University of Alberta

A longitudinal study of functional outcomes following surgical resection and microvascular reconstruction for oral cancer: Tongue mobility and swallowing function

by

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of

Master of Science

in

Speech Language Pathology

Department of Speech Pathology and Audiology

Edmonton, Alberta

Spring 2008

Your file Votre référence
ISBN: 978-0-494-45783-2
Our file Notre référence
ISBN: 978-0-494-45783-2

Abstract

Resection of the tongue for treatment of oral cancer has been a topic of interest in head and neck cancer research for several years. However, there remain shortcomings in the literature in terms of group homogeneity and within-subject measures across time.

Using a group of patients who underwent surgical resection and reconstruction of the anterior 2/3rds of the tongue, this study examined swallowing function and tongue mobility before surgery and at 1-, 6-, and 12-months post-surgery. The ability to swallow liquids was significantly worse at the 1-month follow-up when compared to pre-operative measures. Posterior-tongue mobility was significantly impacted for the same time comparison. No other significant differences were found. All measures were at or near baseline by 12-months.

In contrast to the findings from studies done on more heterogeneous populations, the results of this study suggest that patients with anterior-tongue resections have functional swallowing ability and tongue mobility.

Acknowledgements

This thesis was funded in part by the University of Alberta Queen Elizabeth II Graduate Scholarship.

I'd like to take this opportunity to focus on the many people who contributed to the successful outcome of this project.

Dr. Jana Rieger, my supervisor, was incredibly dedicated and supportive throughout the entire process. I appreciate the long hours she spent reading and making suggestions on draft copies of grant applications, proposals, and the final product, as well as keeping me sane during my data analysis! Her friendship, encouragement and enthusiasm all meant so much.

My committee members, Drs. Carol Boliek and John Wolfaardt, both provided invaluable comments and suggestions that helped shape my thesis into the finished product you have before you. I am a more accomplished researcher thanks to the support and critical thinking of my entire committee.

Judith Lam Tang and Jana Zalmanowitz, the best and most organized research associates at COMPRU! Without them, I would still be looking for someone to help randomize and blind me to my participants, fine-tune my methodology and perform measures of reliability. I am grateful for the time they spent working on my project.

Dr. Shamchuk, Radiologist at the Misericordia Hospital, whose valuable insights on the anatomy of the head and neck helped me define some of the anatomical landmarks used in my study.

My thesis cohorts who were there to celebrate the highs and help me work through the lows from beginning to end! There are also many friends and family members who provided humor, encouragement, and prayers throughout this project.

Finally, I would like to acknowledge my partner, Robin, for his incredible support and understanding and his ability to turn calamity into calmness! I'm sure he learned things about my thesis and the SLP program that he never really wanted to know!

* * *

This thesis is dedicated to my grandmother, Iris Brown - the kind of roommate that drives you crazy with questions, but then makes up for it with warm chocolate chip cookies and a glass of cold milk. Thank-you for your unwavering support.

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A longitudinal study of functional outcomes following surgical resection and microvascular reconstruction for oral cancer: Tongue mobility and swallowing function

INTRODUCTION

Resection of the tongue for treatment of oral cancer has been a topic of interest in head and neck cancer literature for several years. The primary objective of surgical resection has revolved around removal of the lesion for cancer cure and thereby, preservation of life. However, as surgical techniques improve and microvascular reconstruction becomes commonplace in head and neck surgery, factors such as cosmesis, functional outcomes and quality of life for the patient become more significant in determining the best treatment approach. While microvascular surgical procedures have advanced the surgeon's ability to reconstruct a defect, progress also continues to be made in the methods used for functional outcomes research on patients with head and neck cancer. Improvements in clinical evaluations, as well as better instrumentation and radiographic techniques, have permitted researchers and clinicians to assess a patient's swallow in a more objective manner for normality, efficiency and, most important, safety.

Studies of oral cancer patients that have been completed to date reflect a variety of conclusions, with many indicating that there are swallowing impairments in patients who undergo a radical change in the structural anatomy of their tongue as compared to controls or published standards[1-4]. The results of these studies have been collected in a variety of ways. Subjective patient reports or interviews have contributed some details to the growing body of literature on swallowing in patients with oral cancer. Direct clinical observations and standardized patient questionnaires are other approaches for evaluating a patient's swallow and provide valuable information beyond subjective reports or nonstandardized interviews. The primary approach and current 'gold standard' for assessing swallowing and tongue mobility, however, is via a videofluoroscopic swallow study (VFSS). This method allows the examiner to evaluate several aspects of the swallowing mechanism including the duration and efficiency of different swallowing parameters, such as adequacy of bolus transport, airway protection, and the estimated amount and location of residue or stasis.

Although advances in surgical treatment and evaluation techniques have been made, there remain challenges to overcome when interpreting the literature on outcomes, especially those related to reconstruction of the anterior portion (i.e., the anterior mobile 2/3rds) of the tongue. Much research in this area is characterized by reports on patients as a heterogeneous population; it is challenging to find literature that reports on this population in smaller, more homogeneous groups. For example, there are several studies that report collective outcomes related to resection of the anterior and posterior portions of the tongue, the mandible, the maxilla, the soft palate, the pharynx, the larynx or any combination thereof. In contrast, there are only a limited number of studies that have measured functional swallowing outcomes following resection of only the anterior 2/3rds of the tongue. Furthermore, of these studies, very few include outcomes collected over a longitudinal time frame, but instead include outcomes at differing points in treatment across patients. Fewer studies, still, include measurements of the remaining mobility of the anterior aspect of the tongue following resection and microvascular reconstruction. This type of description is necessary to prevent the unwarranted promotion of alternative methods of treatment for oral cancer that potentially could be based on unproven claims of tongue dysmotility after surgical reconstruction.

Background

Patient-Report and Clinical-Observation Studies

Although patient report and clinical observation studies do not use what might be considered the 'gold standard' as outlined above, they are useful for a variety of reasons. These types of studies provide researchers and health practitioners with information about a patient's overall quality of life or function post-surgery as well as valuable qualitative data. Only the treatment recipient can make judgements about their quality of life and, as greater importance is placed on designing therapies that take this factor into consideration, research in this area will be emphasized as well. To illustrate this point, a study of this topic revealed patients' cumulative scores on the University of Washington Quality of Life questionnaire (UW-QOL) to be lower at one year for posterior oral lesions versus anterior oral lesions[5]. This research also revealed that the percentage of patients reporting the highest achievable scores pre-operatively for many categories (i.e., pain, mastication, and shoulder function) had a tendency to report poorer outcomes at the first post-operative measure but rose to (or close to) baseline measures by the time the last post-operative measure was taken.

However, the percentage of people who reported the highest achievable scores for swallowing during the pre-operative period reported poorer outcomes following surgery and did not improve significantly by the study's end.

As mentioned, these types of studies provide some understanding of patients' perceptions about their remaining abilities in addition to rating quality of life. Patients are typically asked to rate their function in an attempt to look for patterns that are theoretically and clinically useful. The results from a study by Nicoletti (2004) revealed that patients with small and medium lateral tongue resections and hemiglossectomies had better recovery of mastication than swallowing. Furthermore, the degree of resection, rather than the site of resection, appeared to be the most important factor in predicting better functional outcomes[6]. By using a water drinking task and calculating means for bolus volume, duration of swallow and volume swallowed per second, Diz Dios et al. (1994) also concluded that deglutition is negatively correlated with the quantity of lingual tissue removed in patients who had undergone partial glossectomy[1].

Another team of researchers used a water drinking task to compare patients with primary closure to those who were reconstructed with a free flap following anterior tongue resection. Those patients who received flaps had significantly better mean rates and volumes for ingestion. The research team concluded that microvascular reconstruction resulted in better overall deglutition[7]. This team of researchers also suggested that a free flap provides bulk and allows the remaining tongue a certain degree of movement, both of which are necessary for adequate swallowing function following surgery.

Interestingly, a study by Hirano et al. (1992) involving interview and review of patients' medical records revealed no significant relationships between the extent of resection of the mobile tongue and the textures of food the patients could eat, the degree of aspiration they suffered from or the duration of any tube feeding that took place following surgery[8]. This is a conclusion contrary to what some of the previously mentioned research has revealed, but one that highlights the variability that can be seen in the outcomes and conclusions for swallowing research in patients with head and neck cancer. This type of variability may very well be due to the differing methods that have been used to evaluate swallowing.

Functional Swallowing Outcomes from Studies using Videofluoroscopy

Although patient report and clinical observation do provide useful information, many research teams choose to use videofluoroscopy alone or at least in combination with the alternatives to measure swallowing outcomes. This might lead one to conclude that, while other methods of evaluation are good for providing some information about a patient's abilities, it is not until the results have been verified using a videofluoroscopic swallowing study that the judgements or conclusions to be made will be considered convincing. It has been shown in the literature that perceptions and reports of swallowing difficulties in head and neck cancer patients correlate with what can be observed in their videofluoroscopic evaluations[9]. However, it would appear that patients may not always be aware of or perceive all swallowing dysfunction. For example, studies within and outside the head and neck cancer domain of research show that the incidence of silent aspiration can range from 22-59%[10,11]. Silent aspiration is a concern because it means the patient is unaware of food or fluid entering the respiratory tract and, thus, makes no attempt to clear these potentially harmful items away. Research in other domains has shown that silent aspiration can contribute to pneumonia[12]. Identification of aspiration, silent or not, in addition to other swallowing difficulties and implementing treatment strategies for such may help to preserve the patient's health and quality of life by reducing the risk of malnutrition, dehydration and pneumonia[13]. The uncertainty surrounding a patient's ability to accurately perceive the efficiency with which they swallow is justification for using a more objective and reliable method, such as videofluoroscopy, in order to judge this life-sustaining task. The modified barium swallow study is administered and interpreted using guidelines to limit some of the variation that could be attributed to patient perception and clinical interpretation. It is a technique that allows the examiner to systematically study the series of events that make up a swallow from the moment the patient accepts the bolus into the oral cavity to the time it enters the esophagus for continued transport to the stomach. This prevents unnecessary guesswork about what is happening within the oral and pharyngeal cavities and allows the examiner to see what problems arise from the patient's underlying physiology. From this, a treatment plan can be designed to effectively target concerns or weaknesses.

As an example of differences that can be delineated by a videofluoroscopic swallow study, one can turn to the research reported by Hirano and colleagues in 1992. In addition to using patient interview and medical chart review, these authors selected some of the study's subjects to undergo videofluoroscopic evaluations. For this portion of the study, the researchers concluded that, despite differences in proportions of glossectomies, all patients had difficulty holding the bolus on the tongue and transporting it from the oral cavity to the pharynx without relying on gravity to move it posteriorly. Propulsion in the pharynx also was weakened and thus each bolus was not completely transported to the esophagus[8]. These results were not revealed in the patient report portion of the study, thereby providing novel and valuable information about patients' swallowing function following tongue resection.

In contrast to the Hirano et al. (1992) study, Hsiao et al[14] concluded that anterior holding and effective propulsion of the bolus at the onset of the swallow were present for every patient with hemiglossectomy and free flap reconstruction. The team also noted that there was ample tongue-to-palate contact both anteriorly and posteriorly and no premature spillage of the bolus. Small amounts of residue in the floor of the mouth and greater mean oral transit times compared to controls were the only deficits in this population[14]. The conflicting results seen in these two studies may be due to the differences in proportion of tongue resected in the two groups or the point in treatment time that the videofluoroscopic evaluations were recorded. Hirano and colleagues[8] included those patients who had 50 to nearly 100 percent of their oral tongue resected and performed their videofluoroscopic evaluations before or at 5 months post-surgery. Hsiao and colleagues only included patients who underwent hemiglossectomy (i.e., 50% of the anterior tongue) and reported a strict timeline of evaluation at 6 months post-operation.

Functional Outcomes from Longitudinal Studies

While the modified barium swallow study provides clinicians with a snapshot of swallowing function at one point in time, it is possible that changes in function will occur across time as healing continues and as other interventions, such as radiation therapy, are delivered. Therefore, longitudinal assessment of swallowing function becomes vital in establishing overall outcomes related to tongue reconstruction. Longitudinal studies have provided mixed results regarding the post-operative difficulties that patients experience. The points at which researchers select to measure swallowing ability seem to play a role in the resulting conclusions. This is illustrated by various studies. Pauloski and colleagues[4] demonstrated that most measures for oral transit times and oral residue for liquids, pastes and solids increased from pre-operative to 1 month post-operative. At the 3 month post-operative time point in the same study, the results were varied; oral transit times for liquid and cookie were at pre-operative levels with no significant change in time for paste from the 1 month evaluation; oral residue following liquid consistencies increased at this time point whereas residue for paste and cookie decreased but not significantly. The authors state that proximity to adjuvant radiation therapy may be a reason for the lack of improvement and the variability in the measures[4]. In a different study, Hamlet et al[2] confirmed that swallowing durations decreased for all consistencies from the first post-surgery measure between 2 to 5 weeks to the second post-surgery/post-adjuvant radiotherapy measure between 14 to 27 weeks. This team of researchers also found that all the patients who completed their swallowing protocol were on some form of oral intake diet, including at least soft foods and liquids, within 27 weeks following initial resection and unlike Pauloski et al. did not believe adjuvant radiation therapy hindered patient recovery[2]. One reason behind the differences in the results of these two studies may be the different points in time that the authors chose to complete their evaluations – Hamlet's team of researchers allowed for more time to pass before the last measurement was taken. Another longitudinal study looked at swallowing evaluations pre-operatively, 1 month post-operatively and approximately 6 months post-operatively[15]. The researchers found that there was a significant reduction in laryngeal penetration of liquid boluses in the two post-operative visits when compared to the pre-operative evaluation. No evidence of penetration was noted in any evaluations of the pudding or cookie consistencies. The authors also state that there were no significant changes in any of the parameters associated with the oral or oral preparatory phases of a swallow. This suggests that the prognosis for recovery is good for those patients with anterior hemi-tongue resection followed by reconstruction with a radial forearm free flap.

Studies of Tongue Mobility

The advent of microvascular free flap reconstruction has changed the face of treatment for patients with head and neck cancer. As previously mentioned, effective removal of a lesion, combined with advances in microvascular reconstruction, have expanded many of the considerations given to a patient's remaining function, appearance and quality of life. In order to restore a patient's swallowing ability and to maintain quality of life, it is essential for the surgeon to choose a method of reconstruction that will allow for tongue mobility so that the main physiologic components of an efficient swallow are preserved. Although there are several types of flaps available for microvascular reconstruction, many surgeons prefer to use the radial forearm free flap because of: 1) its pliable nature that allows for potential recovery of tongue mobility; 2) the relative ease with which it can be obtained; 3) the low donor-site morbidity; and 4) the reduction of hospital stay due to its use in single-stage form of reconstruction[16,17].

Turning our attention back to the studies by Hirano[8] and Hsiao and colleagues[14], conflicting results were revealed regarding tongue mobility as judged by anterior bolus hold and the ability to propel the bolus into the oropharynx to initiate the rest of the swallowing sequence. As discussed, reasons for these differences may be associated with volume of tongue resected and/or evaluations at different points in time. Another explanation may be microvascular reconstruction versus primary closure. Both research teams make note of subjects who had one or the other. Hirano and colleagues do not describe the data separately between patients who underwent microvascular reconstruction and those who had primary closure whereas Hsiao's team of researchers does[8,14]. Thus, it is possible that these two studies report conflicting results regarding tongue mobility due to the way in which the patients were grouped. If the Hirano researchers had looked at the differences between their subject groups, they may have discovered different outcomes for the people who underwent reconstruction versus those with primary closure. The comparison of these two studies highlights the variability between studies and the difficult task of interpreting the literature on tongue mobility following surgical resection and microvascular reconstruction of the anterior tongue.

Panchal and colleagues[18] used videofluoroscopy to clinically assess fasciocutaneous and osteocutaneous forearm free flap reconstruction in patients with mainly floor of mouth and tongue lesions and found that initial tongue mobility, as visually judged by the patients' ability to propel a bolus from the oral cavity into the oropharyngeal cavity, was compromised in nearly all of the study's subjects, thereby causing some swallowing difficulty. Sixty-two percent of the study's participants regained enough movement to display a safe and functional swallow 4 to 6 months post-surgery[18].

Another study of note in the discussion of tongue mobility following microvascular reconstruction was performed by Hara and colleagues[3]. These researchers compared tongue mobility of a control group to patients who underwent microvascular reconstruction with either a radial forearm free flap or a lateral upper arm free flap. The researchers imposed lines of reference onto the subject's videofluoroscopic swallowing evaluations; as the tongue moved around the reference axes during the swallow, the greatest amount of change between the lines and predetermined points on the tongue was measured and reported as mobility. When compared to controls, the researchers found that mobility was significantly diminished for those who had undergone microvascular reconstruction; with the results being similar for both types of flaps. The site and volume of resection had a large effect on mobility. Anterior resections in the oral cavity impaired the tip, mid-portion and posterior movements of the tongue whereas posterior resections in the oral cavity reduced posterior but not the tip or mid-portion tongue movements. Increased area of resection resulted in greater impairments of tongue mobility regardless of site of resection[3].

Although the results of studying tongue mobility in patients with anterior tongue resection followed by microvascular reconstruction seem inconclusive, the Hara research is seminal because it is one of the first attempts to quantitatively measure tongue mobility. Although no pre-operative measures were completed, and only one measure was taken post-operatively, this is an important step towards the characterization of remaining physiological function in a quantitative manner. More studies like this will result in giving a clearer picture of swallowing outcomes following surgical treatment for oral tongue cancer to researchers, health practitioners and patients.

Purpose

Characterization or measurement of tongue mobility following surgical resection and microvascular reconstruction remains elusive in the head and neck cancer research domain. In a traditional framework, swallowing is seen to be comprised of several distinct phases. These include: the oral preparatory phase, the oral phase, the pharyngeal phase and the esophageal phase. Research under this view has focused mainly on the timing of swallowing events and bolus flow with the conclusion that any deviation from what is considered to be within normal limits will indicate the existence and severity of a swallowing disorder[13,19]. More recently, some researchers have begun to support the idea that all aspects of a swallow are interrelated and thus cannot be separated into different phases[20]. Impairment in a singular aspect of the swallow early on has the potential to cause deficits in the organization of the swallow and its effectiveness later. Evidence to support this view comes from Martin-Harris et al.[20] in a study that reports on the strong correlation between oral and pharyngeal onsets and offsets and the inability to separate them into their more traditional oral and pharyngeal phases because of high interdependence. The Martin-Harris team indicates that attention must be given to the underlying physiologic impairment that causes an abnormality in timing and bolus flow in order to better characterize a deficit in swallowing. Furthermore, a reliable method of quantifying the physiological aspects of a swallow (e.g., tongue mobility) must be established, outside of measurements of time, in order to make accurate conclusions about any type of intervention that has an effect on swallowing[20].

As previously mentioned, there are limitations in the research on head and neck cancer especially in terms of homogeneity of the patient population, characterization of changes in function over time and the use of a patient as their own control. We know that the tongue plays a crucial role in the physiological events that produce a safe and effective swallow and more research is needed to define and quantify the deficits in mobility following surgical treatment for oral cancer. Hence, the purposes of this study were to:

1. Report any impairment in the swallowing ability of patients following resection and reconstruction of the anterior 2/3rds of the tongue
2. To measure and characterize tongue mobility in this patient population.

3. To characterize the observations from 1) and 2) across time to determine the progression of outcomes in this patient population.

Hypotheses

Based on the literature reviewed for this study, the following hypotheses were made:

1. That the videofluoroscopic evaluations used to assess the qualitative aspects of swallowing function following resection and reconstruction of the anterior 2/3rds of the tongue would reveal some observable problems with swallowing. This hypothesis was based on the studies that reported swallowing impairments in the patient population being studied following surgical treatment for oral tongue cancer[2-4,8,14,18]
2. That cephalometric-based analysis of still images from the videofluoroscopic records would reveal that tongue mobility (i.e., superior-inferior movement at the mid-point of the oral tongue and superior-posterior movement at posterior-point of the oral tongue) during swallowing would decrease following resection of the anterior 2/3rds of the tongue and microvascular reconstruction. This assumption was made under the guidance of the Hara article in which measures of tongue mobility were significantly reduced in this patient population than in the control group[3].
3. That the observations for both 1) and 2) would be recorded as being the most deficient at the first post-operative measure with progress toward

more normal patterns of swallowing function and tongue mobility being made, and possible return to near baseline measures by the patients' one-year assessment records. Support for this hypothesis came from studies that recorded improvements in measures of swallowing function and observable tongue mobility as more time elapsed post-operatively[2,15,18].

METHODS

Participants

This study was approved by the Human Research and Ethics Board at the University of Alberta. The medical records of patients who underwent tongue resection and reconstruction at the University of Alberta Hospital followed by functional assessment and follow-up at the Craniofacial Osseointegration and Maxillofacial Prosthetic Rehabilitation Unit (COMPRU) were reviewed to determine whether they met the proposed study's inclusion or exclusion criteria. The experimental group consisted of patients with resection to the anterior two-thirds of the tongue, with or without resection to the floor of mouth, followed by microvascular reconstruction using a radial forearm free flap. Exclusionary criteria included any resection to the base of the tongue, the mandible, the maxilla, the soft palate, the pharynx or the larynx. Adjuvant radiotherapy was not considered exclusionary. Swallowing and tongue mobility data from four evaluation times (pre-operative and 1-, 6- and 12-months post-operative) were analyzed for this group to describe changes that occurred throughout the course of treatment and recovery. Based on the patient files, any patient who missed more than one evaluation time was excluded from the study. In addition to using a within-subject design to document changes in deglutition and tongue mobility across time, a comparison patient group also was used to determine whether the experimental group demonstrated swallowing or tongue mobility problems prior to undergoing treatment. The comparison group consisted of patients with nasopharyngeal cancer who had undergone pre-intervention assessments at COMPRU. These patients had been seen previously within COMPRU for clinical assessment, and had records of modified barium swallow studies stored within the clinic. Because patients with nasopharyngeal cancer do not have a lesion within the tongue body, it was theorized that they would present clinically with an essentially normal swallow before any oncological intervention is initiated. Support for this theory comes from studies that have documented pre-treatment swallowing ability in head and neck cancer patients. One team reported that, prior to commencing treatment for nasopharyngeal cancer, patients perceived very minimal to no problems in oral and pharyngeal symptoms. The evaluation included reporting on: oral ulcers; swelling of the parotid glands; dry mouth; taste change; difficulty opening mouth and/or swallowing; hoarseness; and sore throat, teeth and/or gums[21]. Logemann and colleagues found that, before chemoradiation, patients with nasopharyngeal cancer had 100% oral intake with no instances of aspiration on any swallowing task[22]. Finally, another study assessed pre-treatment swallowing function of patients with sinonasal and nasopharyngeal carcinoma as a comparison group for patients with head and neck cancers that affected the structures of the oral and oropharyngeal cavities[23].

This team of researchers found that the nasopharyngeal comparison group had the best mean scores on the Swallowing Performance Status Scale (SPSS). In the Stenson study, the majority of patients in the nasopharyngeal comparison group were within normal limits on the SPSS with no modifications or precautions necessary for safe swallows. Additionally, the percentage of patients without oral impairments was higher in the nasopharyngeal group than the group with lesions located in the oral cavity[23]. These findings justified the use of a nasopharyngeal comparison group to characterize the pre-treatment deficits in swallowing function and tongue mobility for the patient population observed in the present study.

Instrumentation

Each participant who met the inclusion criteria of the study had his or her videofluoroscopic records studied for measures of tongue mobility and swallowing function. Videofluoroscopic images were recorded and analyzed with a KayPentax Digital Swallowing Workstation (Model 7200, Lincoln Park, NJ). The recordings were completed with a radiologist in the Diagnostic Imaging and Radiology Department at the Misericordia Community Hospital. Three consistencies of food were given to each patient, including: water mixed with liquid barium (Polibar Plus liquid, barium sulfate suspension, Therapex) in a 3:1 ratio; approximately 10 cc pudding mixed with paste barium (Esobar, barium sulfate cream, Therapex) in a 3:1 ratio; and ¼ of a Digestive cookie coated with barium paste. Two trials of each consistency were consumed while videofluoroscopic recording took place. The liquid bolus was presented in a cup and patients were instructed to take a normal mouthful of the liquid and swallow it. Pudding was presented on a teaspoon by the examiner and patients were instructed to clear all material from the spoon and swallow it. The ¼ piece of cookie was handed to each patient; they were asked to chew and swallow the whole piece. All patients consumed as many of the 3 consistencies of food as possible, with some consistencies excluded for certain patients because of anatomical constraints (i.e., absence of dentition) or clinician-perceived clinical risk to the patient.

Measures of Swallowing Function

Within this study, key clinical markers for evaluation of a safe and effective swallow were documented. Using previously-described guidelines for what constitutes a normal swallow,[19,24] the researcher answered the following questions to determine the nature of this group's swallowing ability for all three consistencies administered during the videofluoroscopic evaluation:

- *Question 1:* Did the patient have trouble touching the tongue tip to the alveolar ridge in order to hold the bolus within the oral cavity?
- *Question 2:* Was there premature spillage of the bolus into the pharynx because the base of the tongue didn't touch the soft palate prior to the onset of posterior bolus movement?

- *Question 3:* Was tongue to hard palate contact incomplete as the tongue pushed the bolus posteriorly in preparation for the start of the pharyngeal phase?
- *Question 4:* Did the hyoid remain in its resting position at or after the time the bolus passed the most superior line of the ramus of the mandible?
- *Question 5:* Was there an absence of superior hyo-laryngeal excursion thereby leaving the airway vulnerable as the bolus moved toward the esophagus?
- *Question 6:* Was nasal regurgitation present due to incomplete soft palate elevation?
- *Question 7:* Was there poor contact between the base of the tongue and the posterior pharyngeal wall after the bolus entered the pharynx?
- **Question 8:* Was the patient unable to attempt the cookie bolus?
- **Question 9:* Was the ability to form a cohesive bolus with the cookie impaired?
- **Question 10:* Was water required to move the cookie bolus into the esophagus?
- *Question11:* How many additional swallowing attempts after the first swallow did the participant require to clear the oral and pharyngeal cavities following administration of a single bolus?
- ***Question 12:* What was the patient's score on the penetration/aspiration scale?

See Appendix A for a comprehensive data checklist.

(*) questions are relevant only to the cookie bolus.

See (**) Appendix B for a description of the Penetration-Aspiration Scale.

The questions outlined above assisted with a description of swallowing function. Questions 1 to 10 required yes or no answers; each "yes" answer counted as one point toward a total swallowing score and indicated a form of impairment in swallowing function or deviation from what would be expected in a typical evaluation. Question 11 was rated as one point for every additional swallowing attempt (following the first) that was required to clear the bolus. Scores given for question 12 were equivalent to the patient's rating on the penetration/aspiration scale. Following these scoring guidelines, a person with a completely unimpaired swallow would have been expected to have a score of zero whereas a maximally impaired person swallowing a cookie bolus might have had a score of 20. This hypothetical maximum score would be based on 2 additional swallowing attempts to clear the bolus following the first, a score of 8 on the penetration-aspiration scale as well as impairment on all of the other swallowing function variables. The total score allowed the researcher to see the total combined deficits in a patient's swallowing outcomes and also compare how the total score changed across the different evaluation points.

In addition to the *total swallowing score*, sub-scores of swallowing function were created in order to determine the outcomes for a specific portion or phase of a patient's swallow and to see if any patterns arose within the sub-scores that may have contributed directly to a higher overall total swallowing score. Separate sub-scores were calculated for each food consistency. The sub-scores included:

1) *Total Oral Score* – defined as the sum of scores for questions 1 to 3 for liquid and pudding boluses and the sum of scores for questions 1 to 3 and 8 to 10 for the cookie boluses. A score of 3 for liquid or pudding boluses and 6 for cookie boluses on the total oral sub-score would have indicated the patient was impaired on all aspects of oral swallowing function.
2) *Total Elevation Score* – defined as the sum of scores for questions 4, 5 and 12 for all consistencies. A score of 9 on the total elevation sub-score would have indicated maximal impairment for hyolaryngeal movement and airway protection during the swallow.

Measures of Tongue Mobility

Still-images from each patient's swallowing evaluation, while they were filmed in the lateral view, were used to measure tongue mobility. Evaluation of tongue mobility was completed for pudding swallows only. In pilot work, this consistency was judged by the researcher to be superior to a thin bolus for providing clarity when assessing the tongue movements in question. Furthermore, clinician report from COMPRU revealed that the pudding bolus was more frequently administered than the cookie bolus as many patients were unable to masticate the cookie consistency due to lack of dentition. Using frame-by-frame slow motion advancement, 3 points in each patient's swallow were identified for measures of tongue mobility to take place:

- The *Start of the Swallowing Sequence (SOS)*: defined as the first moment the patient has withdrawn the spoon from his or her mouth and fully accepted the bolus into the oral cavity.
- The *Onset of Posterior Bolus Movement (OPM)*: defined as the first upward movement of the tongue in preparation to send the bolus towards the pharynx.
- As *the Bolus Head Passed the Ramus (HPR)*: defined as the first image where any portion of the bolus head has passed the ramus of the mandible.

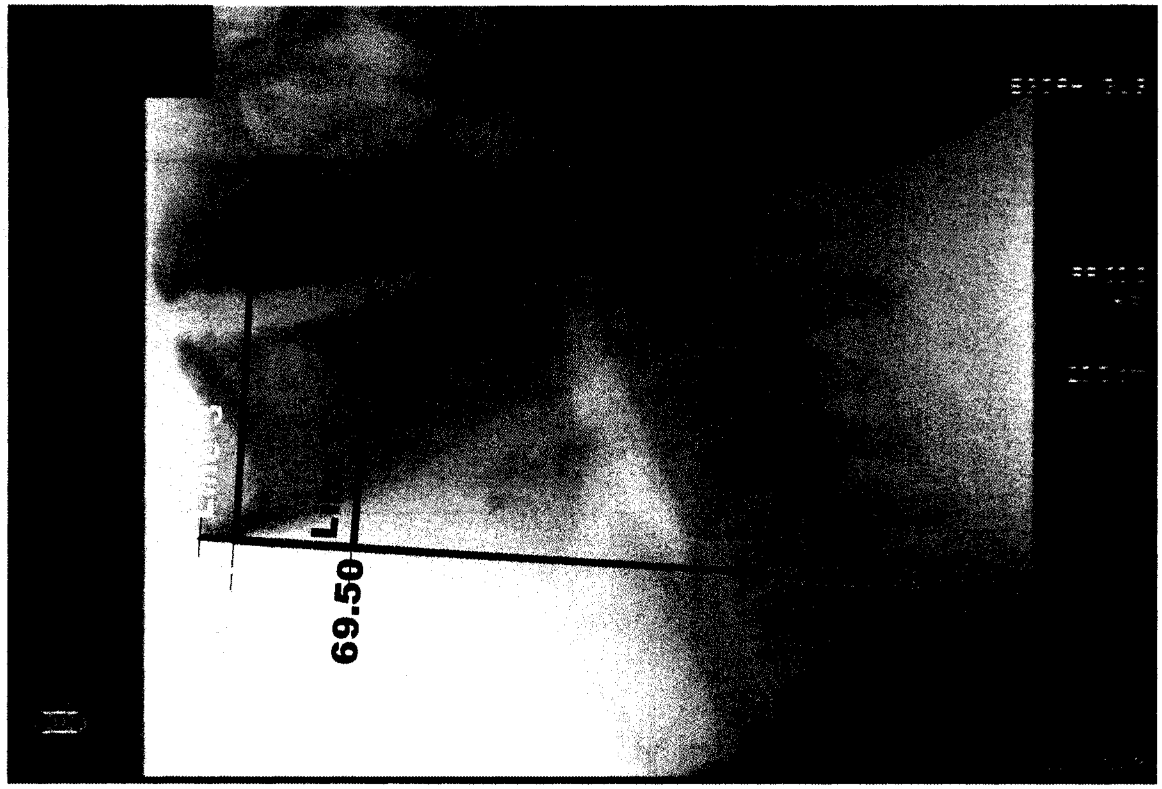
Once each frame of interest was identified and catalogued appropriately, it was exported and saved as a j-peg image within the KayPentax system. This jpeg image was opened in CorelDraw Version 9. Within CorelDraw, the researcher imposed a system of specific grid lines that allowed for the measurements of tongue mobility to be calculated.

Choosing the gridlines to establish the measurements of tongue mobility was based in part on previous research by Hara and colleagues[3] and also on concepts pertinent to cephalometry. One notable study in the field of cephalometry was completed by Malkoc et al. where they reproduced tongue and hyoid positions using concepts from cephalometric analysis with a significant degree of success[25]. Both of the aforementioned teams of researchers used anatomical landmarks to ensure continuity in their measurement systems. The landmarks and imposed grid lines within each image of the specified points in the patients' swallows in this study are described below and illustrated in *Figures 1 & 2*:

<u>Mid-Tongue Mobility</u> (See Fig. 1)

- *Line 1*: a straight line drawn from the intersection of the anterior wall of the maxillary sinus and the plane of the nasal surface of the hard palate running posteriorly along the superior surface of the hard palate to the anterior portion of the first cervical vertebrae.
- *Line 2*: a straight line parallel to line 1 that stretched from the most anterior-inferior tip of the mandible to the most anterior part of the vertebral column (approximately the fifth cervical vertebrae depending on the angle of the line).
- *Line 3*: a line that was perpendicular to and connected lines 1 and 2 in the most anterior position possible.
- *Line 4*: a line that was perpendicular to line 3 but ended at a distance of approximately one-third the length of line 1 and demarcated the most superior line of the tongue. This line was intended to identify the mid-tongue point of reference.
- *Line 5*: a line that extended from line 2, perpendicularly, to meet the tip of line 4 where it demarcated the superior line of the tongue.

Figure 1 – Sample of Mid-Tongue Mobility Gridlines



<u>Posterior-Tongue Mobility</u> (See Fig. 2)

- *Line 1*: a straight line which was drawn from the most anterior tip of the maxillary alveolar ridge to the most anterior-inferior tip of the third cervical vertebrae.
- *Line 2*: a straight line that intersected and was perpendicular to line 1 at its midpoint and stretched upward to most superior point on the posterior tongue.

Figure 2 – Sample of Posterior-Tongue Mobility Gridlines

All lines were measured in millimeters.

Assessment of mid- and posterior oral tongue mobility was predicted to be revealing in terms of highlighting restrictions in movement as these portions of the tongue are directly affected by surgical resection and reconstruction. In pilot work the anterior tip of the tongue proved to be the most difficult to outline and unreliable to measure due to visual obstruction (i.e., from the teeth or the bolus) or unintentional diagnostic imaging omission (i.e., the anterior tip of the tongue was not in full view). To determine mobility of the mid-tongue, a ratio value was calculated by dividing line 5 by line 3. This ratio describes superior-inferior movement of the mid-tongue and was compared across evaluations in order to determine mobility that had been gained or lost pre- or post-surgery. *Figure 1* depicts the grid for measuring mid-tongue mobility as described above; the length of line 5 as illustrated is 69.50 mm while the length of line 3 is 84.55 mm. The calculated ratio is 0.82 which is equivalent to the measure of mid-point tongue mobility for the patient in question. To determine mobility of the posterior-tongue, a ratio was needed that encompassed superior-posterior movement. For this reason, the calculated ratio compared the horizontal aspect to the vertical aspect; thus, line 2 was divided by line 1. In *Figure 2* above, the length of line 1 is 116.26 mm while the length of line 2 is 29.75 mm. The calculated ratio for posterior tongue mobility of *Figure 2* is .26.

Overall, it was expected that better tongue mobility for both the mid- and posterior portions of the tongue would be indicated by higher ratio values, whereas decreased mobility would result in smaller ratio values. All final ratio values, in conjunction with the relationships of each of the lines within the grid, accounted for any differences in image sizes due to increased or decreased distances between the patient and the recording device across evaluations.

Data Analysis

Swallowing Data Preparation

The video and still-images used to measure swallowing function and tongue mobility for both patient groups were selected by an independent research associate in the supervisor's laboratory who was familiar with the instrumentation and the study protocol, and for whom COMPRU's confidentiality agreement was already in effect. As appropriate video and images were identified, they were exported and saved within the KayPentax system. The research associate was responsible for removing all identifying information from the file names and cataloguing them so as to provide randomization to the researcher. Removal of identifying and contextual information allowed the researcher to be blinded to as many details as possible, including: whether the patient belonged to the experimental or comparison group; the point in the swallowing sequence from which the image was taken; and the point in treatment at which the evaluation occurred. This blinding procedure was used to circumvent observer bias. Once the selections were randomly organized, they were provided to the researcher for final assessment and measurement.

Reliability

In addition to the blinding procedure, reliability was addressed in the following ways:

1) First, the research associate randomly duplicated 20% of the continuous swallowing films and 15% of the j-peg still-images that were selected for study from the original patient videofluoroscopic evaluations. The associate removed all identifying information from the still images and video, catalogued them – making sure to note in the key that they were duplicates – and returned the images for further analysis by the researcher. This provided a means to calculate intra-rater reliability of the researcher on measures of swallowing function and tongue mobility.

2) Another research associate used the swallowing function questions and mobility measurement guidelines to assess swallowing function and measure tongue mobility from the re-duplicated video and still-images. The data from this research associate were used to calculate inter-rater reliability.

Intraclass correlation coefficients (ICCs) were used to calculate intra- and inter-rater reliability. The researcher used a two-way mixed model with absolute agreement which is the model appropriate for calculating reliability between a known and specific number of raters who rated all subjects in a sample. The variability among the raters is accounted for and considered relevant in this model however the inferences that can be made are confined to those raters alone. Single measures ICCs were used for all variables except for those where comparisons were made between summed scores or measurements, in which case average measures ICCs were used. At times, the researcher was unable to calculate an ICC. This occurred for two main reasons:

1) ratings in a particular data set were constant or;

2) minimal to no variance could be calculated between the two data sets.

In these instances, a percent agreement was calculated by dividing the number of absolute agreements between raters by the total number of cases in the data set.

Missing Data

Following completion of collection and organization of the data it was noted that several cells, particularly for tongue mobility, were empty. Missing data occurred for one of the following reasons:

1) The patient missed the evaluation point and thus, no information for that session was available at that point in time.
2) The landmarks necessary for creating the grid to measure tongue mobility were cut off during the videofluoroscopy or difficult to determine with any degree of certainty due to poor image quality and thus gridlines could not be established.
3) The tongue position was not adequately visible due to poor contrast or obstruction and thus, could not be measured.

In order to deal with missing data, the following strategies were implemented:

1) If a patient was absent from an evaluation period being used in a comparison, his or her data were removed entirely from that analysis. For example, if the subject x was absent from the 1 month post-operative evaluation and the researcher was comparing pre- and 1 month post-operative measures, none of subject x's data would be included for either time period.
2) If more than 40% of a data set for swallowing function or tongue mobility for any one particular patient was missing at any evaluation period being used in a comparison, then the subject's data were removed from that analysis.

3) If less than 40% of a subject's data in a set were missing at one evaluation time then a series mean value, calculated from the values of all remaining subjects, was inserted in order to fill the empty cell and carry out the analysis.

These strategies were found to be most effective for managing missing data and were used as required.

Swallowing Function

To analyze the data for measures of swallowing function, the researcher completed statistical analyses that were appropriate for a one-way, within-subject, repeated measures, prospectively-collected data design. There was one factor (evaluation time) with 4 levels (pre-operative, 1-, 6- and 12-months post-operative) to be considered for analysis. The data for *total swallowing* function and the sub-scores of *total oral* and *total elevation* were analyzed using independent samples t-tests. Each food consistency was analyzed separately in order to account for the subjects who were unable to complete the swallowing tasks for some consistencies of food during the swallowing protocol. This type of statistical analysis allowed for the most complete picture of swallowing function to be reported as it kept subject data where it might otherwise have been discarded due to missing information.

A total of 6 comparisons for each food consistency were made: pre-operative versus 1-month post-operative (T1 vs. T2); pre-operative versus 6-months post-operative (T1 vs. T3); pre-operative versus 12-months post-operative (T1 vs. T4); 1-month post-operative versus 6-months post-operative

(T2 vs. T3); 1-month post-operative versus 12-months post-operative (T2 vs. T4); and 6-months post-operative versus 12-months post-operative (T3 vs. T4). A Bonferroni adjustment of the alpha value was done in order to account for family-wise error (p/6 = .008).

Tongue Mobility

For tongue mobility data, the researcher completed statistical analyses that were appropriate for a one-way, within-subject, repeated measures, prospectively-collected data design. There was one factor (evaluation time) with four levels (pre- operative,1-,6-, and 12-months post-operative) to be considered for analysis. A separate analysis was completed for both the mid-tongue mobility and posterior-tongue mobility measures. There were three dependent variables in each analysis (ratio at SOS, ratio at OPM, and ratio at HPR). This research design allowed the researcher to independently test the two different points on the tongue, at all the points in the swallowing sequence, in 6 different intervals of time. The 6 comparisons for each measure of tongue mobility included: pre-operative versus 1-month post-operative (T1 vs. T2); pre-operative versus 6-months post-operative (T1 vs. T3); pre-operative versus 12-months post-operative (T1 vs. T4); 1-month post-operative versus 6-months post-operative (T2 vs. T3); 1-month post-operative versus 12-months post-operative (T2 vs. T4); and 6-months post-operative versus 12-months post-operative (T3 vs. T4). Once all the analyses were complete, a Bonferroni adjustment of the p-values was performed in order to account for family-wise error and determine whether the results for measurements on either point on the tongue were significant ($p/6 = .008$).

Pre-Operative Group Comparison

In addition to the aforementioned analyses, both swallowing function and tongue mobility had a between-group component for the data taken at the pre-operative evaluation point (i.e., at baseline). The data for swallowing function at baseline were analyzed using statistical tools appropriate for a multivariate one-way, between-subject, prospectively-collected data design. The factor (group) had 2 levels (oral cancer and nasopharyngeal cancer). The dependent variables in the analysis were the *total swallowing function score* and the *oral and elevation sub-scores.* As with the other data on swallowing function, each food consistency was analyzed separately in order to account for subjects who were unable to complete all levels of the swallowing protocol. Paired sample t-tests were used to compare the swallowing function values between each group.

For the measures of tongue mobility, the researcher completed statistical analyses that were appropriate for a multivariate one-way, between-subject, prospectively-collected, data design. The factor (group) had 2 levels (oral cancer and nasopharyngeal cancer). Separate analyses were run for mid-tongue and posterior-tongue mobility. The dependent variables in the analyses were the ratio at SOS, ratio at OPM and ratio at HPR. Multiple analysis of variance (MANOVA) tests were run to determine the differences in tongue mobility between the two groups at baseline.

RESULTS

Demographics

Following comprehensive chart reviews of those patients who underwent functional assessments at COMPRU prior to and following surgical resection and reconstruction of the anterior 2/3rds of the tongue, it was determined that 16 people met this study's inclusion criteria for the oral-tongue cancer group. There were 8 women and 8 men. Their ages ranged from 29 to 76 years old (median = 61, mean = 57). T-Stages included: T2 (n=12) and T3 (n=4). The degree of resection was between 50-75% of the anterior 2/3rds of the tongue. All but one of the subjects had at least a portion of the floor of mouth resected. Twelve patients had the lingual nerve preserved during surgery or were reconstructed with a sensate flap. Six out of the 15 patients had radiation therapy which started and ended sometime between 1-month and 6-months post-operative evaluation periods. One (1) subject in this group was excluded from the study after it began due to extremely poor visibility of the videofluoroscopic evaluations and an inability to measure swallowing function or tongue mobility with any degree of accuracy. At the study's end there were 15 subjects in the oral-tongue cancer group. *Table 1* outlines the subject information for the oral cancer group.

Table 1 – Oral Cancer Group Demographics

PT. #	AGE	SEX	T STAGE	% ORAL TONGUE	SIDE OF RECONS-TRUCTION	SENSATE	RT
1	39	M	T2	50	Right	Yes	No
2	38	M	T2	50	Right	No	Yes
3	69	F	T2	50	Left	Yes	No
4	71	F	T2	50	Left	Yes	No
5	55	F	T2	50	Right	Yes	No
6	70	F	T3	75	Right	Yes	Yes
7	59	M	T3	50	Right	Yes	Yes
8	43	M	T2	50	Right	Yes	No
9	63	M	T3	50	Left	Yes	Yes
10	42	M	T2	50	Left	Yes	Yes
11	67	M	T2	50	Left	No	No
12	72	F	T2	50	Left	Yes	No
13	69	F	T3	75	Left	Yes	Yes
14	76	F	T2	50	Right	Yes	No
15	29	F	T2	50	Left	No	No

The comparison nasopharyngeal cancer group consisted of 14 subjects. There were 3 women and 11 men. Their ages ranged from 32 to 73 years old (median = 48.5, mean = 50). T-Stages were not available. None of the nasopharyngeal cancer group had undergone any form of cancer treatment prior to their evaluations. Additionally, none of the nasopharyngeal cancer group had lesions present in any area outside of the nasopharynx. No one in the comparison group was excluded from the study following its inception.

Swallowing Function

The procedures used for missing data allowed the researcher to maximize the number of subjects that could be included in any given statistical comparison but also created variation in the number of subjects that remained in every comparison between different evaluation periods. The data for swallowing function required no imputation. *Table 2* shows the number of subjects that remained for each comparison under every consistency of food trialed as well as the p-values for every comparison done of the *total swallowing scores* and the *total oral* and *total elevation sub-scores*. No statistical analyses were done on the data for the cookie bolus due to low group numbers on each comparison and thus, no p-values are given.

Table 2 – Swallowing Function: Number of subjects remaining per comparison and resultant p-values

Measure	Comparison	Number of Subjects	P-Values		
			Total	Oral	EEA
Liquid Swallow	T1 vs. T2	n = 12	p = **.003**	p = .096	p = .009
	T1 vs. T3	n = 10	p = .051	p = .051	p = .060
	T1 vs. T4	n = 10	p = .037	p = .343	p = .026
	T2 vs. T3	n = 10	p = 1.00	p = .468	p = .693
	T2 vs. T4	n = 10	p = .443	p = .269	p = .864
	T3 vs. T4	n = 8	p = .180	p = .451	p = .019
Pudding Swallow	T1 vs. T2	n = 13	p = .721	p = .082	p = .012
	T1 vs. T3	n = 11	p = 1.00	p = 1.00	p = .074
	T1 vs. T4	n = 11	p = .343	p = .443	p = .066
	T2 vs. T3	n = 11	p = 1.00	p = .341	p = .733
	T2 vs. T4	n = 10	p = .678	p = .104	p = .196
	T3 vs. T4	n = 8	p = .351	p = .104	p = .015
Cookie Swallow	T1 vs. T2	n = 8	n/a	n/a	n/a
	T1 vs. T3	n = 5	n/a	n/a	n/a
	T1 vs. T4	n = 5	n/a	n/a	n/a
	T2 vs. T3	n = 4	n/a	n/a	n/a
	T2 vs. T4	n = 5	n/a	n/a	n/a
	T3 vs. T4	n = 2	n/a	n/a	n/a

All p-values in **bold** are significant at p/6 = .008 following the Bonferroni Correction

T1 = Pre-operative; T2 = 1-month post-operative; T3 = 6-months post-operative; T4 = 12-months post-operative

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. For the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

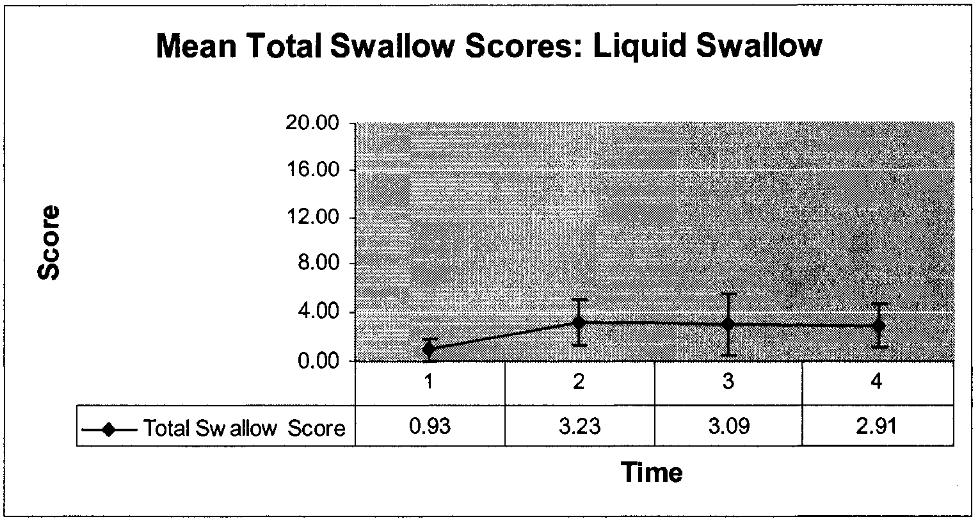
EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

To help summarize the changes in swallowing function, nine tables with corresponding figures were created in order to help identify any changes over time in the *total swallowing function scores* as well as the two sub-scores: *total* *oral* and *total elevation across all consistencies*. Please refer to *Figures 3a-c* to *5a-c* below to see the visual representations of the descriptions that follow for liquid, pudding and cookie boluses.

Liquid Swallow

The statistical analyses revealed that only one comparison for this consistency was found to be significant. Total swallowing scores differed significantly between the pre-operative and 1-month post-operative assessment time ($p=.003$). The results revealed that although the 1-month scores were relatively low when compared to the total possible impairment points, the mean total swallowing scores double from 0.93 at the pre-operative evaluation to 3.23 at the one-month evaluation. *Figure 3a-c* below illustrate the mean outcomes for swallowing function on liquid boluses.

Figure 3a – Mean Total Swallow Scores: Liquid Swallow

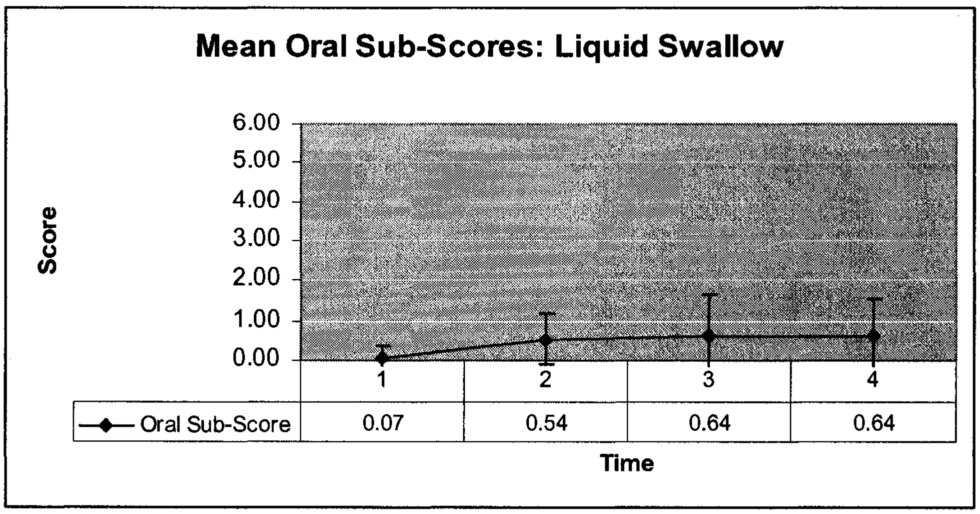


Time:

1 = Pre-operative	2 = 1-month post-operative
3 = 6-months post-operative	4 = 12-months post-operative

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Figure 3b – Mean Oral Sub-Scores: Liquid Swallow

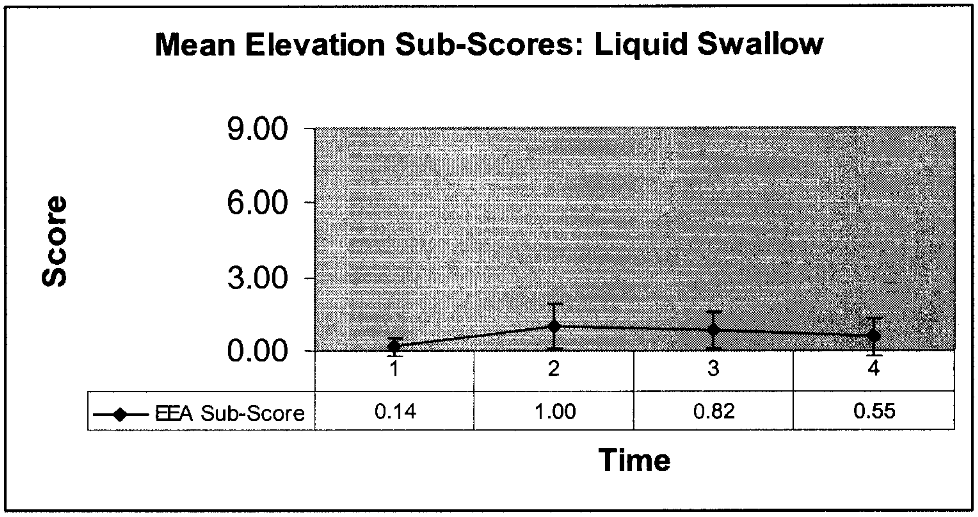


Time:

1 = Pre-operative	2 = 1-month post-operative
3 = 6-months post-operative	4 = 12-months post-operative

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

Figure 3c – Mean Elevation Sub-Scores: Liquid Swallow



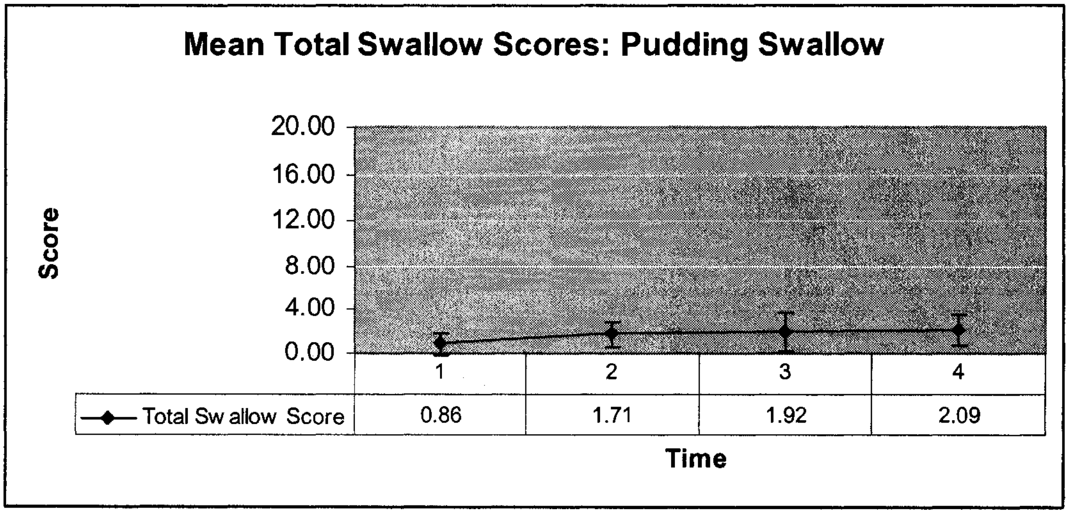
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Pudding Swallow

There were no significant differences found for any of the comparisons for the pudding swallow. *Figures 4a-c* demonstrate the mean total swallowing scores and sub-scores for this consistency.

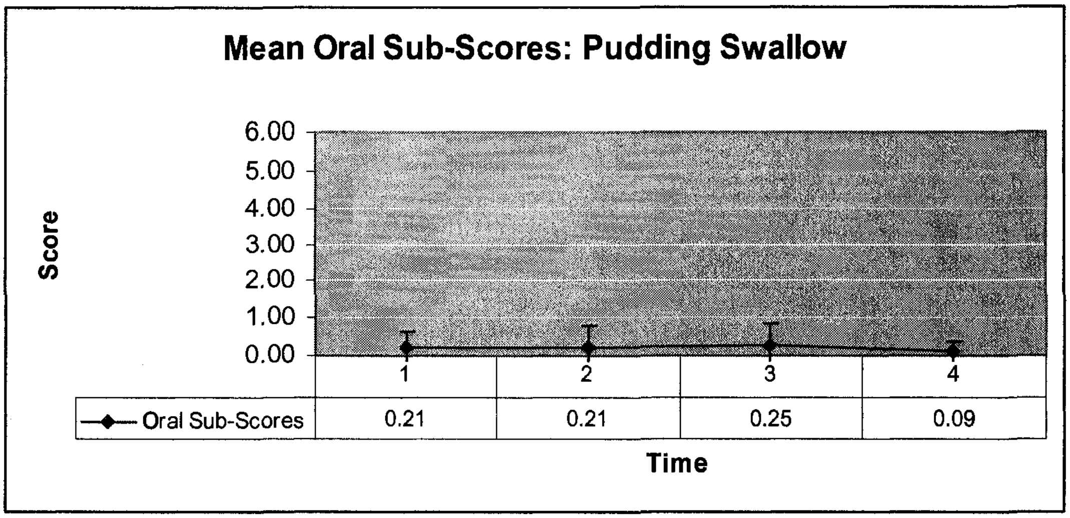
Figure 4a – Mean Total Swallowing Scores: Pudding Swallow



Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Figure 4b – Mean Oral Sub-Scores: Pudding Swallow

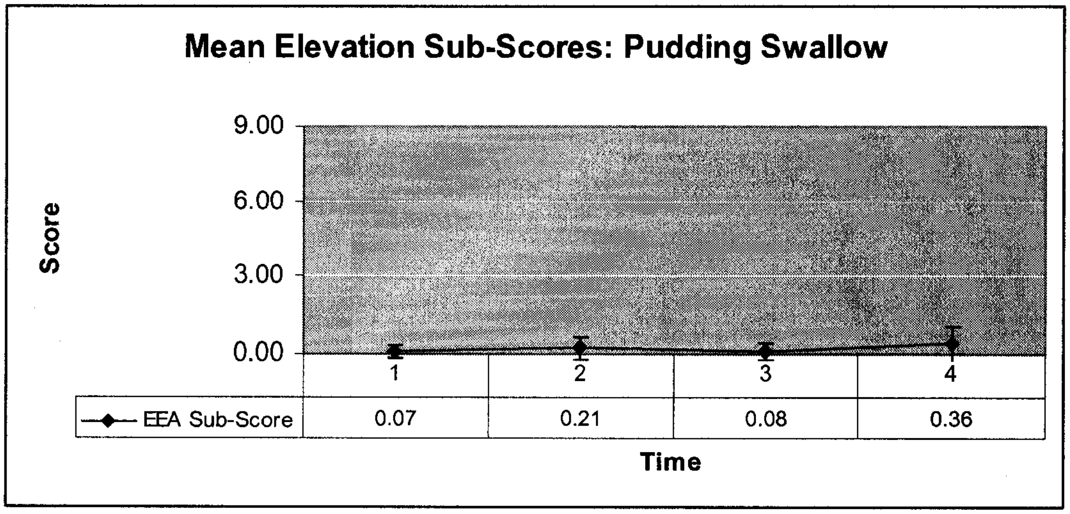


Time:

1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

Figure 4c – Mean Elevation Sub-Scores: Pudding Swallow



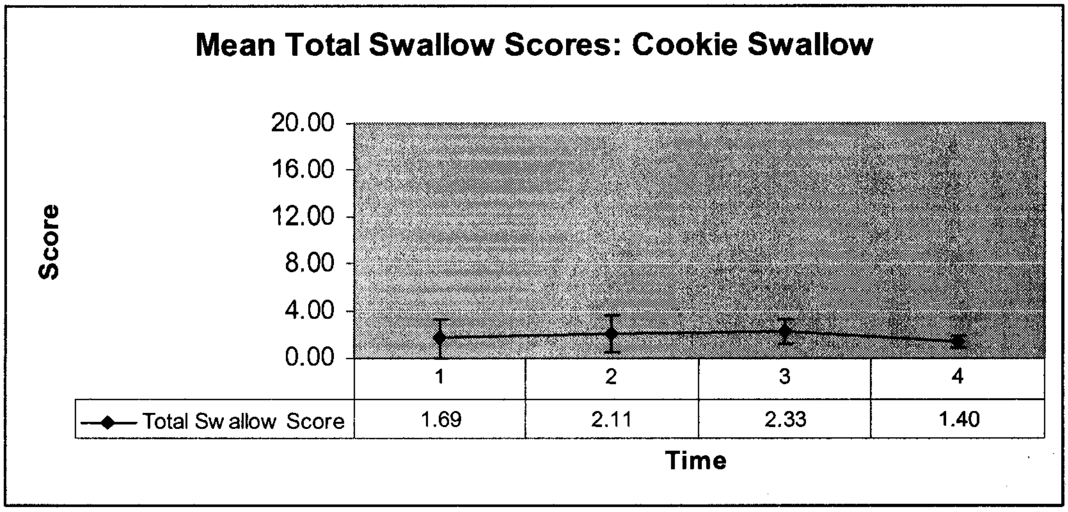
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Cookie Swallow

Since the number of subjects remaining in the comparisons for the cookie swallows was very low, no statistical analyses were completed for that set of data. The average *total swallowing score* for the cookie bolus was 1.69 at the pre-operative evaluation. The mean continued to increase at the 1- and 6-month evaluations to 2.11 and 2.33 respectively. On the final assessment at 12 months however, the mean total swallowing score decreased to 1.40 – a measure that was less than the pre-operative baseline measure (see *Figure 5a*). The mean *total elevation sub-score* was a consistent average of 0.0 across all the evaluations. The mean *total oral sub-score* was 0.46 at the pre-operative evaluation and increased just small amounts on the first and second post-operative measures. By the study's end, the mean *total oral sub-score* for cookie boluses was below baseline at 0.00.

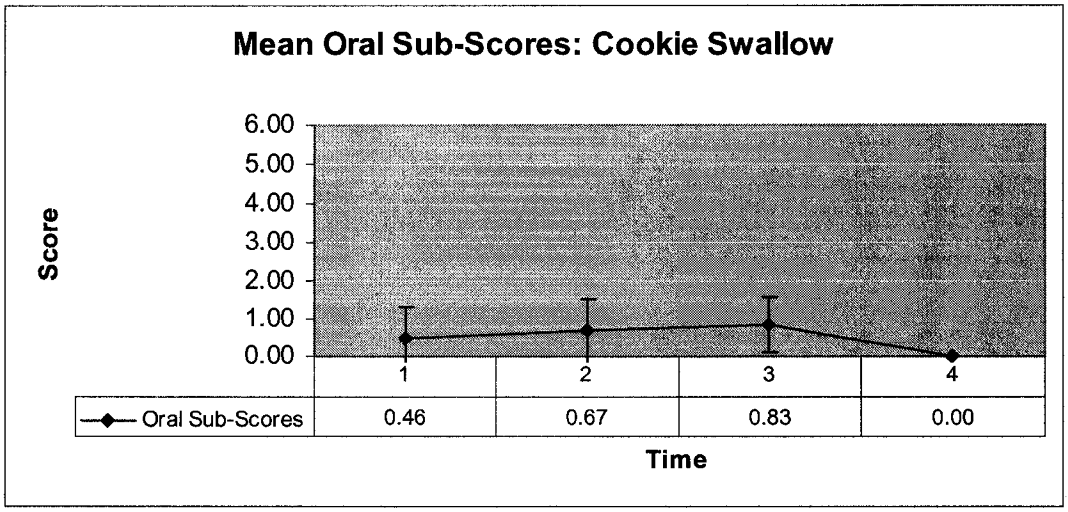
Figure 5a – Mean Total Swallowing Scores: Cookie Swallow



Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Figure 5b – Mean Oral Sub-Scores: Cookie Swallow

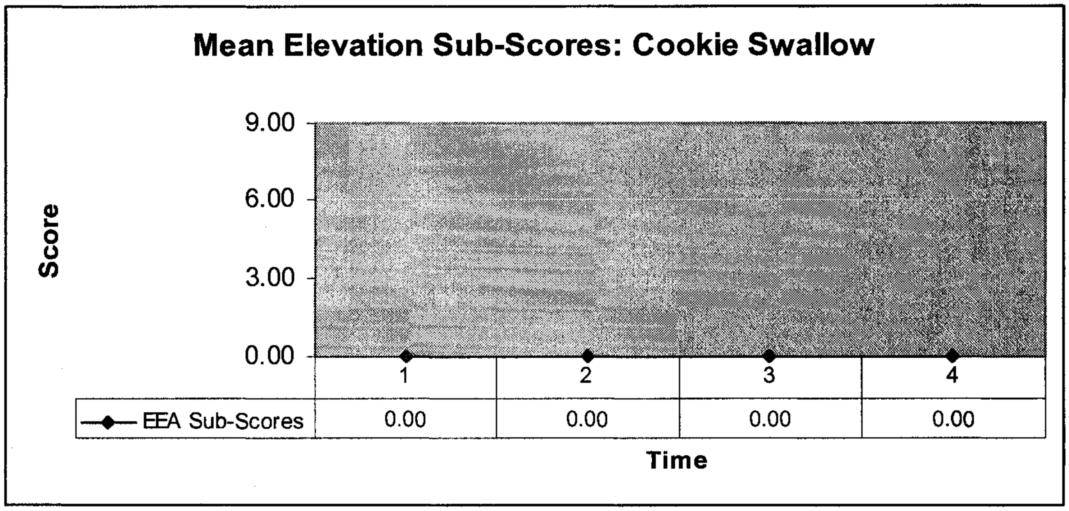


Time:

1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

Figure 5c – Mean Elevation Sub-Scores: Cookie Swallow



Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Tongue Mobility

The procedures used for missing data allowed the researcher to maximize the number of subjects that could be included in any given statistical comparison but also created variation in the number of subjects that remained in every comparison between different evaluation periods. On average the data for mid- and posterior-tongue mobility contained 3 empty or missing data points per comparison which were replaced using a series mean value (range = 0-5 replacements or 0-13% of the data). *Table 3* shows the number of subjects that remained for each comparison of mid- and posterior tongue mobility ratios as well as the p-values for every comparison done with SOS, OPM and HPR on both mid-tongue mobility and posterior-tongue mobility.

Table 3 – Tongue Mobility: Number of Subjects remaining per comparison and resultant p-values

Measure	Comparison	Number of Subjects	P-Values		
			SOS	OPM	HPR
Mid-Tongue Mobility	T1 vs. T2	n = 8	p = .268	p = .188	p = .203
	T1 vs. T3	n = 8	p = .678	p = .412	p = .472
	T1 vs. T4	n = 8	p = .449	p = .133	p = .630
	T2 vs. T3	n = 7	p = .060	p = .464	p = .946
	T2 vs. T4	n = 8	p = .737	p = .499	p = .526
	T3 vs. T4	n = 7	p = .245	p = .028	p = .182
Post-Tongue Mobility	T1 vs. T2	n = 6	p = .020	p = .176	p = **.003**
	T1 vs. T3	n = 6	p = .908	p = .092	p = .975
	T1 vs. T4	n = 8	p = .700	p = .569	p = .744
	T2 vs. T3	n = 5	p = .141	p = .928	p = .266
	T2 vs. T4	n = 6	p = .305	p = .649	p = .164
	T3 vs. T4	n = 6	p = .978	p = .035	p = .887

All p-values in **bold** are significant at p/6 = .008 following the Bonferroni Correction

T1 = Pre-operative; T2 = 1-month post-operative; T3 = 6-months post-operative; T4 = 12-months post-operative

SOS = Start of the Swallowing Sequence
OPM = At the Onset of Posterior Movement of the bolus
HPR = As the bolus Head Passed the Ramus of the mandible

To summarize the changes in tongue mobility, several graphs with corresponding figures were created in order to help identify any changes across time for the mid- and posterior tongue measurements at all three points in the swallowing pattern: the start of the swallowing sequence (SOS), the onset of posterior bolus movement (OPM), and as the bolus head passed the ramus of the mandible (HPR). Please refer to *Figures 6a-c* and *Figures 7a-c* below to see the visual representations of the descriptions that follow for mid- and posterior tongue mobility. For all measurements, a ratio that is lower in value than that obtained at baseline is considered to indicate less mobility.

Start of the Swallowing Sequence (SOS)

There were no significant differences detected between evaluation times for either mid-tongue mobility or posterior-tongue mobility at the start of the swallowing sequence. At this point in the swallow, it was observed that the mid-portion of the tongue had a slight decrease in tongue elevation at the 1-month postoperative evaluation – decreasing from .83 to .79. However, the mid-tongue mobility ratios gradually increased to nearly baseline by the study's end at 12 months with a ratio of .82. Posteriorly, a slightly different pattern was observed – superior/posterior movement was best at the pre-operative evaluation period with a ratio of .22. The ratios gradually decreased to .18 at the 6-month evaluation point and then almost returned to baseline by the 12-month evaluation time with a ratio of .20.

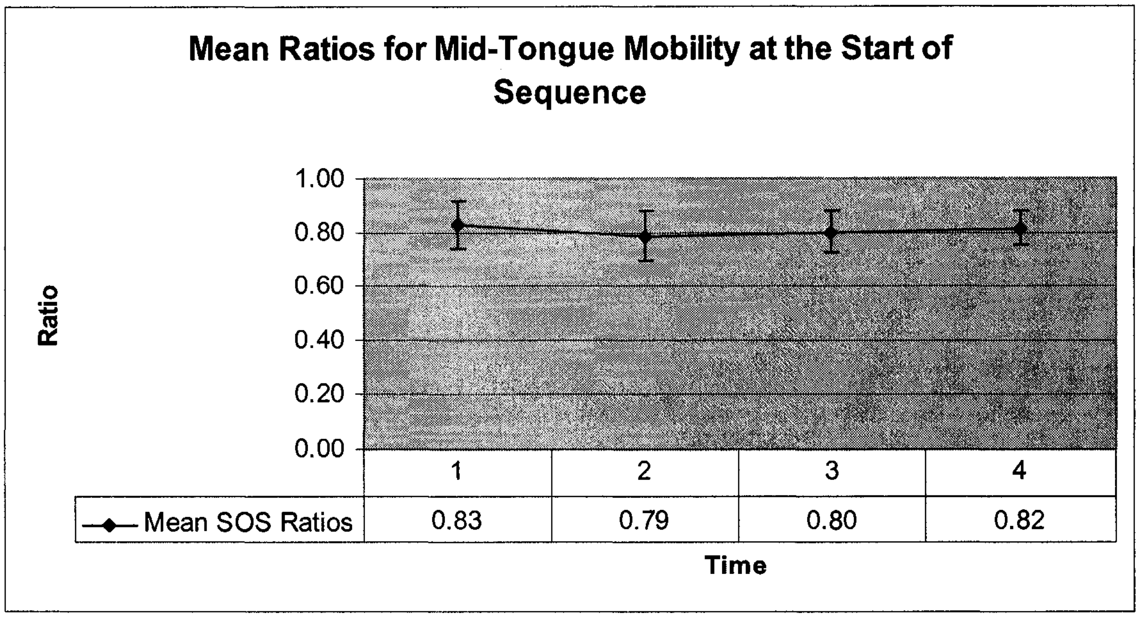
Onset of Posterior Movement (OPM)

There were no significant differences detected between evaluation times for either mid-tongue mobility or posterior-tongue mobility at the onset of posterior movement of the bolus. The results revealed that the mid-tongue elevation at this particular point in the swallowing sequence was lowest during the pre-operative measure at .69 when compared to the three measures taken post-operatively. All of the mid-tongue, post-operative measures for OPM remained relatively stable fluctuating from .80, .76 and .79 on the 1, 6 and 12 month evaluations, respectively. In terms of posterior-tongue mobility, we saw the highest ratio for superior/posterior movement during the pre-operative period at .21, and a gradual decline in the mobility measure until the 6 month evaluation where the movement increased to .19 by 12 months.

As Bolus Head Passed the Ramus (HPR)

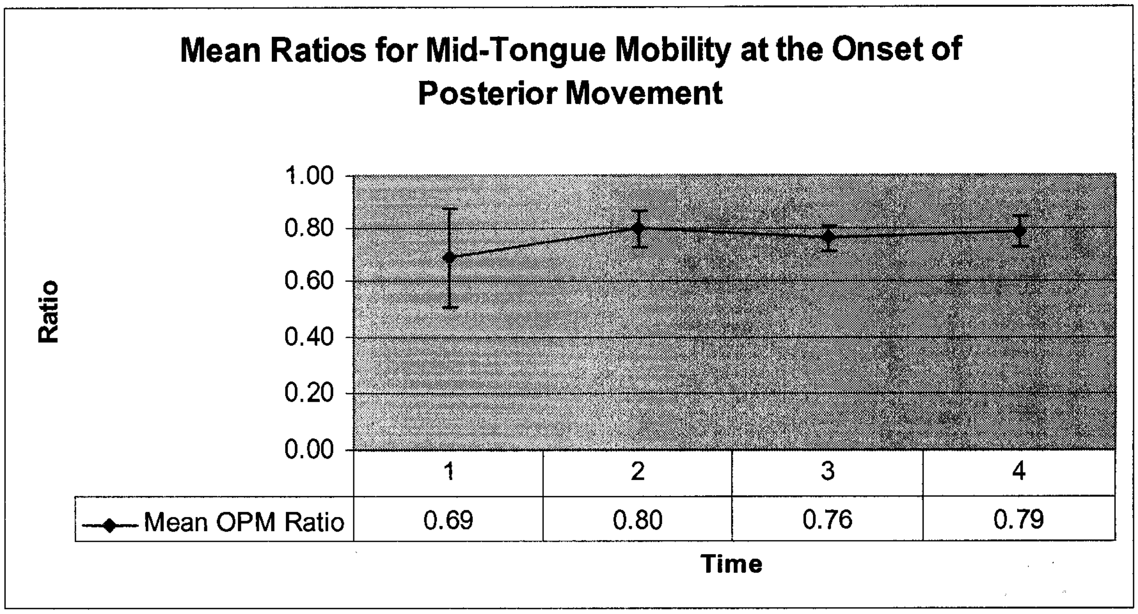
There was one significant finding detected between evaluation times for posterior-tongue mobility at this point in the swallowing sequence. Specifically, the pre-operative measures for posterior-tongue mobility were significantly different from the HPR measures taken at 1-month post-operatively ($p=.003$). Measures of posterior-tongue mobility increased from .18 pre-operatively, to .22 following surgery at the 1-month evaluation. The ratio decreased and returned to near-baseline by the 12-month evaluation at .19. On the other hand, mid-tongue mobility ratios remained relatively high and stable for all of the evaluation periods – fluctuating from .88 to .90 between the pre-operative and 1-month post-operative evaluations and finally stopping at a ratio of .88 at the 12-month evaluation.

Figure 6a – Mean Mid-Tongue Mobility Ratios at the Start of the Swallowing Sequence: Pre-operative and 1, 6, and 12-months Post-operative



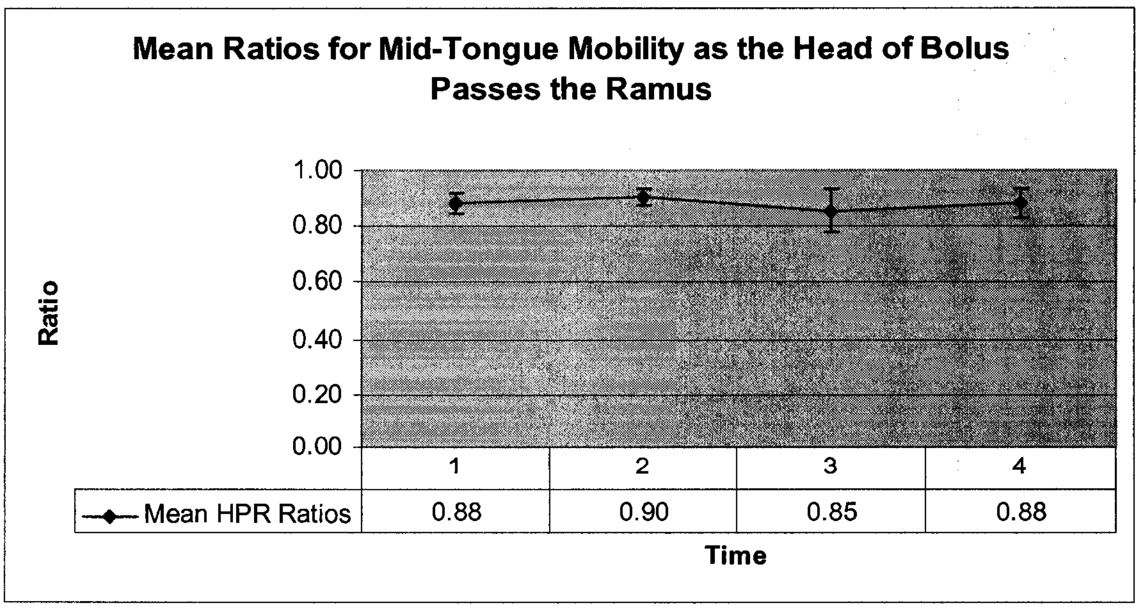
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Figure 6b – Mean Mid-Tongue Mobility Ratios at the Onset of Posterior Movement: Pre-operative and 1, 6, and 12-months Post-operative



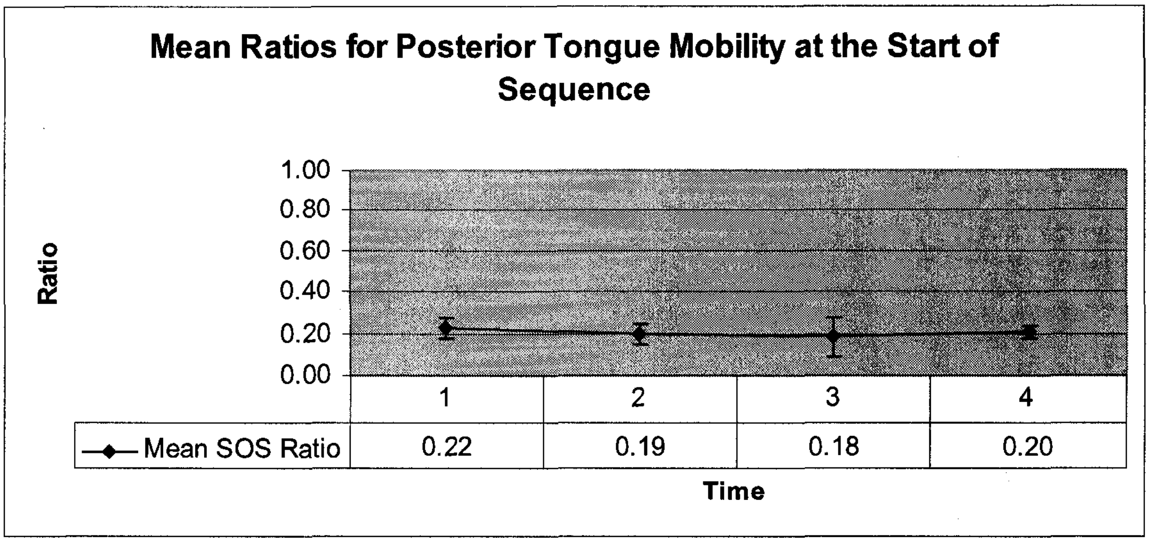
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Figure 6c – Mean Mid-Tongue Mobility Ratios as the Head of Bolus Passes the Ramus: Pre-operative and 1, 6, and 12-months Post-operative



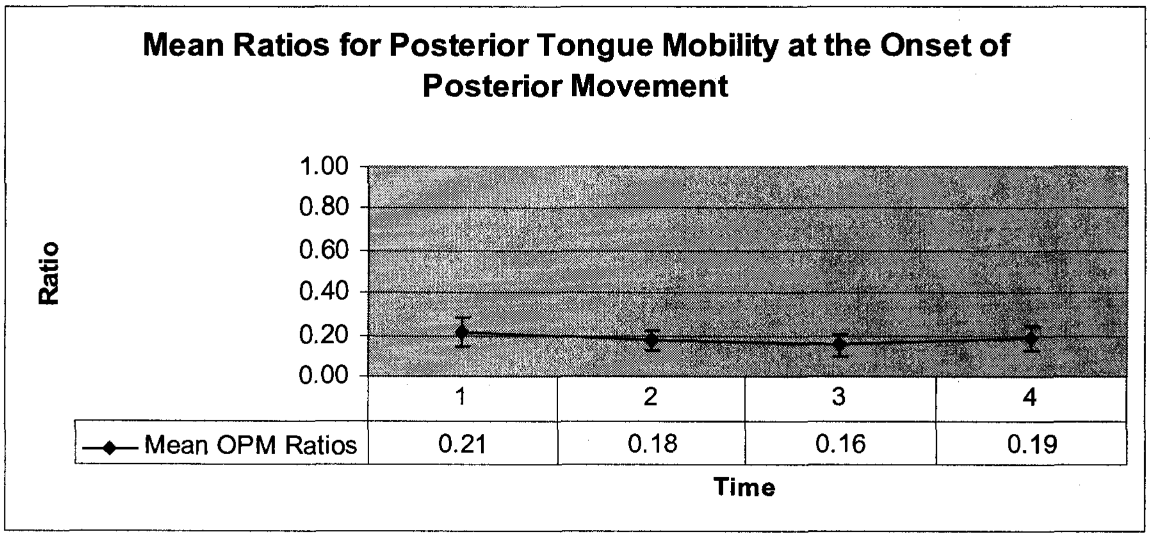
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Figure 7a – Mean Post-Tongue Mobility Ratios at the Start of the Swallowing Sequence: Pre-operative and 1, 6, and 12-months Post-operative



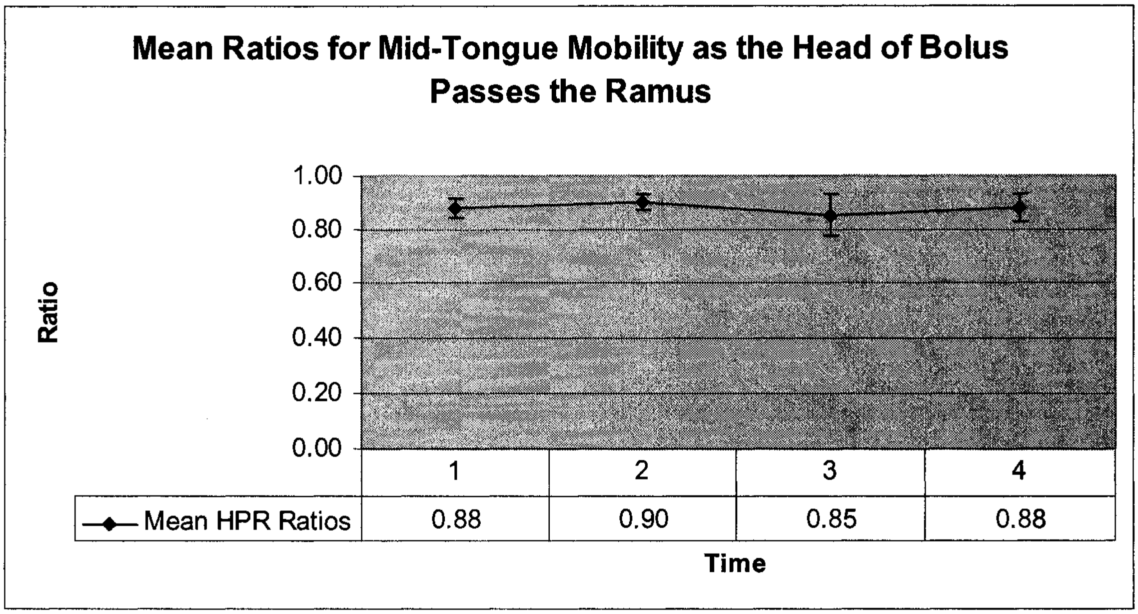
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Figure 7b – Mean Post-Tongue Mobility Ratios at the Onset of Posterior Movement: Pre-operative and 1, 6, and 12-months Post-operative



Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Figure 7c – Mean Post-Tongue Mobility Ratios as the Head of Bolus Passes the Ramus: Pre-operative and 1, 6, and 12-months Post-operative



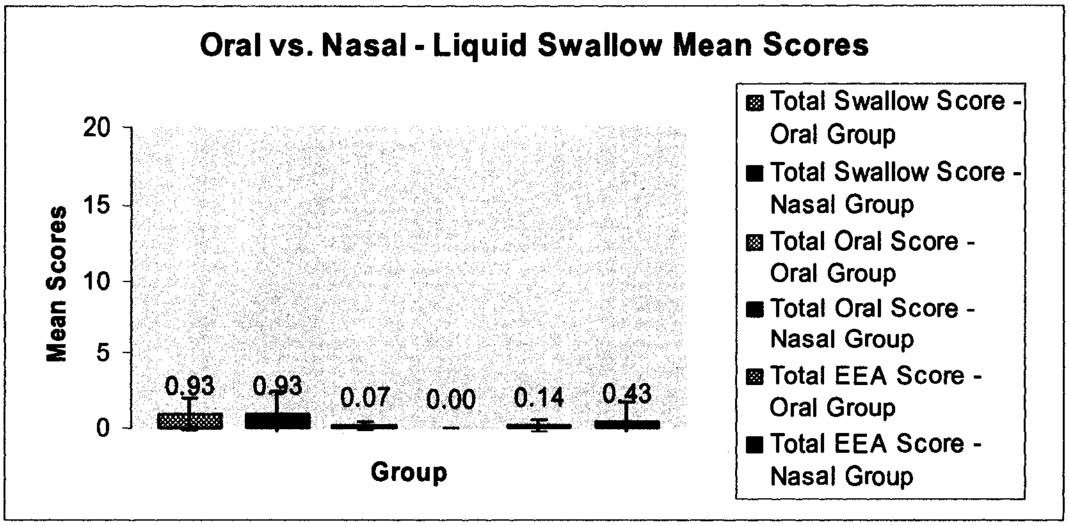
Time:
1 = Pre-operative
2 = 1-month post-operative
3 = 6-months post-operative
4 = 12-months post-operative

Pre-Operative Group Comparison

Swallowing Function

On the tests of pre-operative swallowing function between the oral and the nasopharyngeal cancer groups the same number of subjects remained in both groups for the liquid and pudding consistencies (n=14) and the cookie consistency (n=13). *Figures 8* to *10* below display the means for comparison of both groups on the *total swallowing scores* and the sub-scores: *total oral* and *total elevation*. The data are displayed for all consistencies. Both groups looked very similar in terms of overall swallowing results. No significant differences were found between the two groups, on any consistency, on multivariate analyses.

Figure 8 – Oral vs. Nasal Group Comparison for the Mean Liquid Swallowing Function Scores: Pre-operative



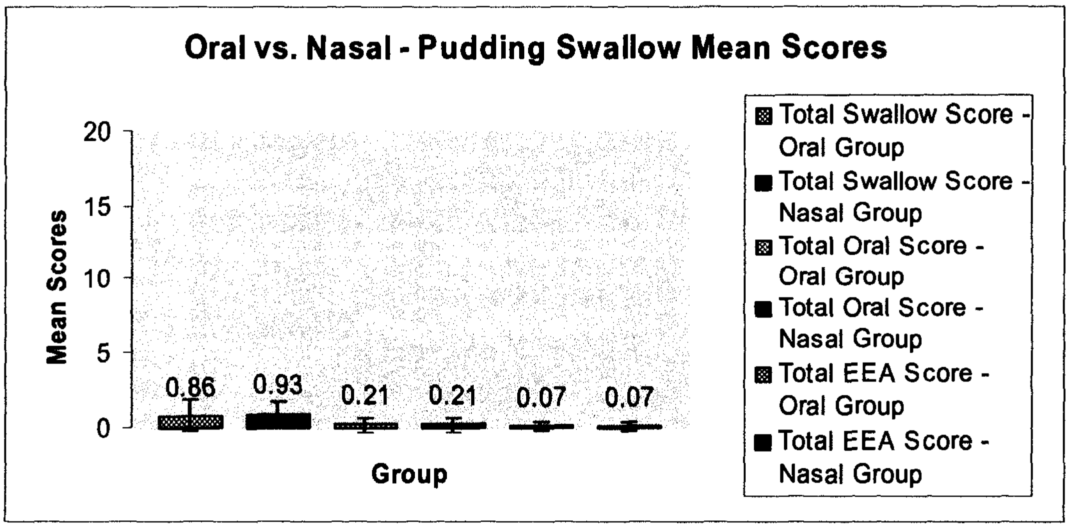
All measures were taken pre-operatively

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Figure 9 – Oral vs. Nasal Group Comparison for the Mean Pudding Swallowing Function Scores: Pre-operative



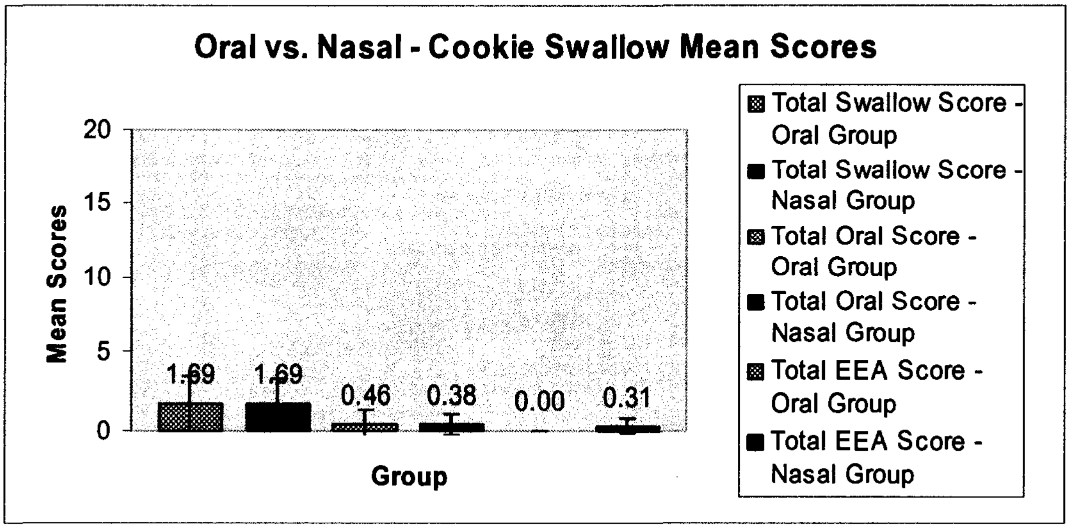
All measures were taken pre-operatively

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Figure 10 – Oral vs. Nasal Group Comparison for the Mean Cookie Swallowing Function Scores: Pre-operative



All measures were taken pre-operatively

Total = Total Swallowing Score (The summed total of all the swallowing function questions.)

Oral = Total Oral Sub-Score (The summed total of items relating to the 'oral' phase of the swallow. the liquid and pudding consistencies these included: the ability to hold the bolus, the presence of premature spillage, and tongue to palate contact. The cookie consistencies included those items listed for liquid and pudding as well as: the ability to attempt the cookie, bolus cohesion and whether water was required to move the bolus.)

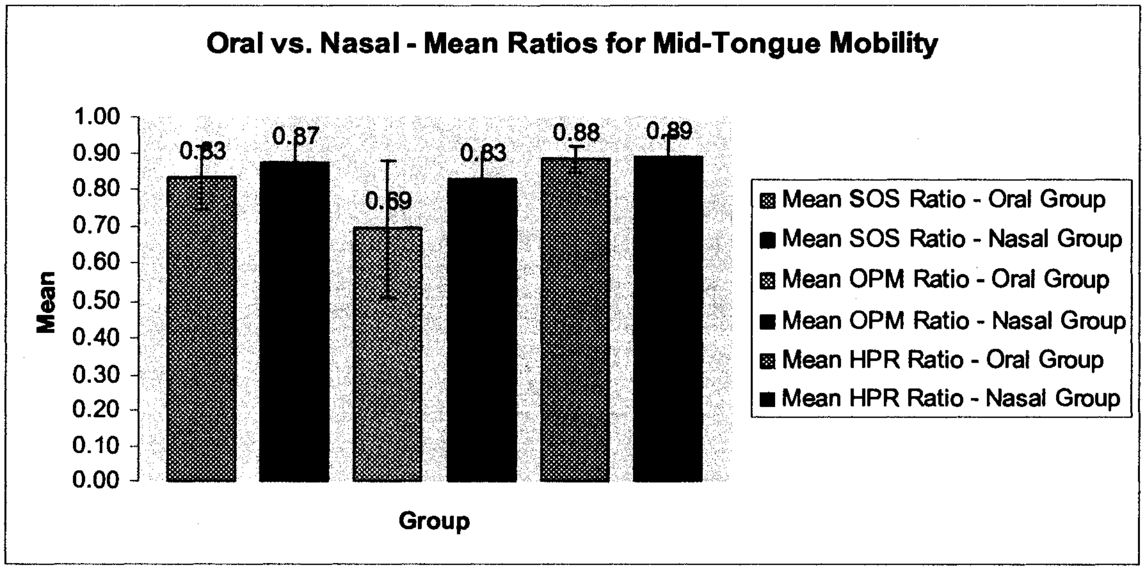
EEA = Total Elevation Sub-Score (The summed total of items relating to airway protection. These included: elevation of the hyoid bone at the appropriate time, hyo-laryngeal excursion and score on the penetration/aspiration scale)

Tongue Mobility

Following the procedures for missing data, 5 subjects were excluded from the oral cancer group (n=10) whereas no one in the nasopharyngeal cancer was excluded (n=14) for measures of mid-tongue mobility. For posterior-tongue mobility measurements, 6 subjects in the oral cancer group (n=9) and 3 subjects in the nasopharyngeal group (n=11) were excluded.

Figure 11 and *Figure 12* illustrate the differences in mid-tongue and posterior-tongue mobility ratios for the oral and nasal pharyngeal cancer groups at the pre-operative evaluation period. A visual inspection showed that most of the data for the two groups looked very similar with the exception of the OPM means for the measures of mid-tongue mobility. Statistical analysis of the data revealed that there were, in fact, no significant differences on multivariate tests for either mid-tongue or posterior-tongue mobility ratios.

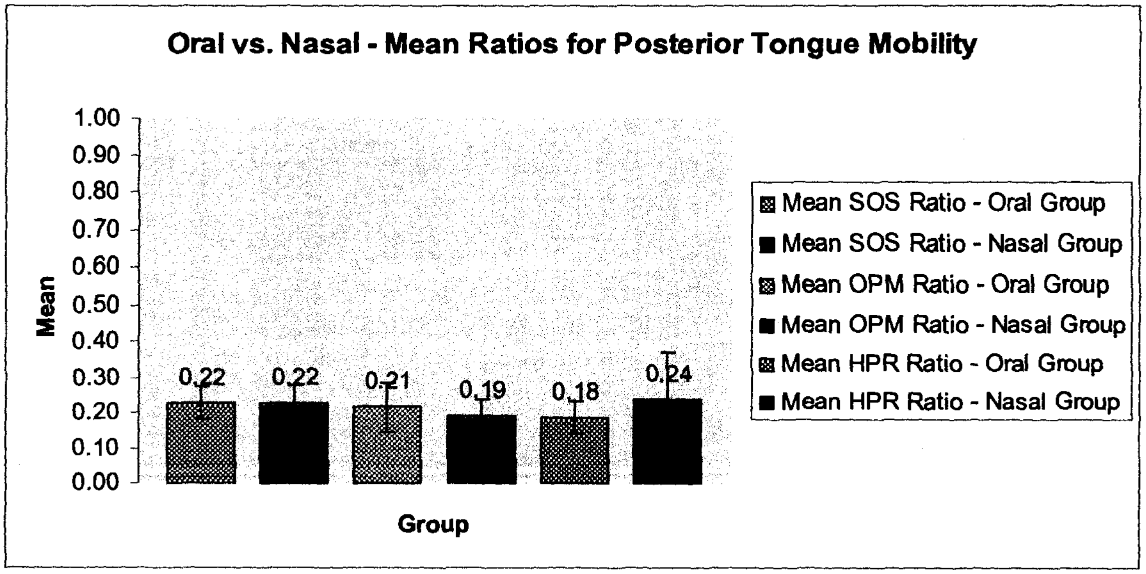
Figure 11 – Oral vs. Nasal Group Comparison for the Mean Mid-Tongue Mobility Ratios: Pre-operative



All measures were taken pre-operatively

SOS = Start of the Swallowing Sequence
OPM = At the Onset of Posterior Movement of the bolus
HPR = As the bolus Head Passed the Ramus of the mandible

Figure 12 – Oral vs. Nasal Group Comparison for the Mean Posterior-Tongue Mobility Ratios: Pre-operative



All measures were taken pre-operatively

SOS = Start of the Swallowing Sequence
OPM = At the Onset of Posterior Movement of the bolus
HPR = As the bolus Head Passed the Ramus of the mandible

Reliability

Swallowing Function

In order to establish measures of inter- and intra- rater reliability for swallowing function, 14 out of the original 66 videofluoroscopic swallowing evaluations used in this study were randomly-selected and re-evaluated separately by the researcher and a research associate following collection of all the primary swallowing function data. Of these, all 14 were evaluated on the liquid and pudding bolus swallows. Only 10 of the 14 patients selected for re-evaluation had the cookie bolus swallows available for measurement. Intraclass correlation coefficients (ICCs) were calculated for all of the swallowing function evaluation criteria (i.e., Questions 1 through 12) as well as the Total Swallowing

Function Score. The research associate's measurements were used to calculate 2 inter-rater reliability scores using the original data collected by the researcher (i.e., Inter 1), as well as the data collected on the 14 videofluoroscopic swallowing re-evaluations (i.e., Inter 2). Intra-rater reliability was calculated using the researcher's original measurements and the second data set collected from the 14 swallowing re-evaluations (i.e., Intra). *Table 4* illustrates every available ICC calculated for inter- and intra- rater reliability. In cases where an ICC could not be calculated, a percent absolute agreement is given.

Table 4 – Intraclass Correlation Coefficients (ICCs) and Percent Agreement for Measures of Swallowing Function: Intra- and Inter-rater reliability

	Measure of Reliability		Q1 - Bolus Hold	Q2 - Premature Spillage	Q3 - Tongue to Palate Contact	Q4 - Hyoid Movement	Q5 - Hyo-laryngeal Excursion	Q6 - Nasal Regurgitation	Q7 - Tongue contact with Pharyngeal Wall	Q8 - Able to attempt Cookie Bolus	Q9 – Ability to form Cohesive Bolus	Q10 – Water to move the bolus	Q11 - Additional Swallowing Attempts	Q12 - Pen/Asp Score	*Total Swallowing Score*
Liquid Swallow (n=14)	Inter 1	ICC		**.44**						**.77**	n/a	n/a	**.78**	**.87**	***.82***
		% agree	86%	86%	93%	71%	93%	100%	93%	93%			79%	86%	
	Inter 2	ICC		**.44**						**.77**	n/a	n/a	**.78**	**.85**	***.87***
		% agree	93%	86%	93%	85%	86%	100%	93%	93%			86%	79%	
	Intra	ICC				**.46**					n/a	n/a		**.86**	***.95***
		% agree	93%	100%	100%	86%	93%	100%	100%	100%			100%	86%	
Pudding Swallow (n=14)	Inter 1	ICC				**.77**					n/a	n/a	**.96**		***.71***
		% agree	93%	71%	100%	86%	93%	100%	100%	100%			93%	100%	
	Inter 2	ICC				**.46**					n/a	n/a	**.96**		***.81***
		% agree	86%	79%	100%	86%	93%	100%	100%	100%			93%	100%	
	Intra	ICC		**.65**		**.65**					n/a	n/a			***.96***
		% agree	93%	93%	100%	86%	100%	100%	100%	100%			100%	100%	
Cookie Swallow (n=10)	Inter 1	ICC				**.64**					.44		**.85**		***.75***
		% agree	100%	100%	100%	90%	100%	100%	100%	100%	80%	100%	90%	100%	
	Inter 2	ICC				**.64**					.44	**.64**	**.65**		*.58*
		% agree	100%	80%	100%	90%	100%	100%	100%	100%	80%	90%	80%	100%	
	Intra	ICC										**.64**	**.96**		***.94***
		% agree	100%	100%	100%	100%	100%	100%	100%	100%	100%	90%	90%	100%	

Intraclass correlation coefficients (ICCs) based on two-way, mixed, absolute value models and percent agreements. All ICCs given in **bold** are significant at p = .05.

Inter 1 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's original evaluations and the research associate's evaluations.

Inter 2 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's re-evaluations and the research associate's evaluations.

Intra = intra-rater reliability as defined by an ICC or percent agreement and calculated from both of the researcher's swallowing evaluations.

Inter-rater ICCs for the swallowing evaluation criteria (Questions 1 to 12 for all consistencies) ranged from .44 to .96. The percent absolute agreement was found to be less than 80% on 4 out of 64 of the swallowing criteria questions and even then, was never less than 71%. In cases where the ICCs were lower than .70, the percent absolute agreement was never less than 80%. Inter-rater reliability ICCs for the total swallowing function scores on all consistencies were generally high and significant at the $p = .05$ level. They ranged from .71 to .96. There was one exception outside of this range for reliability score calculated as Inter 2 on the cookie bolus. The ICC calculated was .58 and was not significant.

Intra-rater ICCs for the swallowing evaluation criteria (Questions 1 through 12) were more difficult to calculate due to the low degree of variance to be found between the two data sets. The ICCs ranged from .46 to .96. The percent absolute agreement was found to be less than 93% on 3 out of 32 of the swallowing criteria questions and even then, was never less than 86%. In cases where the ICCs were lower than .70, the percent absolute agreement was never less than 86%. Intra-rater reliability ICCs for the Total Swallowing Scores on all consistencies were .94 or higher and significant at the $p = .05$ level.

Tongue Mobility

In order to establish measures of inter- and intra- rater reliability for tongue mobility, 30 out of the original 198 j-peg images used in this study were randomly selected and re-evaluated separately by the researcher and a research associate following collection of all the primary tongue mobility data. Intraclass correlation coefficients (ICCs) were calculated for the ratios of mid- and posterior- tongue mobility. The research associate's data were used to calculate 2 inter-rater reliability scores using the original data collected by the researcher (i.e., Inter 1), as well as the data collected from the re-evaluations of tongue mobility measures (i.e., Inter 2). Intra-rater reliability was calculated using the researcher's first and second data sets collected from the 30 still images (i.e., Intra). *Table 5* illustrates the ICCs calculated for inter- and intra- rater reliability. No percentages are given for absolute agreement because it was possible to calculate ICCs for all of the tongue mobility ratios.

Table 5 – Intraclass Correlation Coefficients (ICCs) for Measures of Tongue Mobility: Intra- and Inter-rater reliability

	Mid-Tongue	**Post-Tongue**
Inter 1	**.69**	.33
Inter 2	**.75**	**.65**
Intra-	**.85**	**.67**

Intraclass correlation coefficients (ICCs) based on two-way, mixed, absolute value models and percent agreements. All ICCs given in **bold** are significant at p = .05.

Inter 1 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's original evaluations and the research associate's evaluations.

Inter 2 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's re-evaluations and the research associate's evaluations.

Intra = intra-rater reliability as defined by an ICC or percent agreement and calculated from both of the researcher's swallowing evaluations.

Inter-rater ICCs for the mid-tongue mobility ratios were .69 and .75 for Inter 1 and Inter 2 respectively. Both were significant at the $p = .05$ level. Inter 2 for posterior tongue mobility was .65 and also significant at the $p = .05$ level. Inter 1 for posterior tongue mobility ICC was .33 and not found to be significant.

The intra-rater ICCs for the mid- and posterior tongue mobility ratios were .85 and .67 respectively. Both of these measures were found to be significant at the p = .05 level.

Normality

To help determine whether the data distributions were normal, the researcher examined the measures of skewness and kurtosis for all the data sets. Any measure that fell outside the range of -2 to 2 indicated the data were not normally distributed. For swallowing function, 12 distributions were examined for each consistency. On the data for the liquid and pudding swallows, 5 out of 12 data sets fell outside the prescribed range. Two data sets fell outside the range for the cookie boluses. Both mid- and posterior tongue mobility also had 12 distributions to examine. Mid-tongue mobility data all fell within the range of acceptability for skewness and kurtosis whereas, posterior tongue mobility fell outside the range twice. Skewness and kurtosis for the pre-operative group comparison revealed 6 out of 9 non-normal distributions for swallowing function (3 out of 3 for liquid; 2 out of 3 for pudding; and 1 out of 3 for cookie). One (1) out of 3 of the data sets for both mid- and posterior tongue mobility were also outside the range of a normal distribution.

In addition to skewness and kurtosis, the means and medians of all the data sets were examined. None of the swallowing function and tongue mobility data appeared to be very different.

DISCUSSION

Several previous studies on cancer of the oral tongue have suggested that the outcomes for swallowing function and tongue mobility are less than optimal for those patients who undergo surgical resection followed by reconstruction as their primary method of treatment for the disease[3,4,8,14]. Although some studies with positive results are beginning to emerge[2,15,18], there remain limitations in the data in terms of the type of information provided, the homogeneity of the group studied and the length of time the studies persist. The present study attempted to address the aforementioned concerns by limiting the subject grouping to only those who had between 50 to 75% of the anterior 2/3rds of the tongue resected with subsequent reconstruction using a radial forearm free flap. Furthermore, the data collected came from objective and quantifiable measures over 4 different evaluation periods; pre-operative and 1-, 6- and 12-months post-operative. The study was mainly a within-subject comparison, which allowed the researcher to describe the changes in swallowing function and tongue mobility that this specific population underwent over time. There was a between-subject comparison for the pre-operative evaluation period which helped to determine whether the group with lesions in the anterior 2/3rds of the tongue had significantly different measures of swallowing or tongue mobility from those patient's with nasopharyngeal cancer (i.e., patients with no lesions in the oral or oropharyngeal cavity) prior to treatment.

Pre-operative Group Comparison

The multivariate analyses of data from the oral tongue cancer and the nasopharyngeal group revealed no significant differences on any of the consistencies used to measure swallowing function or on any of the measurements of mid-tongue mobility and posterior-tongue mobility. Based on the data, it appeared that swallowing function and measures of tongue mobility for all of the patients in the oral cancer group were within normal limits prior to undergoing surgical treatment. At first glance, it would appear that the findings of the present study of oral tongue cancer are contrary to findings from the limited number of other studies that have reported findings from patients with lesions in the anterior 2/3rds of the tongue. However, comparison of the present study results to other studies of pre-operative function is challenging due to the heterogeneity of the patient populations in the studies that do exist for comparison. For example, Colangelo et al. reported that 9, 24 and 21% of patients in their study had reduced oropharyngeal swallow efficiency (OPSE) values for liquid, paste and cookie boluses, respectively[26]. This would suggest that their patients performed more poorly than those in the present study. However, only one-quarter of their total sample (n=227) consisted of patients with oral cancer restricted to the anterior portion of the tongue, while the rest had other forms of head and neck cancer. Markkanen-Leppänen and colleagues found that 13% of the patients in their study aspirated pre-operatively, with 83% of those doing so silently[27]. This same team of researchers also reported that only 64% of the patients in this study (n=44) had tumors located in the oral cavity.

Thus, no patent comparisons can be made about the swallowing ability of any specific population pre-operatively due to the lack of homogeneity in the samples that have been used for research. The present study offers evidence of normal swallowing function and tongue mobility in the presence of a single lesion located in the anterior 2/3rds of the tongue prior to head and neck cancer treatment.

Swallowing Function

The data for swallowing function for the patients who had resection of the anterior 2/3rds of the tongue in the current study revealed only one significant difference. This was between the pre-operative and the 1-month post-operative total swallowing scores for liquid boluses only. Of all the data collected, the subsequent analyses suggested that the patients in this study had the most difficulty controlling and swallowing liquids early post-surgery. Having the most trouble with liquid boluses is understandable given the evidence from studies of deglutition that have been done with unimpaired or normal individuals: Robbins et al. found that liquid boluses traveled more quickly through the oral and pharyngeal cavities[28] and a recent study by Daggett and colleagues revealed that airway penetrations were most likely to occur with liquid boluses[29]. Together, these studies provide a reasonable explanation for why a person having undergone tongue resection and reconstruction might have the most difficulty with liquid boluses.

Despite only one significant difference amongst all the comparisons of the swallowing function scores, all of the scores did increase between the pre-operative and the 1-month post-operative evaluations which could be indicative of some mild swallowing impairment for this population. There are a few factors to consider with regard to this:

1) Minor increases to the total swallowing scores and the total oral and total elevation sub-scores did occur however, none of the scores were significantly different from the pre-operative score at the 6-month post-operative evaluation demonstrating at least near-normal if not normal swallowing by 6-months post-op or sooner.
2) Even though the scores increased, they remained low overall. It was determined that a maximally impaired person attempting a cookie bolus could have a total swallowing score of 20. Mean total swallowing scores for all consistencies ranged between 0.93 and 3.23. It is worthwhile to consider that normal individuals would not always have a perfect swallowing score in a swallowing evaluation either. This is substantiated by the findings of the 2007 swallowing study of unimpaired individuals published by Daggett et al., in which over half of the participants penetrated the airway, scoring a 2 on the penetration-aspiration scale[29]. Furthermore, Okada and colleagues found that normal individuals required two or more swallows in order to clear a bolus from the oral cavity in 40% of liquid and food trials[30].
3) The mean total oral sub-scores were less than 1.0 for all consistencies. This number indicates that some patients presented with mild oral

difficulties however, few were maximally impaired as might have been predicted given the location of the patients' resection and reconstruction.

4) The scoring to determine the overall safety of a patient's swallow (i.e., airway protection) was good. The mean total elevation sub-scores were 1.0 or less. An examination of individual scores on the penetration/aspiration scale (see Appendix B)[31] revealed scores that ranged from 1 to 3 indicated that in no instance did a bolus enter the airway below the level of the glottis.

Taking all of the data presented in this study into consideration, we can conclude that, although this population may have had some initial swallowing difficulties, by the study's end (i.e., 12-months post-operative) they were swallowing safely and efficiently.

Tongue Mobility

The data analyses for long-term, mid-tongue mobility and posterior-tongue mobility also revealed one significant difference. This was for the ratios of posterior-tongue mobility calculated for the pre-operative and 1-month post-operative evaluations at HPR. The analyses showed that superior-posterior tongue mobility near the end of the swallowing sequence was significantly higher at the 1-month post-surgery evaluation than at the pre-operative evaluation. Initially, it was felt that a lower ratio for either mid-tongue or posterior-tongue mobility would signify a decrease in functional tongue movements however, upon examining the placement of the tongue for the various parts of the swallow (i.e., SOS, OPM and HPR) it was determined that ideal tongue placement for parts of the swallow might be lower or higher depending on where the bolus was located. *Figure 13* and *Figure 14* demonstrate where the tongue is located in the oral cavity at the beginning and at the end of the swallowing sequence.

Figure 13 – Tongue Position: Start of Swallowing Sequence (SOS)

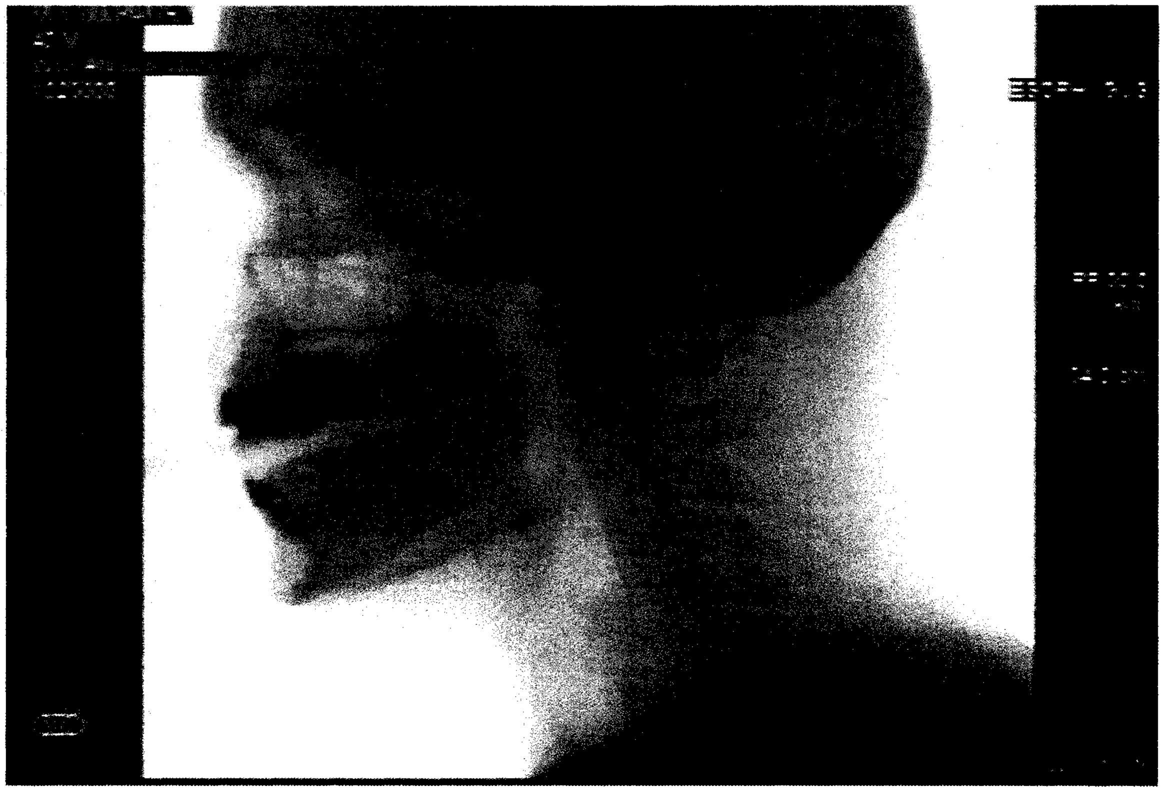


Figure 14 – Tongue Position: As the Bolus Head Passed the Ramus (HPR)

Given the pattern of tongue movements at all points in the swallow being examined, it was felt that what appeared to be an increase in the posterior-tongue mobility ratio between the pre-operative and 1-month post-operative HPR evaluations may actually have been a compensatory posture. Theoretically, this compensation might be attributed to the slightly poorer bolus control at 1-month post-surgery that was observed. In light of poorer bolus control, the patients may have compensated by holding the backs of their tongues higher in the pharynx to control the bolus during the oral phase, thereby creating a higher average of the posterior-tongue mobility ratios at HPR. More research is needed in this area in order to further determine the links between the mobility ratios and function.

Overall, the mid-tongue and posterior-tongue mobility ratios did return to near-baseline and no further significant differences were found indicating that tongue mobility remains relatively stable in this patient population.

Reliability

Although the inter- and intra- rater ICCs fluctuated on the swallowing evaluation criteria, it was felt that the data collected by the researcher were reliable and reproducible – given the high percentages of absolute agreement on the individual swallowing evaluation criteria and that nearly all of the total swallowing function scores showed at least moderate to high reliability.

In terms of tongue mobility reliability, it was evidenced by the ICC values that the measures of mid-tongue mobility were more reliable and easier to reproduce than the measures of posterior tongue mobility. This was reported as being the case by the research associate who felt the superior-posterior movement of the tongue was difficult to measure due to specific portions of the anatomy being cut off or the superior surface of the posterior tongue itself being difficult to locate at times with a high degree of certainty.

LIMITATIONS

Small group sizes were problematic within this study. For example, it would have been desirable to look at percent resection or oral sensory ability as factors in the outcomes of this patient population. In terms of subject groupings, 2 out of 15 patients had 75% of the anterior 2/3rds of the tongue resected while the other patients had 50% resected. Twelve out of 15 patients had reconstruction where the lingual nerve was preserved or where a sensate flap was used. Observation of the means across these groupings revealed many similarities; however, patient numbers per group were too dissimilar to detect any differences with confidence.

Likewise, it would have been informative to complete group comparisons between the 6 patients who underwent radiation therapy (RT) and those who did not (n=9). In the case of using RT as a factor, several subject losses occurred due to missing data, thereby reducing the number of subjects per group and preventing any accurate conclusions about the difference between the two. It was interesting to note that the mean swallowing function scores for the RT group were slightly higher or worse than those of the patients without RT and they continued to worsen all the way to the study's end. That said - the higher means were present in the RT group even prior to treatment so any differences between the groups might have been attributable to something other than the adjunctive treatment. There were no obvious patterns in the means of mid- or posterior-tongue mobility between the RT and non-RT patients.

Successful between-groups analysis using RT as a factor also may have led to a closer examination of the consequences of radiation therapy, such as xerostomia. Any conclusions about the effect of RT on swallowing ability were difficult to determine because by the study's end, an equal number (n=5) of RT and non-RT patients were lost on the evaluation of the cookie bolus. Furthermore, there were no significant differences between the groups in terms of the number of swallows required for any consistency – something we might have predicted to be higher in those patients with xerostomia because the lack of lubrication in the oral cavity could have hindered bolus movement and thus, necessitated an increased number of swallow attempts.

Small group size also was a problem for the other analyses performed in this study. Missing data cells limited the number of subjects that were included, this being especially true for the swallowing function scores and sub-scores resulting from the cookie bolus trials, as well as the ratios of posterior-tongue mobility. In order to keep as many subjects in the study as possible it was necessary to perform data imputation, and to break the analysis up such that the researcher did not compare all four points in time in one analysis, but instead only considered two points in time within each analysis. This method for overcoming missing data was effective for keeping as many subjects in any one analysis as possible but also meant that the same group of subjects was not used for every single comparison. Thus, the repeated-measures within-subject component of the study was not completely satisfied.

Two further limitations arising from the problem of missing data and small group numbers were: the number of comparisons that needed to be done (6) because all four evaluation periods could not be examined at the same time without large subject losses, and observable power. As the number of individual comparisons went up, the p-value used to determine significance became smaller due to corrections being made for family-wise error. Post-hoc power calculations at an alpha level of 5% revealed several fluctuations. In many instances of the tongue mobility measurements, avoiding a beta error would mean increasing the number of subjects in each comparison group. Statistical power of 80% or higher would have required much larger numbers. Unfortunately, the number of subjects required to achieve adequate statistical power for measures of tongue mobility were higher than what was attainable within the scope of this study. Swallowing function measurements had better statistical power with most comparisons achieving over 70%. *Table 6* illustrates a sampling of the power statistics available for this study. Both of the comparisons that were significant in this study had statistical power of over 90%.

Table 6 – Actual vs. Ideal Power and Subject Numbers

Measure		Comparison	Number of Subjects in Comparison	Actual Statistical Power	Number needed for Statistical Power 50%	Number needed for Statistical Power 80%
Mid-Tongue Mobility	**SOS**	T1 vs. T2	8	30%	17	39
	OPM		8	45%	10	23
	HPR		8	45%	10	23
Mid-Tongue Mobility	**SOS**	T1 vs. T4	8	15-20%	43	97
	OPM		8	50%	8	19
	HPR		8	15%	74	169
Posterior-Tongue Mobility	**SOS**	T1 vs. T2	6	>90%	2	4
	OPM		6	40%	7	17
	HPR		6	90%	2	4
Posterior-Tongue Mobility	**SOS**	T1 vs. T4	8	<10%	160	365
	OPM		8	10-15%	82	187
	HPR		8	10-15%	119	271
Swallowing Function	**Liquid**	T1 vs. T2	12	>90%	2	5
	Pudding		13	85%	5	11
	Cookie		8	65%	5	12
	Liquid	T1 vs. T4	10	80%	4	10
	Pudding		11	70%	7	16
	Cookie		5	40%	8	17

Swallowing Function = Power only calculated with the data from the *Total Swallowing Function Scores*

SOS = Start of the Swallowing Sequence
OPM = At the Onset of Posterior Movement of the bolus
HPR = As the bolus Head Passed the Ramus of the mandible

T1 = Pre-operative; T2 = 1-month post-operative evaluation; T4 = 12-months post-operative evaluation

In addition to the problems related to small group sizes and missing data, there are other limitations that a researcher ought to be aware of before endeavoring to complete a study of this nature. The greatest of these surrounds the actual measurements of tongue mobility. Little research has been done in terms of measuring tongue mobility quantitatively and thus, it was difficult to determine what the best course of action might be. To date, the only study available with research in this area belongs to Hara and colleagues[3]. Despite producing ground-breaking work, Hara's protocol was not easy to replicate with the materials available to the present study's research team and thus, a revised system for measuring tongue mobility was required.

Although every effort was made to create measurements that were reliable and reproducible, this proved to be a difficult task. Lower scores for inter-rater reliability suggest that the methods used for measuring tongue mobility were not that easy to reproduce between examiners. Indeed, during the course of the reliability portion of this study, the research associate responsible for measuring tongue mobility asked for a mini-evaluation and discussion surrounding the measures of tongue mobility on the first 10 images of the 40 images selected for reliability due to the uncertainty of the task. This dropped the number of images used to determine the tongue mobility inter-rater reliability calculations for this study down to 30 and the results are reported based on such in the appropriate sections of the present study. The ICC values for inter-rater reliability based on the initial measures of mid-tongue and posterior-tongue mobility calculated by the research associate were .122 and .581 respectively, thus demonstrating the low reliability and reproducibility of the measurements without adequate discussion or training. ICC values for the intra-rater reliability of mid-tongue and posterior-tongue mobility measures for the same 10 files were .600 and .838 respectively.

Inadequate discussion or training are possible reasons for another area of the study where ICC values fell short. The research team wished to report on residue and severity of residue in the oral cavity, the valleculae, the pyriform sinuses and on the pharyngeal wall as part of the swallowing function in this patient population. They are not reported in the course of this paper because inter-rater reliability scores for individual measures of residue and severity of residue were often lower than .70 or less than 70%. Additionally, almost all of the ICCs calculated for inter-rater reliability based on a *total residue score* (i.e., the sum of all the residue and severity scores together) were less than .40. On the other hand, intra-rater reliability was better - ICC values were still low (often less than .70) but the percent absolute agreement was at least 70% or higher in all but one instance. The intra-rater reliability ICC values for *total residue* were all greater than .80. *Table 7* illustrates the available ICCs calculated for inter- and intra- rater reliability in terms of residue and severity. In cases where an ICC could not be calculated, a percent absolute agreement is given.

Table 7 – Intraclass Correlation Coefficients (ICCs) and Percent Agreement for Residue and Severity of Reside: Intra- and Inter-rater reliability

	Measure of Reliability		**Oral Residue**	**Vallecular Residue**	**Pyriform Residue**	**Pharyngeal Wall Residue**	**Oral Severity**	**Vallecular Severity**	**Pyriform Severity**	**Pharyngeal Wall Severity**	***Total Residue Score***
Liquid Swallow (n=14)	**Inter 1**	ICC	.093	.235	**.772**		**.217**	**.519**	**.772**		.353
		% agree	36%	57%	93%	71%	36%	43%	93%	71%	
	Inter 2	ICC		**.356**	**.381**		**.124**	**.679**	**.381**		**.366**
		% agree	14%	64%	71%	79%	7%	43%	71%	79%	
	Intra	ICC		**.772**	**.552**	.451	**.451**	**.683**	**.552**	.451	**.850**
		% agree	79%	93%	79%	79%	79%	79%	79%	79%	
Pudding Swallow (n=14)	**Inter 1**	ICC	.058	**.447**			.023	.695			.118
		% agree	29%	71%	71%	50%	29%	57%	71%	50%	
	Inter 2	ICC		.152				.594			.169
		% agree	14%	57%	50%	79%	14%	29%	50%	79%	
	Intra	ICC		**.458**	**.589**	**.447**		**.805**	**.589**	**.447**	**.826**
		% agree	86%	86%	79%	72%	79%	79%	79%	72%	
Cookie Swallow (n=10)	**Inter 1**	ICC	.308	.308			.151	**.617**			**.748**
		% agree	70%	70%	80%	60%	60%	60%	80%	70%	
	Inter 2	ICC		.060				.388			-.055
		% agree	60%	30%	70%	80%	50%	30%	70%	80%	
	Intra	ICC		.308	**.757**	.438	**.743**	**.597**	**.757**	**.757**	**.836**
		% agree	90%	70%	90%	60%	80%	70%	90%	90%	

Intraclass correlation coefficients (ICCs) based on two-way, mixed, absolute value models and percent agreements. All ICCs given in **bold** are significant at p = .05.

Inter 1 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's original evaluations and the research associate's evaluations.

Inter 2 = inter-rater reliability as defined by an ICC or percent agreement calculated from the researcher's re-evaluations and the research associate's evaluations.

Intra = intra-rater reliability as defined by an ICC or percent agreement and calculated from both of the researcher's swallowing evaluations.

A study of inter- and intra-judge reliability of videofluoroscopic swallowing evaluation measures (including residue but not severity) by McCullough and colleagues also found measures between different raters to be much worse than those made with the same rater[32]. Scott et al. found that inter-rater reliability scores were lowest when the examiner was only given a scale to read prior to an evaluation and best when the judges discussed an evaluation as it progressed[33]. Furthermore, reliability scores were still higher on individual evaluations following online discussions than in the first condition where only a hand-out scale was provided.

Considering the differences between the inter- and intra-rater reliability measures of the present study and previous research, it seems likely that the judges for some aspects of swallowing function (i.e., residue and severity of residue) might have benefited from more collaboration just as more discussion and training appeared to help with the reliability of tongue mobility measures.

CONCLUSION

Despite its limitations, it is felt that the present study offers some valuable information regarding the functional outcomes of head and neck cancer patients who undergo surgical resection and reconstruction of the anterior 2/3rds of the tongue. By selecting a very specific and homogenous population, using each patient as his or her own control and following them for a period of 12-months, this study addressed certain limitations in the literature of head and neck cancer.

There were no significant differences at the pre-operative evaluation period between the experimental and the comparison group signifying normal swallowing function and tongue mobility despite the presence of a lesion in the anterior 2/3rds of the tongue. Overall, there were few significant differences in terms of swallowing function and tongue mobility between the pre-operative and the post-operative periods and those that were significant returned to baseline or near-baseline measures by the study's end. This study will allow for clinicians and other healthcare practitioners to broaden their knowledge of functional outcomes for patients with oral tongue resection followed by microvascular reconstruction. Patients in this population can be provided with more detailed information about what they can expect in terms of their own functional recovery rather than the recovery of patients within the much larger head and neck cancer group. Although more research is needed, this study represents an important step towards building accurate and reliable measurements of swallowing function and tongue mobility in a specific group of oral cancer patients.

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Appendix A

Measures of Swallowing Function

Date of Assessment:	Case #			Case #			Case #		
Bolus Consistency: L – Liquid; P – Pudding; C – Cookie	L	P	C	L	P	C	L	P	C
Measure of Swallowing Function:									
1. Trouble touching the tongue tip to the alveolar ridge to hold the bolus?									
2. Premature spillage into pharynx prior to the onset of posterior bolus movement									
3. Tongue to hard palate contact incomplete as bolus is pushed posteriorly									
4. Hyoid at resting position at or before the time the bolus passes the most superior line of the ramus.									
5. Absence of superior hyo-laryngeal excursion leaving the airway vulnerable.									
6. Is nasal regurgitation present due to incomplete soft palate elevation?									
7. Poor contact between the base of the tongue and the posterior pharyngeal wall									
8. Was the patient unable to attempt the cookie bolus?									
9. Was the ability to form a cohesive bolus with the cookie impaired?									
10. Was water required to move the bolus into the esophagus?									
11. How many additional swallowing attempts required to clear the bolus?									
12. Patient's score on the penetration/aspiration scale (0 to 7)?									
Total Scores:									
Comments:									

Appendix B

Penetration-Aspiration Scale[31]

0 – Contrast doesn't enter the airway

1 – Contrast enters the airway, remains above the vocal folds, no residue

2 – Contrast remains above the vocal folds, visible residue remains

3 – Contrast contacts the vocal folds, no residue

4 – Contrast contacts the vocal folds, visible residue remains

5 – Contrast passes the glottis, no sub-glottic residue visible

6 – Contrast passes the glottis, visible sub-glottic residue despite patient's response

7 – Contrast passes the glottis, visible sub-glottic residue, absent patient response