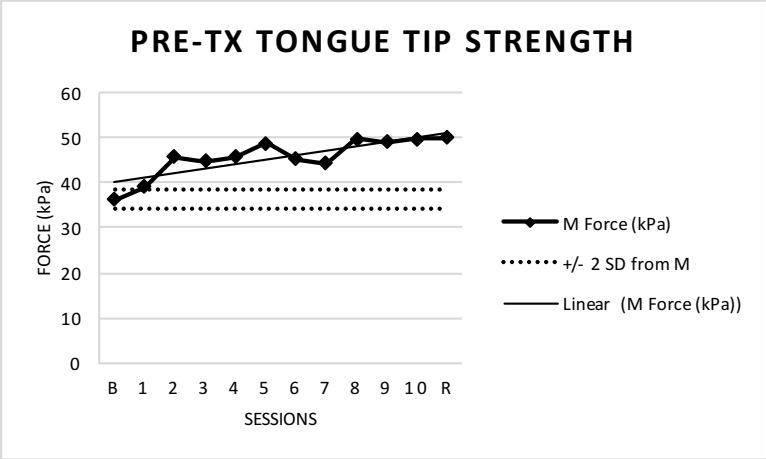

Figure 9. Subject 2 IOPI Measurements for Pre-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

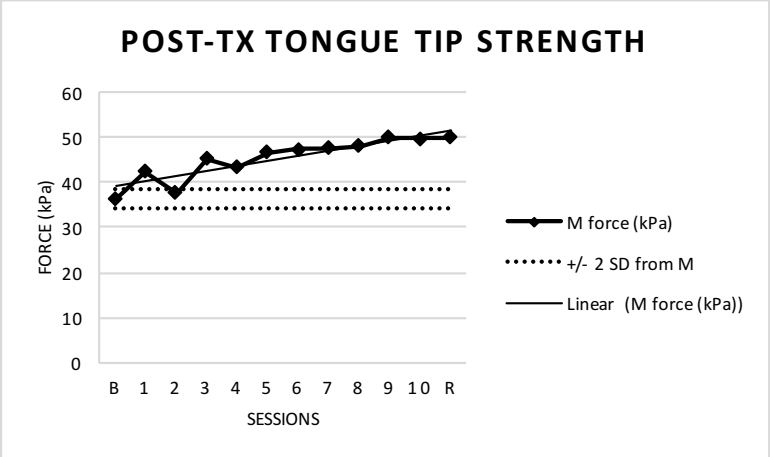

Figure 10. Subject 2 IOPI Measurements for Post-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

Table 3

Subject 2 IOPI Measurements for Tongue Tip and Dorsum Strength (force in kPa)

	Pre-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	36	35	38	36.33	44	43	43.33	43.78
1	37	44	36	39	47	50	39	45.33
2	47	48	42	45.67	50	48	47	48.33
3	46	45	43	44.67	49	52	54	51.67
4	43	45	49	45.67	42	50	48	46.67
5	48	51	47	48.67	47	49	52	49.33
6	46	42	48	45.33	52	49	53	51.33
7	47	35	51	44.33	55	53	51	53
8	49	47	53	49.67	58	60	53	57
9	50	50	47	49	57	59	60	58.67
10	52	52	45	49.67	62	64	64	63.33
R	50.33	49.67	49.67	49.89	61	59	55.67	58.56
	Post-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	36	35	38	36.33	44	43	43.33	43.78
1	44	42	41	42.33	46	45	43	44.67
2	41	35	37	37.67	43	47	38	42.67
3	46	48	42	45.33	54	56	51	53.67
4	47	40	43	43.33	49	49	49	49
5	47	46	47	46.67	52	54	54	53.33
6	48	48	46	47.33	47	54	57	52.67
7	48	48	47	47.67	54	57	56	55.67
8	47	49	48	48	59	61	58	59.33
9	48	52	50	50	60	63	61	61.33
10	51	55	43	49.67	58	63	58	59.67
R	50.33	49.67	49.67	49.89	61	59	55.67	58.56

Note. Tx = 50 repetitions of the slurp-swallow exercise. IOPI measurements were taken pre- and post-treatment each session. B = Baseline. R = Retention.

Measures of tongue dorsum strength showed similar increases compared to baseline over the course of intervention. Trend lines in Figures 11 and 12 show positive increases in tongue dorsum strength pre- and post-treatment. Measures of both pre- and post-treatment tongue dorsum strength fall above the two standard deviation band midway through intervention demonstrating significant treatment effect.

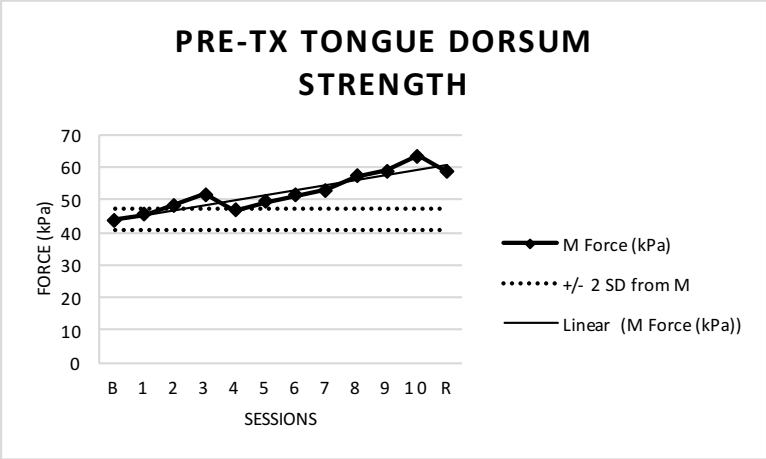

Figure 11. Subject 2 IOPI Measurements for Pre-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

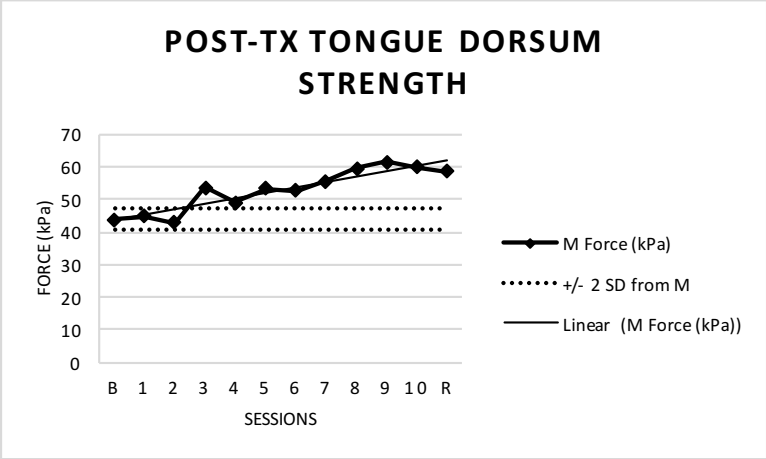

Figure 12. Subject 2 IOPI Measurements for Post-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

Measurements of lip strength over the course of intervention are shown in Figures 13 and 14. Both pre- and post-treatment measures show all measures falling within the two standard deviation band. Additionally, Figures 15 and 16 show measurements for maximum phonation time of the /ɑ/ vowel over the course of treatment. All measures both pre-and post-treatment fall within the two standard deviation band indicating the demonstrated treatments effects are attributable to intervention.

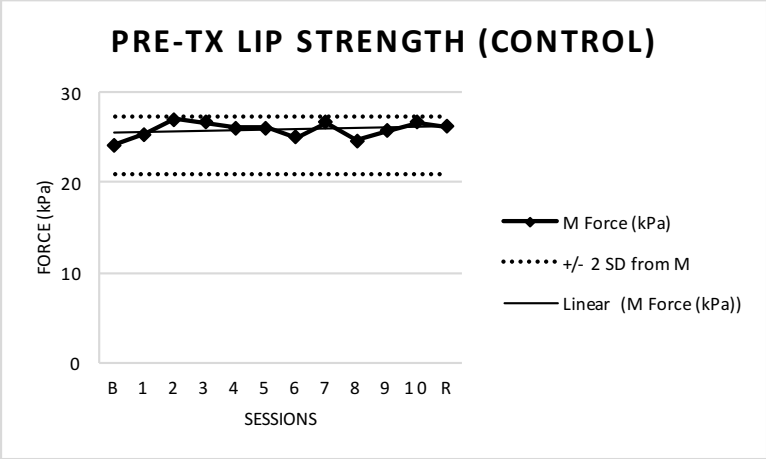

Figure 13. Subject 2 IOPI Measurements for Pre-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

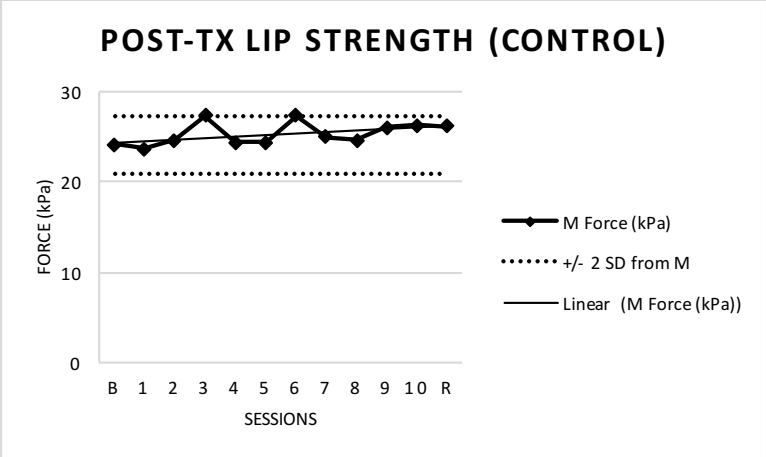

Figure 14. Subject 2 IOPI Measurements for Post-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

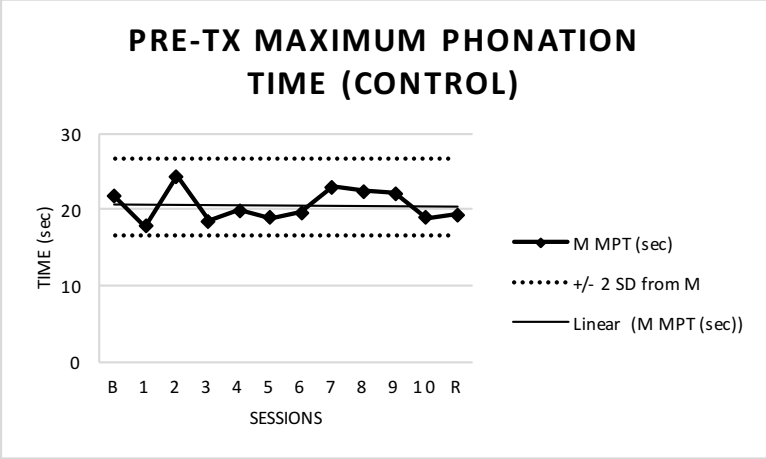

Figure 15. Subject 2 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

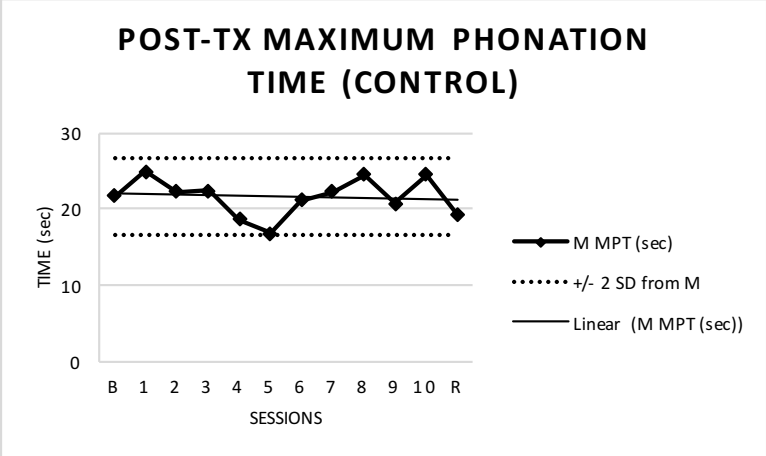

Figure 16. Subject 2 Measurements for Post-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

Subject 3

Subject 3 participated in 10 treatment sessions, twice a week over five weeks and reported 60% compliance with the home treatment program. Baseline tongue tip strength was measured at 33.44 kPa, and baseline tongue dorsum strength was measured at 30.88 kPa.

Over the course of treatment, measures of tongue tip and dorsum strength showed increases compared to baseline (see Table 4). Trend lines in Figures 17 and 18 show positive increases in tongue tip strength pre- and post-treatment. Measures for both pre- and post-treatment tongue tip strength fall above the two standard deviation band early during intervention with gains retained four weeks' post-intervention.

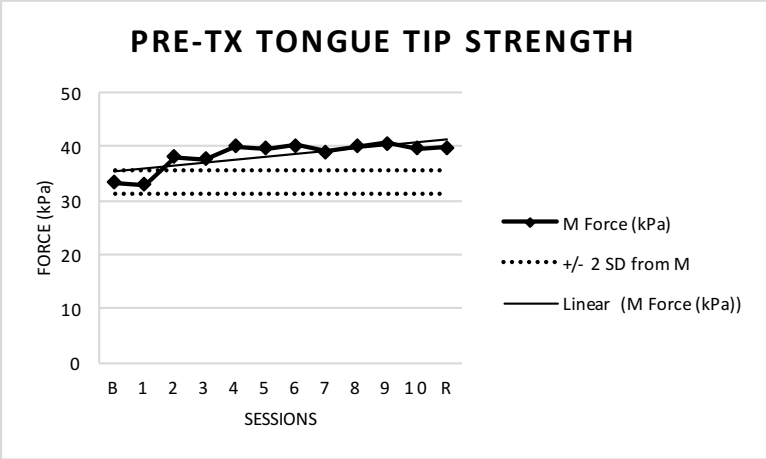

Figure 17. Subject 3 IOPI Measurements for Pre-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

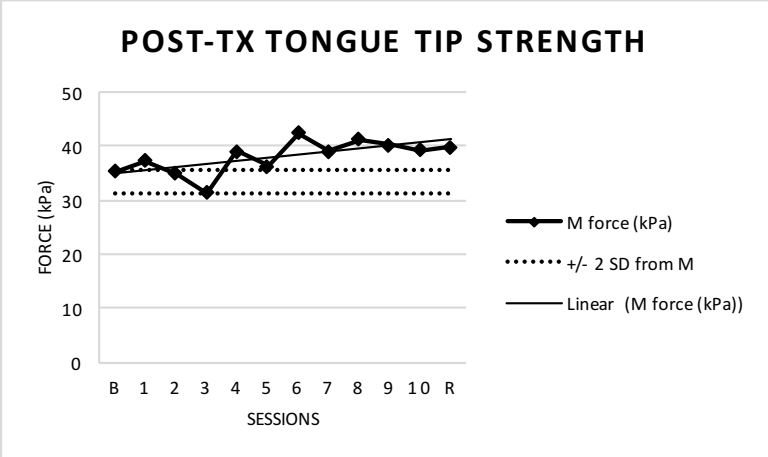

Figure 18. Subject 3 IOPI Measurements for Post-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

Table 4

Subject 3 IOPI Measurements for Tongue Tip and Dorsum Strength (force in kPa)

	Pre-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	32	34.67	33.67	33.44	30	31.33	31.33	30.89
1	37	33	29	33	34	31	25	30
2	37	37	40	38	35	40	35	36.67
3	41	38	34	37.67	36	33	33	34
4	41	43	36	40	34	38	40	37.33
5	38	41	40	39.67	38	38	35	37
6	44	40	37	40.33	38	31	32	33.67
7	44	38	35	39	36	35	38	36.33
8	44	38	38	40	38	34	32	34.67
9	44	39	39	40.67	41	40	35	38.67
10	40	38	41	39.67	39	38	30	35.67
R	40	40	39.67	39.89	37	36.33	36.33	37.11
	Post-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	32	34.67	33.67	33.44	30	31.33	31.33	30.89
1	42	37	33	37.33	42	27	33	34
2	33	37	35	35	37	31	30	32.67
3	30	34	30	31.33	33	30	27	30
4	41	38	38	39	38	33	28	33
5	34	35	40	36.33	38	34	37	36.33
6	44	43	40	42.33	42	37	37	38.67
7	38	37	42	39	38	37	37	37.33
8	44	38	42	41.33	40	35	34	36.33
9	43	40	38	40.33	38	32	37	35.67
10	43	37	38	39.33	34	38	38	36.67
R	40	40	39.67	39.89	37	36.33	36.33	37.11

Note. Tx = 50 repetitions of the slurp-swallow exercise. IOPI measurements were taken pre- and post-treatment each session. B = Baseline. R = Retention.

Measures of tongue dorsum strength showed similar increases compared to baseline over the course of treatment. Trend lines in Figures 19 and 20 show positive increases in tongue dorsum strength pre- and post-treatment. Measures of both pre- and post-treatment tongue dorsum strength fall above the two standard deviation band towards the end of intervention with gains retained four weeks' post-intervention.

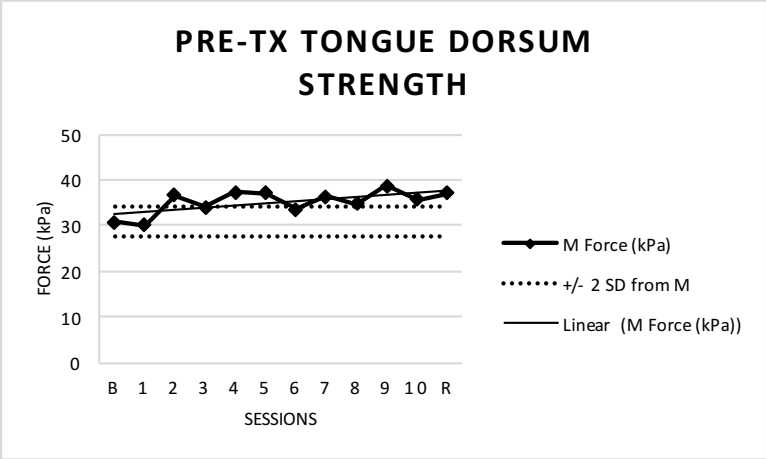

Figure 19. Subject 3 IOPI Measurements for Pre-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

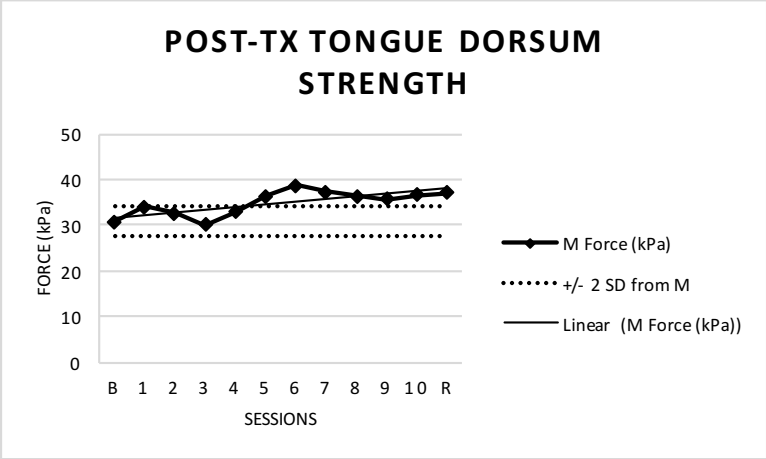

Figure 20. Subject 3 IOPI Measurements for Post-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

Measurements of lip strength over the course of treatment are shown in Figures 21 and 22. Both pre- and post-treatment measures show all measures falling within the two standard deviation band. Additionally, Figures 23 and 24 show measurements for maximum phonation time of the /ɑ/ vowel over the course of treatment. All measures both pre-and post-treatment fall within the two standard deviation band, indicating that demonstrated treatments effects are attributable to intervention.

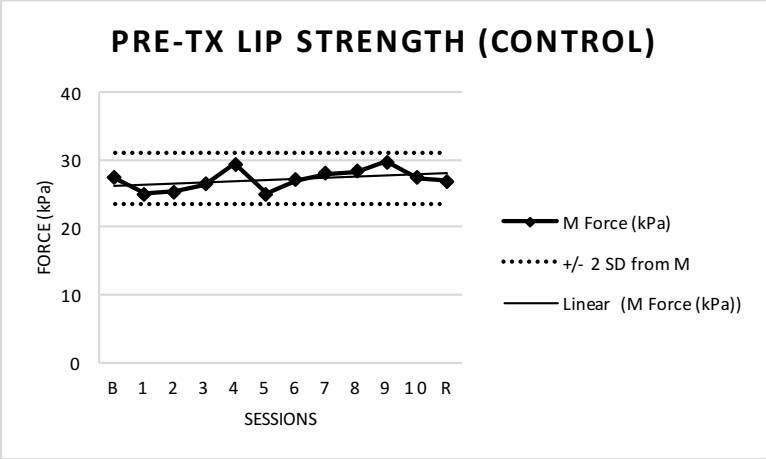

Figure 21. Subject 3 IOPI Measurements for Pre-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

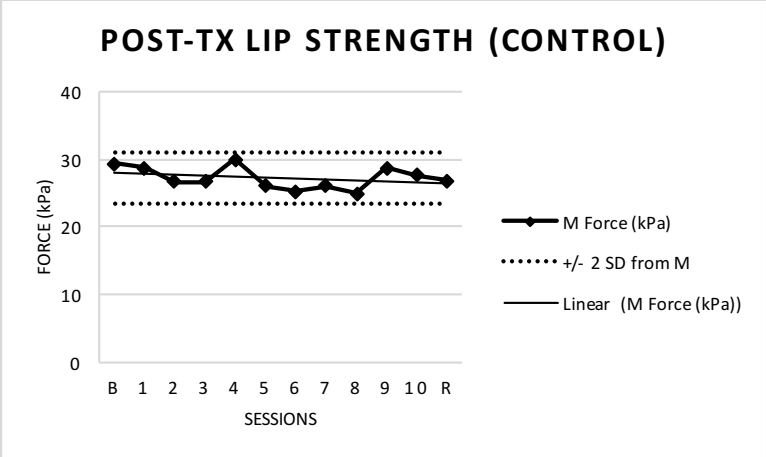

Figure 22. Subject 3 IOPI Measurements for Post-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

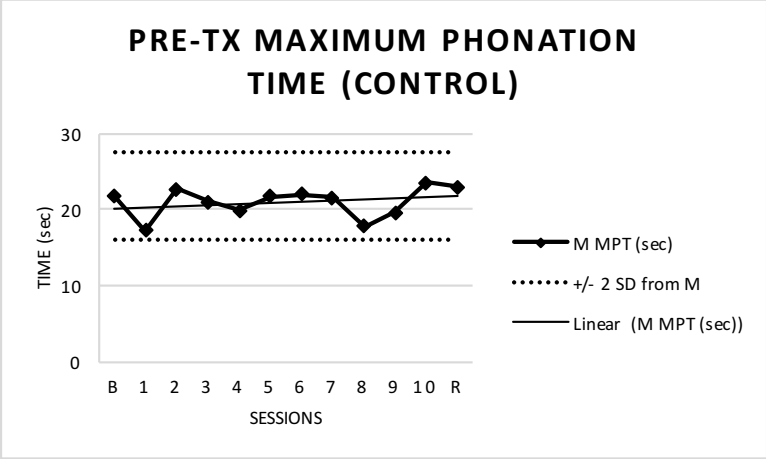

Figure 23. Subject 3 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

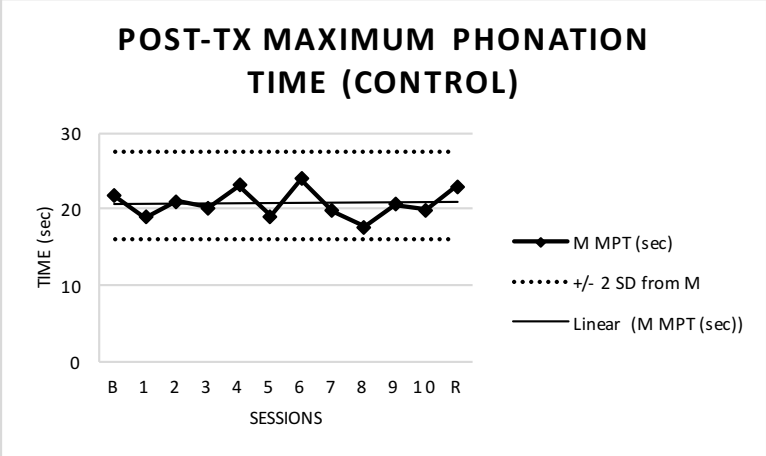

Figure 24. Subject 3 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

Subject 4

Subject 4 participated in 10 treatment sessions, over six weeks and reported 85% compliance with the home treatment program. Baseline tongue tip strength was measured at 28 kPa, and baseline tongue dorsum strength was measured at 29.33 kPa.

Over the course of intervention, measures of tongue tip and dorsum strength showed increases compared to baseline (see Table 5). Trend lines in Figures 25 and 26

show positive increases in tongue tip strength pre- and post-treatment. Measures for both pre- and post-treatment tongue tip strength fall above the two standard deviation band early during intervention with gains retained four weeks' post-intervention.

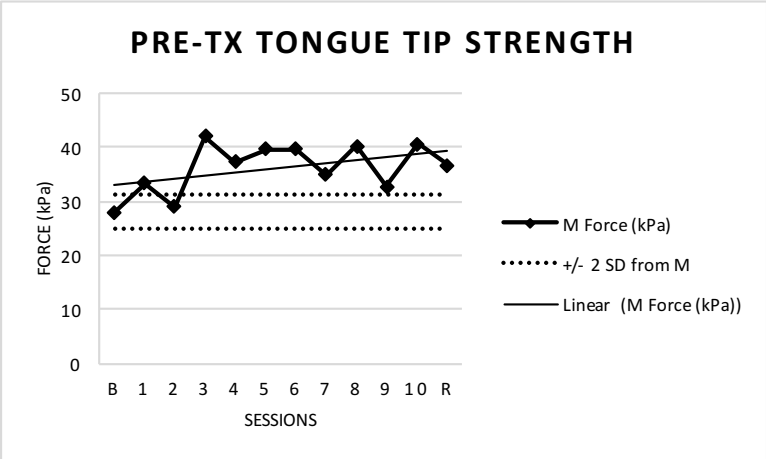

Figure 25. Subject 4 IOPI Measurements for Pre-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

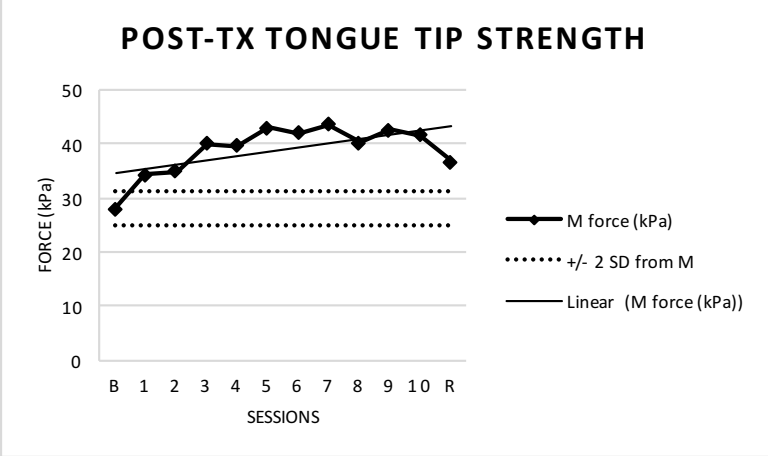

Figure 26. Subject 4 IOPI Measurements for Post-Tx Tongue Tip Strength (force in kPa). B = Baseline; R = Retention.

Table 5

Subject 4 IOPI Measurements for Tongue Tip and Dorsum Strength (force in kPa)

	Pre-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	25	28.67	30.33	28	30	26	32	29.33
1	31	34	35	33.33	39	26	31	32
2	32	26	29	29	32	34	33	33
3	46	38	42	42	35	37	30	34
4	38	39	35	37.33	45	35	33	37.67
5	43	37	39	39.67	49	45	40	44.67
6	48	36	35	39.67	54	47	43	48
7	43	30	32	35	47	49	48	48
8	38	53	30	40.33	46	46	47	46.33
9	34	33	31	32.67	50	46	46	47.33
10	44	38	40	40.67	54	47	48	49.67
R	36.33	37.33	36.67	36.78	40.33	43.33	44.33	42.67
	Post-Tx Trials							
	Tongue Tip				Tongue Dorsum			
Session	1	2	3	M	1	2	3	M
B	25	28.67	30.33	28	30	26	32	29.33
1	42	31	30	34.33	33	31	30	31.33
2	37	32	36	35	30	37	39	35.33
3	48	35	37	40	48	51	47	48.67
4	44	39	36	39.67	51	46	39	45.33
5	43	45	41	43	53	45	51	49.67
6	38	44	44	42	54	48	48	50
7	44	42	45	43.67	55	41	48	48
8	44	35	42	40.33	44	49	44	45.67
9	41	43	44	42.67	44	42	51	45.67
10	38	44	43	41.67	49	46	45	46.67
R	36.33	37.33	36.67	36.78	40.33	43.33	44.33	42.67

Note. Tx = 50 repetitions of the slurp-swallow exercise. IOPI measurements were taken pre- and post-treatment each session. B = Baseline. R = Retention.

Measures of tongue dorsum strength showed similar increases compared to baseline over the course of treatment. Trend lines in Figures 27 and 28 show positive increases in tongue dorsum strength pre- and post-treatment. Measures of both pre- and post-treatment tongue dorsum strength fall above the two standard deviation band midway through intervention with gains retained four weeks' post-intervention.

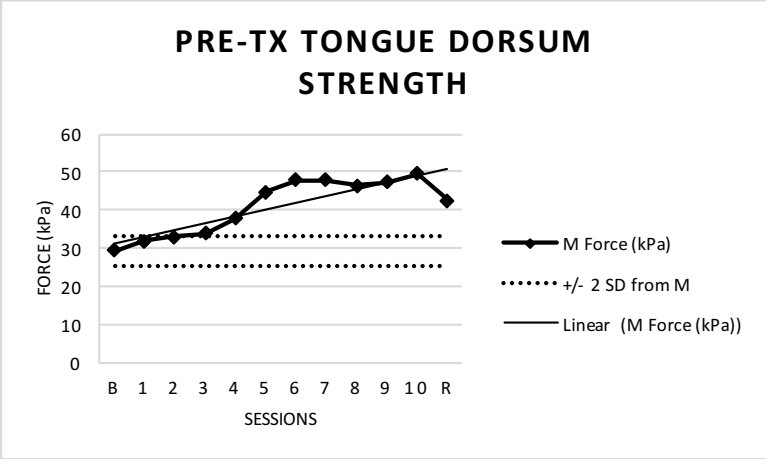

Figure 27. Subject 4 IOPI Measurements for Pre-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

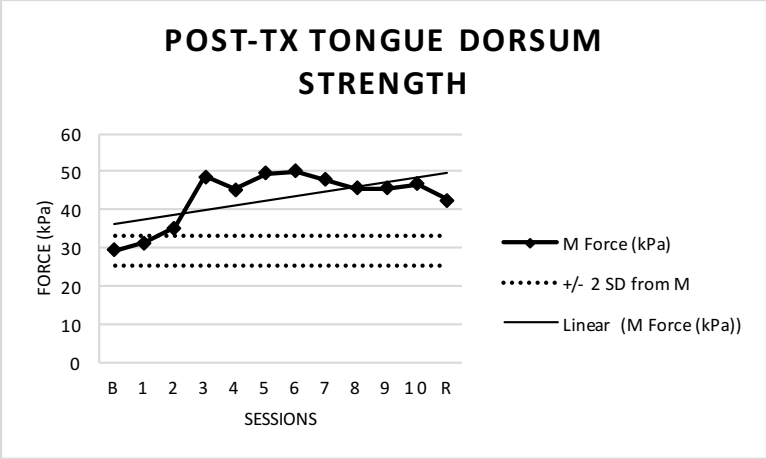

Figure 28. Subject 4 IOPI Measurements for Post-Tx Tongue Dorsum Strength (force in kPa). B = Baseline; R = Retention.

Measurements of lip strength over the course of treatment are shown in Figures 29 and 30. Both pre- and post-treatment measures show all measures falling within the two standard deviation band. Additionally, Figures 31 and 32 show measurements for maximum phonation time of the /ɑ/ vowel over the course of treatment. All measures both pre-and post-treatment fall within the two standard deviation band, indicating that demonstrated treatments effects are attributable to intervention.

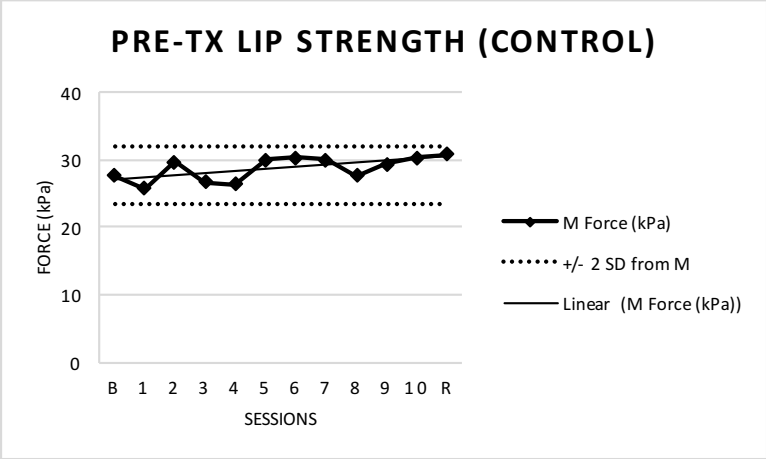

Figure 29. Subject 4 IOPI Measurements for Pre-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

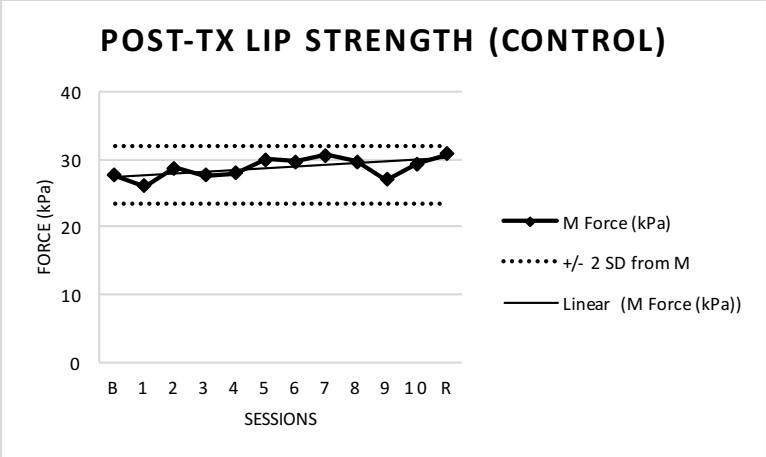

Figure 30. Subject 4 IOPI Measurements for Post-Tx Lip Strength (force in kPa). B = Baseline; R = Retention. Used as a control measure.

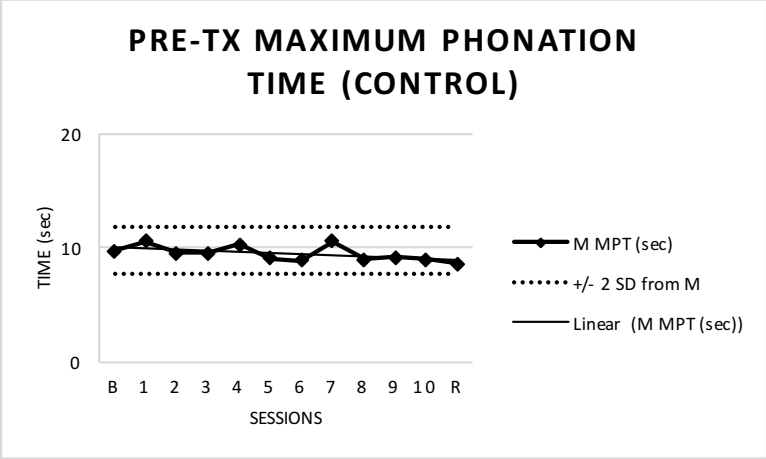

Figure 31. Subject 4 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

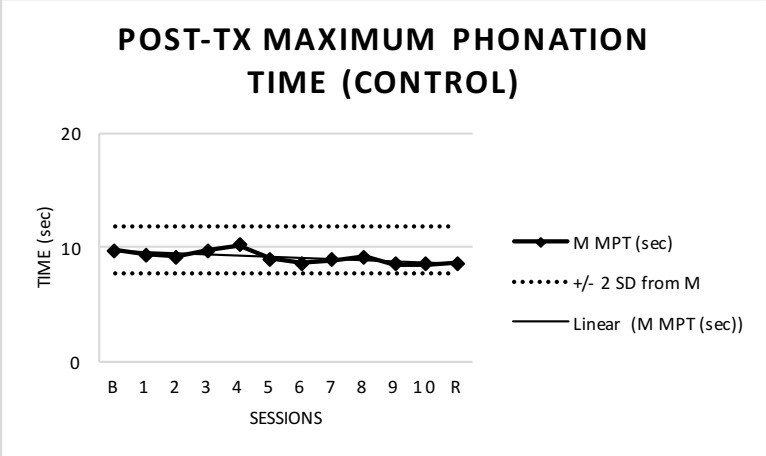

Figure 32. Subject 4 Measurements for Pre-Tx Maximum Phonation Time (sec). B = Baseline; R = Retention. Used as a control measure.

Aggregate Group

The studies conducted by Buchannan (2007), Durrant (2013), Torrey (2013), Krause (2014), and this current study include a total of 17 subjects having received intervention with the slurp swallow Exercise. In each of these studies, subjects had IOPI baseline data collected prior to intervention, and participated in at least nine treatment sessions with pre-treatment IOPI data taken each session.

Buchannan's study (2007) did not include post-treatment IOPI data each session. Only Torrey (2013) and this current study include retention data taken post-intervention. For purposes of this aggregate group analysis, only pre-treatment tongue tip and tongue dorsum strength will be considered, as these data are common to all subjects of the aggregate group.

Table 6

Aggregate Group IOPI Measurements for Tongue Tip Strength (force in kPa)

Tongue Tip Strength										
	Sessions									
Subjects	B	1	2	3	4	5	6	7	8	9
1	64	66	40	36.67	40.33	36.33	54	58.33	59.33	58.76
2	34.33	37	35.33	34.37	31.33	41	37	42	43.33	46.67
3	26.67	20.33	31	38.67	34.33	42	37.67	46.33	44.67	41
4	40.33	43.33	40	42.67	48.33	45	40.67	44	57	42
5	22.33	30	26	24	23.67	23.67	26	19.67	32	29.33
6	29.67	27	36	50	50.33	47.33	48.33	49.33	45.67	56.33
7	25	10	11	13.67	7.33	16.33	22	32.67	32	25.33
8	14.67	40.67	39.33	37.33	38	56.67	55.33	53.33	32.33	51.33
9	9.33	9.67	11.67	12.33	12.67	17	17.33	20.67	20.67	22
10	18.33	18.67	18.33	19	22	22.67	27.33	32.33	36	36
11	11.33	12.67	19.67	17	22.33	8.33	18	16.67	18.33	24.33
12	28	27	28.33	28.33	36.33	35.33	31.33	34	31	33.67
13	25.33	29	26	30	31.67	32.67	31	34.33	35.33	35.33
14	31.89	35	35	35	34.67	38.67	38.67	37.67	36.33	39.67
15	36.33	39	45.67	44.67	45.67	48.67	45.33	44.33	49.67	49
16	33.44	33	38	37.67	40	39.67	40.33	39	40	40.67
17	28	33.33	29	42	37.33	39.67	39.67	35	40.33	32.67

Note: IOPI measurements were taken pre-treatment each session. B = Baseline. All data are means of multiple maximum effort trials.

Over the course of intervention, measures of tongue tip strength generally increased compared to baseline for the majority of subjects (see Table 6). Measures of tongue dorsum strength also generally increased compared to baseline for the majority of subjects (see Table 7).

Table 7

Aggregate Group IOPI Measurements for Tongue Dorsum Strength (force in kPa)

Tongue Dorsum Strength										
	Sessions									
Subjects	B	1	2	3	4	5	6	7	8	9
1	57	67.67	48.33	64	54.67	57.33	43	58.33	39.67	68
2	25.33	35	38	33	30	37.67	35.67	38.67	45	43.67
3	29	28.33	26.67	38.67	38.67	40.67	40.67	48.33	45.33	40.33
4	47	43	49	42	45	54.33	59	57	52.67	54.67
5	37.33	40	35.67	36.33	49	43.67	43.33	44.67	44.33	49
6	30	38	41.33	51.67	49	47.33	45.33	47.67	46.67	50.67
7	7.67	9.67	5	8.33	6.33	11.67	18	24.67	22.33	25.33
8	37.67	36	37.67	44.67	44.67	50.67	46.67	47.33	48.33	51
9	15	14.67	18.33	24.33	37.67	42.33	48.67	54	58.33	60
10	31	33.67	35	44.33	45	53.33	62	68.33	69	70
11	41.33	48.33	53.33	52	53.33	53.67	51.67	53	51.67	55.33
12	35	33.33	48	54.67	57.67	60.33	21.67	63.67	66.67	66.67
13	26.33	29.67	30.67	31.67	31.67	33	31.67	34.67	39	40
14	27	27.33	29.33	27	28.33	31.67	29.33	30.33	33	33
15	43.78	45.33	48.33	51.67	46.67	49.33	51.33	53	57	58.67
16	30.89	30	36.67	34	37.33	37	33.67	36.33	34.67	38.67
17	29.33	32	33	34	37.67	44.67	48	48	46.33	47.33

Note: IOPI measurements were taken pre-treatment each session. B = Baseline. All data are means of multiple maximum effort trials.

A matched pairs *t*-test was calculated comparing baseline and session nine means for tongue tip strength, $t(16) = 4.568632$, $p = .000158$. The result is significant at $p \leq$

0.05. A matched pairs *t*-test was also calculated comparing baseline and session nine means for tongue dorsum strength, $t(16) = 6.682656$, $p = .00001$. The result is significant at $p \leq 0.05$.

Chapter 4 – Discussion

Summary

The purpose of this study was to replicate and expand upon the previous studies conducted by Buchannan (2007), Durrant (2013), Torrey (2013), and Krause (2014) to ascertain whether a treatment regimen using the slurp swallow exercise will increase measures of tongue strength in individuals with tongue thrust. Additionally, this study examined the combined aggregate data of the previous studies with this current study in a group analysis.

All subjects showed increased measures of tongue tip and dorsum strength compared to baseline. Subjects all reported being motivated to participate in the study and committed to completing the home treatment program. Of the four subjects, three reported 80% or higher compliance with home practice on non-intervention days. The other subject reported 60% compliance with the home treatment program. It is unclear whether the level of participation with the home treatment program correlated with gains of tongue strength over the course of intervention.

During intervention sessions all subjects appeared highly motivated in completing the 50 repetitions of the slurp swallow Exercise. Subjects were compliant with all given instructions and generally completed each intervention session in between 5 and 10 minutes. Due to the fatiguing nature of intervention, repetitions of the exercise were broken into sets of 10 repetitions. To facilitate easier swallowing, squirts of water were provided in between repetitions to moisten the mouth and allow for a small bolus to swallow.

Conclusion

All four subjects demonstrated significant treatment effect for both tongue tip and dorsum strength over the course of intervention. Both pre- and post-treatment IOPI data points fell above the two standard deviation band in all subjects for both tongue tip and dorsum strength measures. All subjects demonstrated retained gains four weeks' post-intervention. Control measures for all four subjects remained within the the two standard deviation band, indicating that treatment effects were due to the intervention of the slurp swallow Exercise and not due to extraneous variables.

The aggregate group *t*-tests calculated for tongue tip and dorsum strength both indicate a statistically significant treatment effect for the 17 subjects having participated in slurp swallow exercise intervention studies. The results of this study further add to the existing evidence base that the slurp swallow exercise is effective in increasing tongue strength in individuals with tongue thrust. Taken together, the data show that the slurp swallow exercise increases both tongue tip and dorsum strength when completed according to the instructions given by Pierce (1993).

Limitations

This study involved a relatively small sample size of four subjects. The subjects in this study were all Caucasian adults of middle-class socioeconomic status. Results of this study may not generalize to more ethnically or economically diverse populations. The limitation of sample size is partially addressed through the aggregate group analysis of the 17 subjects who have participated in this and previous studies.

Duration and frequency of the intervention are another limitation of this study. In various clinical settings, duration and frequency are highly variable and depended upon

myriad external factors. It is not clear whether the results of this study will generalize to other dosages of treatment.

Future Research

Future research may focus on differences between age, gender, ethnicity and socioeconomic status in regards to efficacy of the slurp swallow exercise. It may also examine the effects of intervention dosage in regards to treatment efficacy. While the results of this study indicate that the slurp swallow exercise is effective in increasing tongue strength in individuals with tongue thrust, future research may examine whether increasing tongue strength in this population is an effective remediation for tongue thrusting behavior.

Continued research on the efficacy of tongue thrust treatment including the slurp swallow exercise may examine the preliminary links between tongue thrust and signs and symptoms of dysphagia later in life (Holzer, 2001). Research may examine if those same links exist for individuals who have received treatment for tongue thrust.

References

American Speech-Language and Hearing Association. (2015). *Orofacial myofunctional disorders (OMD).* Retrieved from http://www.asha.org/public/speech/disorders/OMD/

Andrianopoulos, M. V., & Hanson, M. L. (1987). Tongue-thrust and the stability of overjet correction. *The Angle Orthodontist, 57*, 121-135.

Arvedson, J. C., & Brodsky, L. (2002). *Pediatric swallowing and feeding: Assessment and management (2nd ed.).* Albany, NY: Singular Publishing Group.

Benkert, K. K. (1997). The effectiveness of orofacial myofunctional therapy in improving dental occlusion. *International Journal of Orofacial Myology, 23*, 35-46.

Buchanan, A. (2007). The effectiveness of slurp swallow as a tongue strengthening exercise for children with tongue thrust. (Master's Thesis, Idaho State University, 2007).

Carroll, W.R., Locher, J. L., Canon, C. L., Bohannon, I. A., McColloch, N. L., & Magnuson, J. S. (2008). Pretreatment swallowing exercises improve swallow function after chemoradiation. *Laryngoscope, 118*(1), 39–43. doi: 10.1097/MLG.0b013e31815659b0

Clark, H. M., & Shelton, N. (2014). Training effects of the effortful swallow under three exercise conditions. *Dysphagia, 29*, 553-563. doi: 10.007/s00455-014-9544-7

Christensen, M. S., & Hanson, M. L. (1981). An investigation of the efficacy of oral myofunctional therapy as a precursor to articulation therapy for pre-first grade children. *Journal of Speech and Hearing Disorders, 46*, 160-167. doi: 10.1044/jshd.4602.160

de Felício, C. M., & Ferreira, C. L. P. (2007). Protocol of orofacial myofunctional evaluation with scores. *International Journal of Pediatric Otorhinolaryngology, 72*, 367-375. doi: 10.1016/j.ijporl.2007.11.012

Delaney, A. L., & Arvedson, J. C. (2008). Development of swallowing and feeding: Prenatal through first year of life. *Developmental Disabilities Research Reviews, 14*, 105-117. doi: 10.1002/ddrr.16

Dodds, W. J. (1989). The physiology of swallowing. *Dysphagia, 3*, 171-178.

Dodds, W. J., Stewart, E. T., & Logemann, J. A. (1990). Physiology and radiology of the normal oral and pharyngeal phases of swallowing. *American Journal of Roentgenology, 154*, 953-963. doi: 10.2214/ajr.154.5.2108569

Doeltgen, S. H., Witte, U., Gumbley, F., & Huckabee, M. (2009). Evaluation of manometric measures during tongue-hold swallows. *American Journal of Speech-Language Pathology, 18*, 65-73. doi: 1058-0360/09/1801-0065

Durrant, R. (2013). Effectiveness of the slurp swallow procedure in oromyofunctional therapy. (Master's Thesis, Idaho State University, 2013).

Evers, D. L. (2013). Comparison of individuals with oromyofunctional disorder on oropharyngeal measure ages 7-51. (Master's Thesis, Idaho State University, 2013).

Hale, S. T., Kellum, G. D., Richardson, J. F., Messer, S. C., Gross, A. M., & Sisakun, S. (1992). Oral motor control, posturing, and myofunctional variables in 8-year-olds. *Journal of Speech and Hearing Research, 35*, 1203-1208. doi:10.1044/jshr.3506.1203

Hanson, M. L. (1988). Orofacial myofunctional disorders: Guidelines for assessment and treatment. *The International Journal of Orofacial Myology, 14*(1), 27-32.

Hanson, M. L. (1974). Tongue thrust: A point of view. *Journal of Speech and Hearing Disorders, 41*, 172-184. doi:10.1044/jshd.4102.172

Hanson, M. L., & Barrett, R. H. (1988). *Fundamentals of orofacial myology.* Springfield, IL: Charles C. Thomas Books.

Hanson, M. L., & Mason, R. M. (2003). *Orofacial myology: International perspectives.* Springfield, IL: Charles C. Thomas Books.

Horn, H., Künhanst, K., Axmann-Krcmar, D., & Göz, G. (2004). Influence of orofacial dysfunctions on spatial and temporal dimensions of swallowing movements. *Journal of Orofacial Orthopedics, 5*, 276-388.

Holzer, K. L. (2011). Swallowing function and oromyofunctional disorder across the lifespan. (Master's Thesis, Idaho State University, 2011).

Jean, A. (2001). Brain stem control of swallowing: Neuronal network and cellular mechanisms. *Physiological Reviews, 81*, 929-969.

Kraaijenga, S. A. C., van der Molen, L., Stuiver, M. M., Teertstra, H. J., Hilgers, F. J. M., & van den Brekel, M. W. M. (2015). Effects of strengthening exercises on swallowing musculature and function in senior healthy subjects: A prospective effectiveness and feasibility study. *Dysphagia, 30*, 392-403. doi: 10.1007/s00455-015-9611-8

Krause, A. (2014). The effectiveness of the slurp swallow exercise as a tongue strengthening procedure for tongue thrust: A case study. (Master's Thesis, Idaho State University, 2007).

Leopold, N. A., & Kagel, M. C. (1997). Dysphagia — ingestion or deglutition? A proposed paradigm. *Dysphagia, 12*, 202-206.

Logemann, J. A. (2005). The role of exercise programs for dysphagia patients. *Dysphagia, 20*, 139-140. doi: 10.1007/s00455-005-0005-1

Logemann, J. A. (1998). *Evaluation and treatment of swallowing disorders (2nd ed.)*. Austin, TX: ProEd, Inc.

Logemann, J. A., Veis, S., & Colangeo, L. (1999). A screening procedure for oropharyngeal dysphagia. *Dysphagia, 14*, 44-51.

Mason, R. M., & Proffit, W. R. (1973). The tongue thrust controversy: Background and recommendations. *Journal of Speech and Hearing Disorders, 39*, 115-132. doi:10.1044/jshd.3902.115

Maeda, K., & Akagi, J. (2015). Decreased tongue pressure is associated with sarcopenia and sarcopenic dysphagia in the elderly. *Dysphagia, 30*, 80-87. doi: 10.1007/s00455-014-9577-y

Martino, R., Foley, N., Bhogal, S., Diamant, N., Speechley, M., & Teasell, R. (2005). Dysphagia after stroke: Incidence, diagnosis, and pulmonary complications. *Stroke, 36*, 2756-2763. doi: 10.1161/01.STR.0000190056.76543.eb

Mason, R. M. (2008). A retrospective and prospective view of orofacial myology. *International Journal of Orofacial Myology, 34*, 5-14.

Matsuo, K., & Palmer, J. B. (2009). Coordination of mastication, swallowing, and breathing. *Japanese Dental Science Review, 45*, 31-40. doi: 10.1016/j.jdsr.2009.03.004

Matsuo, K., & Palmer, J. B. (2008). Anatomy and physiology of feeding and swallowing: Normal and abnormal. *Physical Medicine and Rehabilitation Clinics of North America, 19*(9), 691-707. doi: 10.1016/j.pmr.2008.06.001

Miller, A. J. (1982). Deglutition. *Physiological Reviews, 62*, 129-184.

Nourbakshs, M., & Ottenbache, K. (1994). The statistical analysis of single-subject data: A comparative examination. *Physical Therapy Journal*, *74*(8), 768-776.

Palmer, J. B., Drennan, J.C., & Baba, M. (2000). Evaluation and treatment of swallowing impairments. *American Family Physician, 61*(8), 2453-3462.

Peng, C., Jost-Brinkmann, P. G., Yoshida, N., Chou, H. H., & Lin, C. T. (2004). Comparison of tongue functions between mature & tongue-thrust swallowing: An ultrasound investigation. *American Journal of Orthodontics & Dentofacial Orthopedics, 124*(5), 562-570. doi: 10.1016/j.ajodo.2003.06.003

Peng, C., Jost-Brinkmann, P., Yoshida, N., Miethke, R., & Lin, C. (2003). Differential diagnosis between infantile and mature swallowing with ultrasonography. *European Journal of Orthodontics, 25*, 451-456. doi: 10.1093/ejo/25.5.451

Pierce, R. B. (1993). *Swallow right: An exercise program to correct resting posture and swallowing patterns (2nd ed).* Austin, TX: Pro-ed.

Pierce, R. B. (1986). Rest posture therapy. *The International Journal of Orofacial Myology, 12*, 4-12.

Rampp, D. L., & Pannbacker, M. (1978). Indications and contradictions for tongue thrust therapy. *Language, Speech, and Hearing Services in Schools, 9*, 259-264. doi:10.1044/0161-1461.0904.259

Robbins, J., Levine, R., Wood, J., Roecker, E. B., & Luschei, E. (1995). Age effects on lingual pressure generation as a risk factor for dysphagia. *Journal of Gerontology, 50,* M257-M262. doi: 10.1093/gerona/50A.5.M257

Seikel, J. A., King, D. W., & Drumright, D. G. (2010). *Anatomy and physiology for speech, language, and hearing (4th ed.).* Clifton Park, NJ: Thomsom Delmar Learning.

Smithpeter, J., & Covell, D. Jr. (2010). Relapse of anterior open bites treated with orthodontic appliances with and without orofacial myofunctional therapy. *American Journal of Orthodontics and Dentofacial Orthopedics, 137*, 605-614.

Steele, C. M., Alsanei, W. A., Ayanikalath, S., Barbon, C. E. A., Chen, J., Cichero, J. A., Coutts, K., Dantas, R. O., Duivestein, J., Giosa, L., Hanson, B., Lam, P., Lecko, C., Leigh, C., Nagy, A., Namasivayam, A. M., Nascimento, W. V., Odendall, I., Smith, C. H., & Wang, H. (2015). The influence of food texture and liquid consistency modification on swallowing physiology and function: A systematic review. *Dysphagia, 30*, 2-26. doi: 10.1007/s00455-014-9578-x

Steele, C. M., & Cichero, J. A. Y. (2014). Physiological factors related to aspiration risk: A systematic review. *Dysphagia, 29*, 295-304. doi: 10.1007/s00455-014-9516-y

Stierwalt, J. A., & Youmanns, S. R. (2007). Tongue measures in individuals with normal and impaired swallowing. *American Journal of Speech-Language Pathology, 16*, 148-156. doi: 1058-0360/07/1602-0148

Torrey, M. S. (2013). The treatment efficacy of the slurp-swallow exercise in strengthening the tongue in persons with tongue thrust. (Master's Thesis, Idaho State University, 2013).

van den Engel-Hoek, L. de Groot, I. J. M., Esser, E., Gorissen, B., Hendriks, J. C. M., de Swart, B. J. M., & Geurts, A. C. H. (2012). Biomechanical events of swallowing are determined more by bolus consistency than by age or gender. *Physiology & Behavior, 106*, 285-290. doi: doi: 10.1016/j.physbeh.2012.02.018

Yoshida, M., Kikutani, T., Tsuga, K., Utanohara, Y., Hayashi, R., & Akagawa, Y. (2006). Decreased tongue pressure reflects symptom of dysphagia. *Dysphagia, 21*(1), 61-65. doi: 10.1007/s00455-005-9011-6

Appendix A – ISUTTP

ISU Tongue Thrust Protocol

Note: To derive a total score for prediction purposes circle numbers in "score" box for items representing problems.

Name:_____ Examiner:_____

Date:_____

DOB:_____

Case History Information

Characteristic	Presence/ absence	Score	Notation
Feeding History			
Nursed or bottle fed			
Age for solid food (4-6 for cereal)			
Age hard food (carrot, celery)			
Food preferences (hard, soft)			
History swallow problem (choke, gag)			
History regurgitation			
• Tx regurgitation			
• Persistent regurgitation			
Food allergy			
Family Issues (genetics)			
Fam. Hx. Tongue thrust			
Fam. Hx feeding problems			
Fam hx low tone			
Fam hx allergy			
Fam. Hx upper respiratory			
Fam Hx Macroglossia			
Fam Hx Small nares			
Fam Hx Deviated septum			
Fam Hx Dental problems (small mouth requiring extractions)			

Fam Hx Mouth breathing or nasal			
Habits			
Digit sucking (lips, tongue, finger, thumb, hand)			
Late bottle use			
Late pacifier use			
Mouth breathing			
Cheek biting			
Medical/Anatomical history			
Open spaces during mixed dentition			
Diastema?			
Micrognathia?			
Missing dentition?			
Hypertrophied adenoids/tonsils			
Allergies			
• New?			
• Old?			
• When develop?			
• Treated?			
Hypertrophied turbinates?			
Cleft palate?			
Tonsillitis			
• ENT visits for tx?			
• Removed?			
• When			
Neurophysiological issues			
Low sensory awareness /sensation seeking			
Drooling, saliva pooling			
Oral discrimination ability			

Assessment Protocol

Characteristic	Action	Score	Notation
1. Observation	Observe client at rest		
2. Facial tone	Observe client at rest		
3. Facial symmetry	Observe client at rest		
4. Mouth or nose breathing	Observe client at rest		
5. When mouth open, how much of upper dentition is covered by lip?	Criterion: Upper lip covers ½ of upper teeth	Less=1	
6. Rest posture of tongue	observe: contact upper dental arch at rest	If not=1	
7. Lip movement during dry swallow	Observe for open or clamped (watch for wrinkle of chin as sign of clamping)	Present= 1	
8. Tongue out, mouth open	Perception of macroglossia?	1	
Oral Examination:			
1. Dentition	Bite down on molars; Tongue depressor in buccal cavity; Ask to spread lips		
• Class I malocclusion	Mandibular 1st molar ½ tooth ahead of maxillary 1st molar; anterior teeth maligned	1	
• Class II	Retracted mandible	1	
• Class III	Prognathic mandible	1	

• Open bite	Front teeth don't occlude	1	
• Closed bite	Back teeth don't occlude		
• Teeth meet at rest	Observe rest posture re: muscles of mastication	1	
2. Nares:			
• Deviated septum	Ask in Hx; observe		
• Apparent blockage	Ask in Hx; observe breathing		
3. Lips • Contact	Criterion: Rest along entire length without effort	If not=1	
• Chapping?	Chapping indicates mouth breathing, tongue thrust		
• "fat" lower lip: low tone?	Indicates low tone		
• Overjet:	If excessive dental overjet, crease in lower lip where teeth rest	1	
4. Hard palate • High Vault	View with open mouth, flashlight	1	
5. Soft palate • Elevates with /a/?	Transilluminate Watch in /a/ Observe and palpate		
• Length adequate?	Transilluminate Watch in /a/ Observe and palpate		
• Blue coloration? (submucous)	Transilluminate Watch in /a/ Observe and palpate		

6. Tongue • microglossia	Observe, mouth open		
• Lingual frenulum	Protrude tongue; heart shape anterior?	1	
• Macroglossia	Observe, mouth open	1	
• resting posture?	Ask; criterion = contact upper dentition at rest	1	
7. Respiration • mouth versus nose breathing	Observe Sustain vowel Manometer use Listen		
• adequate support?	Manometer; count to 30 at 1 word per second (number of words/breath)		
• easily fatigues?	Observe, ask		
• Respiratory noise (adenoids?)	Observe		
Water Swallow			
1. Water retention	Water on tongue, open mouth, retains water?		
2. Water swallow x3 lips closed • Masseter contract?	Swallow water: Palpate	Fail=1	
• Symmetrical contract?	Swallow water: Palpate		
• Thyroid elevate?	Swallow water: Palpate	Fail=1	
3. Water swallow, lips open x 3 • lip tension?	Swallow water: Lips open, pull lips open Observe protrusion, interdental	Tense=1	
• Water loss?	Swallow water:	Loss=1	

	Lips open, pull lips open; Observe protrusion; interdental; water loss		
• Tongue thrust?	Swallow water: Lips open; pull lips open; Observe protrusion; interdental	1	
Food mastication			
1. Cracker/cookie mastication x 3 • bolus: scatter, tube, ball?	Observe before swallow, after swallow	Scatter= 1	
• Saliva: mixed?	Observe	Dry=1	
• too large bite?	Observe		
• Too small bite?	Observe		
• Lips open when chew?	Observe	1	
2. Cracker/cookie swallow X 3 number of swallows?	Observe	>2 swallow =1	
• Cleaned using tongue?	Observe		
• Followed with water?	Observe	1	
• Lips clamp in swallow?	Observe; watch for wrinkling of mentalis	Clamp or wrinkle =1	
• Masseter contract?	palpate	no contracti on = 2	
• Food remains in sulcus after swallow	Observe after swallow using tongue depressor	1	

• Excessive food on tongue after swallow	Look for position of tongue and lips on glass	1	
• Tongue protrudes in swallow	Pull down lower lip	1	
• Hold water on tongue	Can client cup tongue and hold water?		
3. Type of tongue thrust • Unilateral Left • Unilateral right • Spread • Bilateral • Upper thrust • Lower thrust	Pull lip down Resting posture Swallowing movement Look at dentition		
4. severity • 0=normal • 1= dental contact, but not pass through teeth or over teeth • 2.=dental contact, and between teeth, onto occlusal surface, or contact lips	Observation: be specific!		
Total Score (add circled numbers)			

Revised 9-1-04

Developed by Molly Borgreen, Kerry Bradshaw, Cara Breiter, Judy Carroll, Sharla Castillo, Matthew Hess, Wendy Lee, Emily Orchard, Tony Seikel, Elizabeth Staiger, Megan Summers, Vanessa Sutton

Appendix B – Informed Consent

Idaho State University Human Subjects Committee Informed Consent Form for Non-Medical Research: Adult Participant

You are asked to participate in a research study conducted by Tony Seikel, Ph.D., of Communication Sciences & Disorders, and Education of the Deaf, Idaho State University (208-282-4196). The co-investigator for this study is Dylan Wake. Data from this study will be reported in this student's Master's thesis. You have been asked to participate in this research because you have been identified as having a condition known as tongue thrust.

Between 4 to 12 subjects will be used for this specific study, and your participation in this research project is voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

1. **Purpose of the study:** This study is designed to examine the effectiveness of a particular form of treatment for tongue thrust.

2. **Procedures:** If you volunteer to participate in this study, we will ask you to do the following things:

a. You will be given a brief test in which you drink, eat and swallow small amounts of water and a cracker to determine your swallowing pattern. If it is shown that you have tongue thrust, we can continue with the study procedure. If you have an allergy to wheat products a gluten-free food will be provided. Observation of swallowing function is a standard clinical procedure conducted by Speech-language Pathologists (SLPs).

b. You will be asked to press down on a nylon bulb several times with your tongue and your lips in order to determine the strength of your tongue and lips. This procedure is a standard and commonly used clinical practice in research for determining tongue strength. Then you will also be asked to say "ah" as long as you can three times. This procedure is a common and standard clinical procedure commonly conducted by SLPs.

c. After that you will be asked to press your tongue to the roof of your mouth and then pull your tongue back in your mouth, making a slurping sound. A small amount of water will be squirted onto your tongue before doing this exercise. This will be repeated a number of times. The strength measures and vowel production will be performed again at the end of the session. There will be 10 consecutive sessions in this study. The exercise described above is a standard clinical treatment for tongue thrust given by SLPs.

d. The total time for the first session should be approximately 30 minutes but would not exceed 60 minutes for your participation.

e. Subsequent sessions will take approximately 10-20 minutes.

f. The study will be performed at the ISU Speech and Hearing Clinic in Pocatello, your home or another location of your choosing.

3. **Potential risks and discomforts:** If you are diabetic we will provide foods with artificial sweetener. If you are allergic to the wheat we can provide a gluten-free alternative, or you may elect not to participate in the study. You might feel embarrassment by the attention to your eating habits. You might breathe in some of the food or liquid during the testing, which would make you cough. Each session will be videotaped to ensure reliability. Videos of sessions will be stored on an encrypted drive in a secure location. You should know that you are free to discontinue the study at any time. **Discontinuing or declining to participate in this study will have no negative impact on clinical care or access to ISU clinical services or relationships with care providers.**

4. **Anticipated benefits to subjects:** While it is not probable that participation in this study will completely remediate tongue thrust behaviors in any individuals, there are some possible benefits. Benefits include possible increased strength in the tongue, which may help with swallowing.

5. **Alternatives to participation:** Participation is voluntary, and you may end participation at any time. There are no other alternatives to participation.

6. **Privacy and confidentiality:** The only people who will know that you are a research subject are members of the research team. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except (a) if necessary to protect our rights or welfare (for example, if you are injured), or (b) if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Data will be stored electronically on an encrypted flash drive (Kingston Data Locker G3). The flash drive will be kept in a code locked room in a locked locker. Only the investigators will know the password to the drive. The electronic records will be destroyed after the storage period. The drive will be reformatted to ensure complete deletion of the files. All data will be kept in compliance with HIPPA standards. Data will be stored no longer than 5 years after publication of this study.

7. **Participation and withdrawal:** Your participation in this research is *voluntary*. If you choose not to participate, that will not affect your relationship with Idaho State University, or your right to receive services in any clinics or by healthcare providers. **If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty. Discontinuing or declining to participate in this study will have no negative impact on clinical care or access to ISU clinical services or relationships with care providers.**

8. **Withdrawal of participation by the investigator:** The investigator may withdraw you from participating in the research if circumstances arise which warrant doing so. If you experience any of the following (coughing or hoarse voice after swallowing) you may have to drop out of the research, even if you would like to continue. The investigator (Dylan Wake) will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and welfare, or because it is part of the research plan that people who develop certain conditions may not continue to participate. Withdrawal will not affect your relationship with Idaho State University, or the facility from which you are receiving services. Likewise, withdrawal

will have no effect on your right to receive services from other clinics or healthcare providers.

9. **Identification of investigators:** In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Tony Seikel at 208-282-4196 or seikel@isu.edu at any time.

10. **Rights of research subjects:** You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have any questions regarding your rights as a research subject, you may contact the Human Subjects Committee office at 282-2179 or by writing to the Human Subjects Committee at Idaho State University, Mail Stop 8130, Pocatello, ID 83209.

_____ _____ _____

Name (please print) **Signature** **Date**

Appendix C – Human Subjects Application

IRB #: IRB-FY2017-49 Title: Tongue Strengthening Efficacy of the Slurp swallow Exercise in Individuals with Tongue Thrust Creation Date: 9-14-2016 End Date: 10-24-2017 Status: Approved Principal Investigator: Dylan Wake Review Board: Human Subjects Committee Sponsor:

Date: 2-19-2017

Study History Submission Type Initial

Key Study Contacts

Review Type

Full

Decision

Approved

Member Member Member Member

Dylan Wake John Seikel John Seikel John Seikel

Role Principal Investigator Role Primary Contact Role Investigator Role Investigator

Contact Contact seikel@isu.edu Contact seikel@isu.edu Contact seikel@isu.edu wakedyla@isu.edu

---

Initial Submission

Investigator and Project Information

Use this form for new submissions of research projects to the Human Subjects Committee (HSC, also known as the Institutional Review Board or IRB). This form is used for studies eligible for a Certificate of Exemption or for expedited review, and for those requiring full-board review.

Office location: 1651 Alvin Ricken Dr., Pocatello, ID 83201 | Mailing: Stop 8046

To obtain IRB Review of a research project with human participants, submit this completed form with all of the indicated attachments. Allow sufficient time for review before starting the project. Please consult the IRB website and contact irb@cayuse.edu or (208) 282-2714 with any questions before submitting an application.

Research as used here means a systematic investigation designed to develop or contribute to generalizable knowledge. This includes research, development, testing, and evaluation. This does not typically include classroom exercises, demonstrations, or other course requirements that receive grades. Research does not include customer satisfaction surveys or similar data collections designed to improve the operations of a single institution.

Human Participants The Institutional Review Board (IRB) reviews all research projects at Idaho State University involving human participants. This means living individuals about whom and investigator obtains data through intervention or interaction with the individual or obtains identifiable private information from a separate source such as medical or school records or other individuals such as relatives.

✔ New Submission

Revision/Resubmission

Select this only if you have previously submitted this study to the Human Subjects Committee and have been asked to make changes before it can be approved. If you are revising a study that has already been approved, use the Modifications form.

Name of Study 1.

Do not exceed 150 characters including spaces

Tongue Strengthening Efficacy of the Slurp swallow Exercise in Individuals with Tongue Thrust

Principal Investigator

2.

Please identify the PI for this project. Name: Dylan Wake Organization: Comm Sci Disorders/Deaf Educ Address: 921 S 8th Ave MS 8116, Pocatello, ID 83209 Phone: (801) 362-7944

3. Is the Principal Investigator a current student?

✔ Yes

Student Principal Investigators are required to include an endorsement from their faculty advisor. The signature below certifies that the faculty advisor has reviewed

4.

and approved this complete Application and its attachments and accepts responsibility to supervise the work described herein in accordance with applicable institutional policies.

Name: John Seikel Organization: Comm Sci Disorders/Deaf Educ Address: 921 S 8th Ave Ms 8116 , Pocatello, ID 832090002 Phone: 2082824196

No unknown

Are there Co-Investigators on this project?

✔ Yes

Please identify Co-Investigators

4.a

No

Name: John Seikel Organization: Comm Sci Disorders/Deaf Educ Address: 921 S 8th Ave Ms 8116 , Pocatello, ID 832090002 Phone: 2082824196

Other Research Staff 5.

Identify any others who will be involved as research personnel for this study.

For any research staff not available on the drop-down list above, please provide names (and institutional affiliation, if other than ISU).

Please identify a primary administrative point of contact for this submission (note: for

some submissions, it may be appropriate for the Principal Investigator and Primary

Contact to be the same person) 6.

Name: John Seikel Organization: Comm Sci Disorders/Deaf Educ Address: 921 S 8th Ave Ms 8116 , Pocatello, ID 832090002 Phone: 2082824196

Lay Language Summary

Briefly describe the purpose of the proposed research so that someone outside your field would readily understand it. Avoid abbreviations and technical language. Swallowing is a complex motor act important for maintaining adequate nutrition and hydration. Infants exhibit a swallowing pattern which includes a repeated piston like protrusion of the tongue used to initiate milk flow from the breast while feeding. Typically forward protrusion of the tongue during swallowing is eliminated as dentition

develops and a child matures. When forward protrusion of the tongue during swallowing is not eliminated it is often referred to as tongue thrust.

Tongue thrust when untreated can affect the teeth as well as the roof of the mouth, it can also negatively impact swallowing. Standard clinical procedures for treating tongue thrust focus on training and strengthening the musculature of the tongue. The purpose of this study is to examine whether one particular exercise used to treat tongue thrust, The Slurp swallow, increases tongue strength in individuals with tongue thrust.

Subjects will be assessed using a standard clinical protocol (The ISU Tongue Thrust Protocol) which includes a case history and observation of subjects swallowing cookies and water. The Iowa Oral Performance Instrument (IOPI) is a standard clinical tool for assessing force the tongue exerts against the roof of the mouth. It is a small air filled bulb which subjects place on their tongue and push against the roof of their mouth. The IOPI will be used to measure subjects tongue and lip strength for baseline data collection and during each treatment session of this study. Sustaining an "ah" sound for as long as possible with be used as a control in this study.

During treatment sessions the standard clinical procedure for the slurp swallow exercise will be used. Subjects will press their tongues against the roof of their mouths, slurp, then swallow. This exercise will be repeated 50 time throughout each treatment session. The purpose of this study is to replicate and expand upon the previous studies conducted by Buchannan (2007), Durrant (2013), and Torrey (2013) to further add to body of evidence regarding the slurp swallow's efficacy.

7.

8.

Has this project requested or received external funding?

Yes, external funding has been confirmed

If your proposal has been submitted in Cayuse SP, please enter the proposal identification in the box below.

External funding has been requested, but it's uncertain at this point whether it will be received ✔ No

Check here if this study is funded by an industry sponsor (e.g, pharmaceutical company, marketing firm, manufacturer, etc.).

Do any of the researchers (principal investigator, co-principal investigators, or associated researchers) have any financial, non-financial, or commercial interest in the

---

research? 9.

Research team members must submit an updated Conflict of Interest disclosure within 30 days of discovering or acquiring a new significant conflict of interest (financial or non-financial).

Yes ✔ No

Study site(s) 10.

Where will study procedures be carried out?

✔ Idaho State University (including the Pocatello, Idaho Falls, and Meridian campuses)

Internet research ✔ Other

Please provide a physical address for each site where study procedures will 10(a) take place.

Participant's home

Attach permission letters for each non-ISU site where research will be conducted

---

Application for Certificate of Exemption or for Expedited Review

11.

Are you applying for a Certificate of Exemption or for expedited review? Or does your study require review by the full board?

I am applying for a Certificate of Exemption.

I am applying for expedited review. ✔ This study requires full board review.

Participant information

Please identify the types of participants for this study 12.

Please check all that apply

Adults aged 90 or older

. ✔ Minors (less than 18 years) Are any of these minors wards of the state? Yes ✔ No Medical or other clinical patients/clients Patients receiving emergency medical care Terminally Ill Patients Mentally or Developmentally Disabled or Impared Non-English Speaking or Limited English Proficiency Prisoners, Parolees, or Incarcerated Persons (including people in court-mandated treatment programs) Pregnant Women

. ✔ Students (including university students) to be recruited by teachers or school administrators/staff Residents of nursing homes or other "total institutions" Employees of the investigator (or sub-investigator) or of the study's research site or sponsor Military personnel to be recruited by military personnel Others vulnerable to coercion or undue influence None of the above

13.

Are any of the participants in this study people over whom the investigator has some sort of authority? (E.g., the investigator's students, patients, clients, employees, supervisees, etc.)

Yes ✔ No

Explain how participants will be identified and recruited for this study.

If posters, billboards, radio or TV ads, internet ads, or other recruiting materials will be

used, include an explanation of where these will be placed. Also, contact ISU Marketing

& Communications for guidance about how to format your material. 208-282-4407

Subjects will be recruited through personal contacts of individuals known to the investigators, as well as through contact with orthodontists and speech-language pathologists (SLPs).

Personal contact script example: I am currently working on my Thesis and am investigating the effects of an exercise on tongue strength. I am looking for individuals

who have tongue thrust. Do you know anyone who has tongue thrust? Will you ask them if they'd be interested in participating in my study? Could I get in contact with them?

I would provide contacts with the information sheet attached below.

Attach any recruiting posters, email messages, letters, advertisements, etc. to be used. Include any recordings or videos to be used for radio, television, or internet. (This is NOT the place for attaching consent forms; that comes later.)

Info.docx

Will you use any posters, radio or TV advertisements, billboards, etc. for recruiting patients outside of the ISU campuses?

Yes ✔ No

14.

14(a)

15.

Will subjects be paid or given anything of value in return for their participation?

16.

Will participants in this study have to pay for anything (e.g., parking, medical services).

Yes ✔ No

✔ Participants will

Participants will

Participants will

Participants will

Participants will

Participants will SONA system).

NOT receive anything of value in return for their participation. be paid (cash, check, or gift card) receive a non-monetary item or service be entered into a drawing for something of value.

only be reimbursed for the costs of participation. receive research participation credits as part of an ISU course (e.g., using the

Research Procedures and Methods

Literature Review

Present a summary of the relevant research literature and explain how the proposed study would contribute to knowledge in this field. Explain why the methods, measures, and instruments used are appropriate for this study. Be sure to include citations.

(see chapters one and two of manuscript)

20.

Describe the research procedures and materials, including when and where research activities will take place.

Provide a clear, step-by-step description of what will be done in this study. If participants will be separated into different groups, explain how this assignment will be made, and what will happen for each group. This research summary should be written or

edited specifically for IRB review. Do not simply copy and paste your thesis proposal or grant application.

Be sure that you include citations.

The Idaho State University Tongue Thrust Protocol (ISUTTP) will be used to confirm the presence of tongue thrust in all participants. During the first session of treatment each participant will be evaluated using the ISUTTP (see attachement).

The first part of the ISUTTP is a detailed case history. It includes an inventory of early feeding behaviors, history of negative oral habits such as digit sucking and prolonged pacifier or bottle use, and family history of swallowing. Other behaviors commonly indicative of or related to tongue thrust are also included, such as mouth breathing, allergies, structural and anatomic issues, and medical history.

The second part of the ISUTTP is an standard clinical examination of the oral mechanism. Patient's will be observed for symmetry and tone of their facial features. The resting posture of both both the lips and tongue will be examined by the investigator. Participants will be asked to do things such as, "open your mouth wide" and "stick out your tongue" while the investigator observes oral structures and function.

Participants will be asked to eat small amounts of crackers and drink small amounts of water. They will be observed as they both eat and drink.

Each treatment session, participants will be asked to place the small air filled bulb of the Iowa Oral Performance Instrument (IOPI) in their mouth. They will be instructed to push the bulb against the roof of their mouth as hard as they can three separate times. Participants will also be asked to perform this same task by pressing the bulb between

their lips. Participants will finally be asked to sustain the sound "ah" as long as they can three separate times. These are known as Maximum Phonation Time (MPT) measures.

Participants will be asked to perform 50 repetitions of the Slurp swallow Exercise each treatment session. The verbal for instructions for performing the exercise are as follows:

1.Put your tongue tip up on the spot (behind your top teeth). 2.Bite your back teeth together. They should fit together like a puzzle. 3.Keep your lips wide apart, like a clown smiling. 4.Slurp! 5.Swallow.

Water will be provided to be sipped or squirted onto the tongue between repetitions of the exercise.

After repetition of the exercise participants will repeat the IOPI measures they did at the beginning of the session along with the MPT measures.

ATTACH copies or images of the actual materials to be employed, in final form to the extent possible, otherwise in draft or outline form - such as questionnaires, interview protocols, media to be shown to participants, etc. Indicate whether attachments are draft or final.

20(a) (Do NOT attach consent forms here; that comes later.)

21.

ISU TONGUE THRUST ASSESSMENT PROTOCOL.doc

If this study involves an investigator's brochure (detailing all procedures), attach it here.

Data Storage, Access, & Final Disposition

Explain the following: a) How long will the data be stored? b) How will data be protected? Give details of physical security, passwords, encryption, etc. c) Who will have access to the data during the storage period? d) What will be done with the data at the end of that period? If electronic records will be destroyed, explain what steps you will take to prevent them from being recoverable afterwards.

a) Data will be stored no longer than 5 years after publication of this study. b) Data will be stored electronically on an encrypted flash drive (Kingston Data Locker G3). The flash drive will be kept in a code locked room in a locked locker. Only the investigators will know the password to the drive. c) Only the investigators will have access to the data during the storage period. d) The electronic records will be destroyed after the storage period. The drive will be reformatted to ensure complete deletion of the files. All data will be kept in compliance with HIPPA standards.

Specific study information

To protect the rights and welfare of individuals recruited to participate in research conducted by faculty or students at Idaho State University, ISU policy requires that all research with human participants as defined on Page 1 be reviewed by the ISU IRB. The ISU IRB follows the Common Rule (45 CFR 46) and other applicable federal regulations

as applicable, and generally adopts the policies and guidance published by the Office for Human Research Protections of the U.S. Department of Health and Human Services.

Each of the following elements must be included in this Application. Note carefully the REQUIRED ATTACHMENTS.

Will you be using any Protected Health Information (PHI) in this study? 22.

PHI is any individually identifiable information about someone's health, health care, or payment for health care (whether past, present, or future).

Not sure what PHI is?

Yes ✔ No

Population & Sample Size

a. Describe the population to be studied, including the approximate numbers of participants to be recruited and expected to complete the study. Explain these numbers for each group, phase or type of project element, if multiple. If this is just one of multiple study sites, state both the total number of subjects to be included in the study and the number to be recruited at this site.

This study will include between 4 and 12 participants. Participants will be recruited between ages 5 and 30. Participants in this study will be individuals with tongue thrust who have not been previously treated for tongue thrust.

23.

— —

24.

Explain clearly the Inclusion and exclusion criteria

If inclusion/exclusion criteria include medical factors, explain how these will be determined (e.g., subject self-report, conducting a medical test or exam, retrieving info from medical records).

Participants will be recruited self identifying as having tongue thrust. Presence of tongue thrust will confirmed by the Idaho State University Tongue Thrust Protocol (ISUTTP). Inclusion criteria includes the presence of tongue thrust. Exclusion criteria includes having received therapy or treatment for tongue thrust previously (self-report).

Describe the process of gaining informed consent to participate in each phase or type of research element.

Before completing the study, each participant will be provided with a consent form. Children's parents will be provided with a parental consent form. Children will be verbally read an assent form written to their level. The purpose and procedures of the study will be explained to each participant and participants won't participant in any study procedures until they have signed the appropriate corresponding consent forms. Participants will be informed verbally as well as through emphasized writing in the consent forms that they are able to drop out of the study at any time without impacted their ability to received therapy services at ISU and without any other penalty.

25.

26.

Is temporary participant deception planned for this study?

Yes ✔ No

ATTACH a copy of each written consent of assent form or script is to be used. Include all versions of multiple forms or scripts, if applicable, highlighting relevant differences.

27.

29.

Might any of the adult subjects who will be enrolled in this study need a Legally Authorized Representative (LAR) or next of kin to sign on their behalf?

Consent of parent/guardian will be obtained for subjects < 18 years old.

Yes (other than children) ✔ No

Are you requesting a waiver of documentation of informed consent? (I.e., Participants will provide verbal consent but will not sign a consent form)

Yes ✔ No

Are you requesting a waiver of informed consent? (I.e., the study will be conducted without obtaining even the verbal consent of participants)

30.

31.

28.

A child assent form should be used for participants 7-12 years old, and a youth assent form should be used for participants 13-17 years old. These are used in conjunction with a parent/guardian consent form.

Adult Consent.docx Sample documents: SampleParentalConsentForm.doc , Child Assent.docx SampleMinorAssentForm.doc , SampleAdultConsentForm.doc Parental Consent.docx

Will you be recruiting any participants who have limited or no proficiency in English?

Yes ✔ No

Yes ✔ No

Potential Risks and Benefits

32

33

Will this study have a Data Safety Monitoring Board (DSMB) or other oversight body overseeing the safety of participants?

Yes ✔ No

Describe real and potential risks to the participant including possible inconvenience and discomforts; and any risks to nonparticipants. Include any risks related to breach of confidentiality or anonymity. The extent of risks described here should match the level of risk communicated during the informed consent procedure. For each risk, explain the steps taken to minimize it and for managing any anticipated adverse effects that may arise.

It is important to note that both the treatment and the measurement device are standard clinical procedures in speech-language pathology. There are minimal potential risks associated with participation in this study. These include feelings of embarrassment or discomfort as the participate practices the exercises and mild fatigue and/or mild soreness of the muscles in the mouth. There is also a risk of aspiration which may cause the subject to cough. Participants and/or their parents or guardians will be informed of these risks verbally and in a written format within the informed consent material. They will be informed of their right to withdraw from the study at any time with no penalty. There is a risk of accidental loss of confidentiality.

What is the level of risk to participants?

32(a) Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research is no greater than that encountered in ordinary life (for ordinary, healthy people) or during a routine physical or psychological examination.

✔ Minimal Risk Minor Increase Over Minimal Risk [Use only when participants are children] Greater than minimal risk

---

34

Describe definite or potential benefits to the participant due to completing the study, if any.

Do not include any payments or gifts to participants. If subjects should not expect to benefit directly from their participation in this study, then say so (and explain this in the consent process). Describe definite or potential benefits beyond the participant,

including benefits to the researcher, and to a specific social group or institution, if any. If the risks to participants are greater than minimal, describe the expected scientific benefits that justify exposing participants to above-minimal risk.

While it is not probable that participation in this study will completely remediate tongue thrust behaviors in any individuals, there are some possible benefits. Parents/guardians and participants will be given this information within the informed consent materials and these points will be discussed prior to beginning the study. Not all participants will experience the same level of benefit. Benefits include possible increased strength in the tongue, which may help with swallowing. A second benefit is the potential for increased evidence base regarding the effectiveness of the slurp swallow exercise in the field of speech-language pathology.

Certification

By signing below, the Principal Investigator and co-Principal Investigators (if any) assure the IRB that all procedures performed during this project will be conducted by individuals legally and responsibly entitled to do so, and that any significant systematic deviation from the submitted protocol (for example, a change in principal investigator, sponsorship[. research purposes, participant recruitment procedures, research methodology , risks and benefits, or consent procedures) will be submitted to the IRB for approval prior to its implementation

By signing below, the Principal Investigator and co-Principal Investigators (if any) certify the following:

1. The information in this application is accurate and complete

2. I/we will comply with all federal, state, and institutional policies and procedures to protect human subjects in research
3. I/we understand the ethical responsibilities of research investigators and have received the required training in human research participant protection as specified at the IRB Website
4. I/we will assure that the consent process and research procedures as described herein are followed with every participant in the research
5. I/we will promptly report any deviations or adverse events to the IRB.
6. If a faculty advisor is required (see below), then I/we agree to meet regularly with the faculty advisor listed below to discuss the progress of the study and to address research issues as they arise.

✔ I, and all others identified herein as members of the research team, have read and understand the above statement.

Faculty Advisor

Applicable only when the Principal Investigator is not an assistant professor, associate professor, or professor (or their clinical counterparts) at Idaho State University.

As faculty advisor for this study, I certify that I have read this application and that the information contained in it is complete and accurate. I will ensure that the principal investigator(s) listed above is/are competent to perform the procedures described. I agree

to meet regularly with the principal investigator(s) to discuss the progress of the research and to address research issues as they arise. I will ensure that the research is carried out as described (including storage and destruction of data as described in the protocol), and that all applicable laws and policies will be followed.

✔ I, as faculty advisor, have read and understand the above statement.

_____

_____