Validation of the Test of Masticating and Swallowing Solids (TOMASS)

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Contents

List of abbreviations

BOT = Base of tongue

EMG = Electromyography

ICC = Intraclass correlation coefficient

SLT = Speech-language therapist

TOMASS = Test of Masticating and Swallowing Solids

TWST = Timed Water Swallow Test

UES = Upper Esophageal Sphincter

VFSS = Videofluoroscopic swallowing study

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Abstract

Objective: Clinical swallowing assessment is used to identify patients at risk of swallowing impairment and aspiration. Most clinical swallowing assessments are based on subjective observations instead of quantitative measures and provide very little information on pharyngeal phase pathophysiology. This could affect clinical judgement regarding referral for instrumental assessment. The Test of Masticating and Swallowing Solids (TOMASS) has been developed as an alternative to the Timed Water Swallow Test (TWST) to provide objective information on efficacy of solid bolus ingestion. Previous studies have shown that the TOMASS is able to detect changes in the oral phase but no study has investigated its' sensitivity to changes in the pharyngeal phase of swallowing. This study will validate the TOMASS against videofluoroscopic swallowing study (VFSS) for detecting pharyngeal phase pathophysiology.

Participants: Fifteen patients were recruited from those referred for VFSS to the Rose Centre for Stroke Recovery and Research, Canterbury District Health Board and Counties Manukau District Health Boards. All participants were diagnosed with oral pharyngeal dysphagia and were deemed safe to ingest a cracker with minimal risk of aspiration during their clinically indicated VFSS.

Method: After the completion of their clinically indicated VFSS, the participants were given a quarter of a single Arnott's Salada™ Cracker to ingest for TOMASS. Post-hoc, the VFSS recording was uploaded for biomechanical measurements. Spearman's correlation coefficients were used to evaluate the correlation between the TOMASS measurements that included the number of discrete bites, the number of masticatory cycles, the number of swallows and the total time taken, and the VFSS biomechanical measurements that included oral pharyngeal transit time, glossopalatal approximation duration, hyoid displacement, upper esophageal sphincter (UES) opening duration, the amount of residue in the valleculae and pyriform sinus, and presence of aspiration.

Results: There were few significant correlations between TOMASS measures and VFSS biomechanical measurement and none supported the hypotheses of this study. Also, there was poor inter-rater reliability on the VFSS biomechanical measurements.

Conclusion: The findings of this study do not support the hypotheses, however it has provided some evidence that the TOMASS may be useful to detect pharyngeal phase impairment. Further studies should consider a larger sample size to fully explore the potential of the TOMASS in providing more comprehensive results.

Background

The aim of clinical swallowing assessment is to identify patients at risk of dysphagia and aspiration. It involves speech-language therapists (SLT) gathering medical and feeding history, carrying out oro-motor assessment and observing the patients and their swallowing function (Leonard & Kendall, 2014). As Daniels and Huckabee (2008) have discussed, clinical swallowing assessment cannot define swallowing pathophysiology but it is able to contribute to diagnosis when paired with gathered information from medical and feeding history, oro-motor assessment etc. It also allows the SLT to determine the appropriate time for further evaluation and the need and suitability for instrumental assessment such as videofluoroscopic swallowing study (VFSS)(Daniels, McAdam, & Brailey, 1997; Leonard & Kendall, 2014). However, many studies have documented that clinical swallowing assessment lacks adequate sensitivity and specificity. Smithard et al. (1998) have carried out a study that compared the results of standardised swallowing assessment done by doctors and SLT with VFSS. Based on the results of the study, the sensitivity of clinical swallowing assessment carried out by doctors was 70% whereas those done by the SLT had a sensitivity of 47%. Of the patients who aspirated on VFSS, 30% were missed by the doctors while 53% were missed by the SLT. In another study, Splaingard et al. (1988) evaluated the information regarding aspiration obtained from VFSS and compared findings against the results from the patient's clinical swallowing assessment. It showed that 40% of the participants aspirated on at least 1 consistency during VFSS. Among these participants, only 42% were identified to be aspirating during their clinical swallowing assessment. 21 participants who showed no signs of aspiration during clinical swallowing assessment were silently aspirating during VFSS. It was also noted that there was a low agreement of 0.34 between clinical swallowing assessment and VFSS in diagnosing the presence of aspiration. Thus, clinical swallowing assessments may not only indicate the need of VFSS for some patients who do not need it, but, more importantly, may overlook patients who critically require further assessment. In addition, clinical assessment has also been found to lack adequate test-retest reliability in various different studies (Depippo et al., 1992; Edmiaston, et al., 2010 ; Logemann et al., 1999; McCullough el al., 2001; Smithard et al., 1998). The lack of sensitivity, specificity and test-retest reliability is likely influenced by clinician's observation and clinical judgement. As such, it is important to have objective and measurable clinical assessment tools to increase clinical accuracy and to prevent aspiration pneumonia.

Hughes and Wiles (1996) proposed that combining qualitative aspects of swallowing (e.g. slowness, coughing, altered voice quality post swallow or breathlessness) with three quantitative indices (the volume of bolus swallowed, number of swallows and time taken), when observing patients drinking water would help to screen and monitor those who were at risk of dysphagia or it complications. Hughes and Wiles (1996) developed the Timed Water Swallow Test (TWST) and described performance of healthy subjects and patients with motor neurone disease (MND) using this test. Participants were asked to drink a known volume of water "as quickly as comfortably possible". The study showed that the TWST provides reliable information on swallowing ability and speed but not pathophysiology. Despite the lack of specificity, TWST is sensitive in detecting the presence of dysphagia and provides a practical way to monitor changes in patients with dysphagia (Hughes & Wiles, 1996).

Although the TWST is highly clinically relevant, having the twin benefits of being easy to administer as well as being able to provide reliable information about patient's dysphagia, the TWST is similarly limited by two things. Firstly, due to the fact that a number of dysphagic patients experience difficulty ingesting thin fluids, the TWST cannot be used as a broad based, generic swallowing assessment tool for all patients. Secondly, it does not challenge the oral phase of swallowing. As Matsuo and Palmer (2008) have extensively discussed, there are clear differences during the oral phase of swallowing when eating compared to when drinking. In terms of consuming fluids, the fluid bolus is held in the anterior part of the floor of mouth or on the tongue surface against the hard palate. The oral cavity is sealed posteriorly by the soft palate and the tongue to prevent leakage into the oropharynx before swallowing. During the oral propulsive stage, the tongue tip rises and touches the alveolar ridge of the hard palate just behind the upper teeth, while the posterior tongue drops to open the back of oral cavity. The tongue surface moves upward and expands the area of tongue palate contact from anterior to posterior, squeezing the fluid bolus back along palate and into the pharynx. When drinking fluid, the pharyngeal phase begins during the oral propulsive stage (Matsuo & Palmer, 2008).

Compared to the consumption of fluids, when eating and swallowing solids, the lines between the phases are not so clear and there is a considerable overlap between the oral preparatory, oral propulsive and pharyngeal phases (Matsuo & Palmer, 2008). The description of events during ingestion of solids was first observed in mammals that were adapted to feeding in humans. As Matsuo and Palmer (2008) have discussed, stage I transport starts when the tongue carries the solid to the post-canine region and places it onto the occlusal surface of the lower teeth for food processing. During food processing, the food is softened by saliva and broken into smaller size by mastication. This process continues until the optimal food consistency is achieved for swallowing. In this process the cyclic movement of the jaw is tightly coordinated by the movements of the tongue, cheek, soft palate and the hyoid bone. The activity of masticatory muscles, contraction forces and jaw movements can be affected by the food texture as well as the size of the food (Peyron et al., 1997). A study done by Hiiemae et al. (1996) found that depending on the food texture, the total masticatory cycles could last between 17.58 to 24.47 second. These findings were later confirmed by Hiiemae and Palmer (1999), indicating that it takes an average of 22.8 seconds to ingest an 8g of peanuts sample and 23.61 seconds to consume the same amount of shortbread. Stage II transport occurs when a portion of food is suitable for swallowing. The food is placed on the tongue surface and propelled back to the oropharynx. The basic mechanism of stage II transport is similar to that of oral propulsive stage with fluid. Stage II transport is primarily driven by the tongue and can happen during the food process stage. Chewing continues when food remains in the oral cavity and size of bolus in oropharynx increases by subsequent stage II transport cycles (Matsuo & Palmer, 2008). Engel-Hoek et al. (2012) have noted that tongue pressure is influenced by the bolus consistency. The greater the viscosity of the bolus, the greater anterior tongue pressure required for bolus transportation. From these studies, it is obvious that there are considerable differences in the oral preparatory phase in eating solids vs fluids. This clearly demonstrates that a test of dysphagia that only relies on consuming liquids would not challenge the oral phase sufficiently to give a holistic picture of a patient's dysphagia. As such, while the TWST is valuable in its own way to screen for dysphagia, it is insufficient to rely on a test that only gives information on fluid consumption.

To address this issue, Athukorala and colleagues (2014) developed the TOMASS as an outcome measure for their treatment study of swallowing impairment related to Parkinson's disease. The TOMASS extends on the intent of the TWST by using similar methods but with a solid bolus texture. In doing so, objective information is derived on solid bolus ingestion that challenges oral phase function. Participants are instructed to ingest a quarter of a single Arnott's Salada™ Cracker "as quickly as is comfortably possible". The measurements taken during the test include the number of discrete bites, number of masticatory cycles, number of swallows and total time taken per cracker (Athukorala et al., 2014). Many studies have looked at mastication using different textures like nuts (e.g. peanuts, almond etc.) (Akeel, 1992; Lucas et al., 1986), carrots (Peyron et al., 1997), and different hardness of gelatine (Peyron et al., 2002). However, food such as nuts and carrots are not practical to use as swallowing assessment tools. Nuts and carrots are hard and do not breakdown easily, making them a choking hazard to patients with dysphagia. Also, the size and weight vary which would make it difficult to ensure that the physical properties are the same every time during clinical swallowing assessment. Gelatine would require some preparation before it can be used for assessment. On the other hand, the Arnott's Salada™ Crackers, that are commercially manufactured and easily accessible in major supermarkets, would each be of the same size and weight. The crackers are also easier to breakdown during mastication, making them safer for patients with dysphagia.

Researchers have evaluated the inter-rater reliability, test-retest consistency and sensitivity of the TOMASS (Apperley et al., 2014; Battel & Huckabee, 2014a, 2014b; Huckabee et al., 2014). One study evaluated test-retest consistency and inter-rater reliability of the TOMASS (Huckabee, McIntosh, Fuller, & Curry, 2014). This included 40 participants ingesting an Arnott's Salada™ Cracker twice in a single session. Two raters were present to make independent measures of participant performance. High inter-rater reliability was achieved with Cronbach's α >0.9 for all measures. This was supported by ICC values >0.98 indicating a near perfect relationship between the two raters. Cronbach's α ranged from 0.94 – 0.99 and ICC values between 0.83 and 0.98 also indicated a high level of test-retest reliability. Another study aimed to provide initial validation of the TOMASS by looking at its sensitivity to changes in swallowing associated with oral anaesthesia (Apperley, McIntosh, & Huckabee, 2014). Ten participants ingested an Arnott's Salada™ Cracker "as quickly as is comfortably possible". Each participant performed the task thrice - once with, once without the application of topical oral anaesthetic and once more after anaesthesia had worn off. Significant differences were detected for the parameters of masticatory cycles per bite, time per bite and time per swallow. The results of this study suggest that the TOMASS is sensitive in assessing changes that occur during the ingestion of solid textures (Apperley et al., 2014).

However, while the above studies show that the TOMASS is a useful, objective tool to determine dysphagia, previous studies have not determined the sensitivity and specificity of the TOMASS in detecting changes at the pharyngeal phase of swallowing. Pharyngeal swallowing is a fast sequential activity and has two crucial features which are 1) propelling the bolus through the pharynx and upper esophageal sphincter (UES) to the esophagus and 2) airway protection (Matsuo & Palmer, 2008). During the pharyngeal phase, the soft palate elevates and contacts the lateral and posterior walls of the pharynx to close off the nasopharynx thus preventing nasal regurgitation. The base of tongue retracts, pushing the bolus against the pharyngeal wall and the pharyngeal constrictor muscles contract sequentially from top to bottom, pushing the bolus downward. The pharynx, at the same time, shortens vertically to reduce the volume of the pharyngeal cavity. Airway protection is critical during swallowing and there are several mechanisms to ensure the airway is protected. They are 1) vocal fold closure, 2) the upward and forward movement of the hyoid bone and larynx by contracting the suprahyoid and thyrohyoid muscles, which has the effect of tucking the larynx under the base of tongue and 3) the backward tilt of the epiglottis to seal the laryngeal vestibule. As part of the pharyngeal phase of swallowing, an important element would be the opening of UES. This is important to allow the bolus to enter the esophagus. At rest, the UES is closed through muscle contraction and it is opened through the relaxation of the cricopharyngeous muscle, the contraction of the suprahyoid and thyrohyoid muscles and the pressure of the descending bolus (Matsuo & Palmer, 2008).

While based on the above description it appears as if the pharyngeal phase stands alone, interestingly Ono et al. (2007) argued that the oral cavity combines with the pharynx to form a functional unit. They proposed a conclusion that mastication (which is oral phase) and swallowing (in the pharyngeal phase) are closely related. Several studies appear to support this claim - Matsuo and Palmer (2010) looked at the relationship of the tongue, jaw and hyoid during eating and speech and concluded that the movements of the tongue are closely related to the jaw and hyoid movements. For vertical movements, the anterior part of the tongue is closely connected to jaw movement whereas the posterior part of the tongue is closely connected to the hyoid bone movement. For horizontal movements, the tongue is mainly related to hyoid bone movement instead of jaw movement (Matsuo & Palmer, 2010). Pancherz et al. (1986) compared the electromyography (EMG) recordings of suprahyoid and masseter muscles with videofluoroscopy recordings of cyclic jaw movements. A close relationship was identified between jaw opening/ closing and hyoid bone movements. Other studies have similarly shown relationships between oral phase parameters observed and pharyngeal phase physiology. Studies have shown that there are similar muscles involved in mastication and the hyoid bone movement. (Matsuo & Palmer, 2010; Matsuo & Palmer, 2008; Pancherz et al., 1986).

Further evidence to support that oral and pharyngeal phases may be looked at as a single unit come from studies by Ali et al. (1997). They investigated the influence of altered tongue contour and position on volume-dependent changes in swallowing coordination using maxillary and mandibular splints with 5ml and 10ml of two different fluid densities. They found that the presence of maxillary splint delayed the onset of anterior hyoid movement, UES relaxation and opening without influencing bolus transit time and total swallow duration. The pharyngeal pressure was reduced with both maxillary and mandibular splints in-situ (Ali et al., 1997). Steele and Huckabee (2007) looked at how effortful swallow can affect the temporal characteristic of pressure generation in both the mouth and pharynx. They have found that there was an overall lengthening of duration of pressure events in oral cavity and pharynx. There is a strong influence in tongue-to-palate contact in increasing the pharyngeal pressure in effortful swallow. Based on the above studies, the relationships between the anatomical features of the oral and pharyngeal phases as well as the pressure generation of both phases indicate a likely close relationship between the oral phase parameters and the pharyngeal phase parameters.

Despite the various studies that have looked at the relationship between the tongue, jaw and hyoid bone, no specific studies have been done to examine the correlation between the oral phase and the pharyngeal phase of swallowing. As oral phase parameters are more visible to clinicians during clinical swallowing assessment, studies examining correlation between oral phase and pharyngeal phase parameters would be of significant interest. It would help push the limits of the clinical swallowing assessment in providing more holistic results on oropharyngeal dysphagia.

1.1 Hypothesis

This study aimed to examine the relationship between oral parameters and the pharyngeal phase of swallowing. Several hypotheses were evaluated.

- Firstly, as Leonard and Kendall (2014) discussed, an increase in oropharyngeal transit time could result from a variety of reasons including inadequate glossopalatal approximation, reduced bolus preparation and/or control etc. This study sought to determine if TOMASS measurements would provide any insight on oropharyngeal transit time. Anatomically, the jaw and tongue are involved in mastication, bolus formation and transportation (Matsuo & Palmer, 2008). It was hypothesised that there was a direction relationship between the number of masticatory cycles and oropharyngeal transit time with an increase in the number of masticatory cycles, the oropharyngeal transit time would be increased as well.
- Secondly, inadequate glossopalatal approximation has been found to potentially result in reduced ability to retain a bolus in the oral cavity (Daniels & Huckabee, 2008; Leonard & Kendall, 2014). This study wanted to examine the relationship between glossopalatal approximation and the number of swallows to ingest the given cracker. The tongue contacts the velum to form an approximation (Daniels & Huckabee, 2008). This movement is likely closely related to the hyoid movement (Matsuo & Palmer, 2008). Based on that, if there is an inadequate glossopalatal approximation, there is a possibility that the hyolaryngeal excursion may be reduced resulting in

difficulty in clearing premature spillage (from the reduced glossopalatal approximation) and residue in the valleculae and pyriform sinus. More swallows would be observed to clear the bolus. This study hypothesised that an increased number of swallows could reliably predict reduced glossopalatal approximation.

- Finally, according to Leonard and Kendall (2014), if hyoid movement is reduced, upper esophageal sphincter (UES) opening may be affected and thus the presence of pyriform sinus residue will be observed. With the presence of residue, patients may then present as having multiple swallows per bolus to clear the residue. Based on this, the study hypothesised that with reduced hyoid movement, there would be an increase in the number of swallows.

Methods

2.1 Participants

Fifteen participants (11 males and 4 females) were recruited from the Rose Centre for Stroke Recovery and Research, the Canterbury District Health Board and the Counties Manukau District Health Board. The age range of participants was 20 to 85 (mean= 58.2) years old. The inclusion criteria for this study were as follows:

1) Patients who have clinically identified oral pharyngeal dysphagia and have been referred for VFSS.

2) Patients who, over the course of the VFSS, were deemed safe to ingest a cracker with minimal risk of aspiration by the SLT who was carrying out the procedure.

By recruiting participants from those referred for VFSS, it is ensured that patients would meet the inclusion critieria of suspected oral pharyngeal dysphagia and be safe to participate in the study.

Before the VFSS appointment, the participants were briefed by the primary investigator or their speech-language therapists about the study. An information sheet (Appendix 1) regarding the study was provided to all participants before the VFSS procedure and written informed consent (Appendix 2) was obtained after they are deemed to be suitable for the TOMASS during VFSS. A questionnaire (Appendix 3) was given to all participants to ensure they had sufficient cognitive ability to provide informed consent. The study protocol was reviewed and approved by the Health and Disability Ethics Committee.

2.2 Equipment/material

Videofluoroscopy equipment was used at all data collection sites. Depending on the individual site, the frame rates used for the VFSS ranged between 20 – 28 frames per second. During VFSS, a metal 1.9cm diameter ring was placed under the participant’s chin in the midline position (Figure 2.1). The image of the metal ring on VFSS was used for calibration when the primary investigator was carrying out biomechanical measurements. 5-ml syringes were used to ensure that all participants were given the same amount of liquid boluses during VFSS.

Figure 2.1 *Placement of metal ring during VFSS*

For the TOMASS, a quarter of a single Arnott's Salada™ Cracker (Figure 2.2) was given and a video recording was taken via either a digital camera or mobile phone.

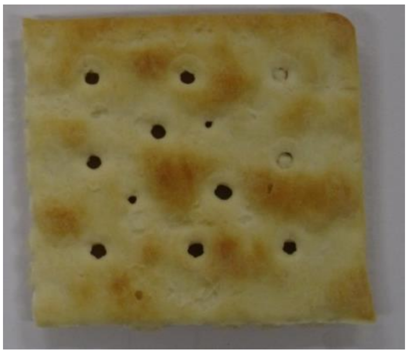


Figure 2.2 *A quarter of a single Arnott's Salada™ Cracker*

2.3 Data collection

During VFSS, all participants were given one 1ml liquid bolus, one 20ml liquid bolus, and a solid bolus (Leonard and Kendall, 2014). All fluids and solids given during the VFSS were mixed or coated with barium sulfate. The participants were first given 1ml liquid bolus and were instructed to hold the bolus in the mouth and swallow when asked to. This would provide a hold image which is used for calibration during biomechanical measurements. After 1ml liquid bolus, the participants were asked to drink 20ml of liquid via cup. Then the SLT in-charge would carry out the procedure as per her clinical judgement including if patient is appropriate for cracker bolus. Post-hoc, the recording of the VFSS was uploaded to what for biomechanical measurements. QuickTime player was used to play the VFSS and TOMASS recordings. ImageJ, Universal Desktop Ruler and Movavi Video Editor 10 were used for biomechanical measurements. The measurements taken were oral pharyngeal transit time, glossopalatal approximation duration, hyoid displacement, UES opening duration, amount of residue in the valleculae and pyriform sinus and the presence of aspiration. The biomechanical measurements are defined below:

- The measurement of oral pharyngeal transit time began when the soft palate and tongue separated and the bolus passed through the oropharynx. It ended when the head of the bolus passed the base of valleculae (Leonard & Kendall, 2014). Measurements were made on the swallows with 20ml liquid bolus and cracker bolus.

- Duration of glossopalatal approximation was measured by comparing the time that the approximation was maintained with the time the bolus is in the oral cavity. The measurement started when the bolus entered the oral cavity and stopped when the base of tongue (BOT) dropped and the bolus started to enter the oropharynx. Measurements were made on the swallows with 20ml liquid bolus and cracker bolus.

- For hyoid displacement, measurement of the distance between the hyoid at rest (1ml liquid hold image) and when it reached the maximum superior-anterior displacement during swallowing was made (20ml liquid bolus) (Leonard & Kendall, 2014).

- Measurement of UES opening duration started from the time the UES opened to the time it closed (Leonard & Kendall, 2014). Measurements were made on the swallows with 20ml liquid bolus and cracker bolus.

- To measure the amount of residue in the valleculae and pyriform sinus, the Normalized Residue Ratio Scale (NRRS) (Pearson et al., 2013) was used. The calculation involved the measurement of distance between the anterior inferior edge of C2 and C4 vertebrae. This would generate an internal anatomical scalar reference. Freehand tool from ImageJ was used to outline the valleculae/ pyriform sinus space and residue. The top of pyriform sinus was defined by using a line extending from the tip of the arytenoid shadow to the posterior pharyngeal wall that is perpendicular to the verterbral axis (Pearson et al., 2013). The measurements were inserted into an Excel spreadsheet provided by Pearson et al. (2013) and the calculation was done by the formula embedded. Measurements were made on both 20ml liquid bolus and cracker bolus.

- The presence of aspiration was defined as observation of a bolus reaching the level of the vocal folds on VFSS.

For the TOMASS, each participant was instructed to eat a quarter of a single Arnott's Salada™ Cracker "as quickly as is comfortably possible". While the participant was taking the given cracker, the lower half of the participant's face was captured in video recording. The measurements taken included the number of discrete bites, the number of masticatory cycles, the number of swallows and the total time taken. These measurements were defined as:

- The number of discrete bites taken to ingest the given cracker.
- Measurement of masticatory cycles only included the up-down jaw movement observed, rotary jaw movement used to clear the residue in the oral cavity was not included.
- The number of swallows taken to finish the cracker was noted by observing the movement of the thyroid cartilage.
- The measurement of the total time taken started the moment the cracker reached the participant's lips and stopped the moment the participant said his/her name.

To ensure inter-rater reliability, 20 percent of the data were randomly selected and analysed by two trained speech-language therapists. The therapists were provided training to ensure that the process of data analysis was consistent. For VFSS, the training covered the types of bolus (1ml and 20ml fluid bolus, cracker bolus) to use, which swallow (the first swallow with targeted bolus) to use and measuring process. For the TOMASS, the training covered the definition of the measurements and how to make measurements correctly, e.g. when to start and stop timing, how to differentiate between masticatory cycles and clearance of the residue in the oral cavity. They were also given three cases to practise before data analysis. The raters analysed the data individually.

2.4 Statistical analysis

For statistical analysis, IBM SPSS Statistics 22 was used. For all analyses, the level of significance was set at $p<0.05$.

The Kolmogorov- Smirnov test was used to determine if the data set was normally distributed. A non-parametric statistic test, Spearman's correlation coefficient, was used for statistical analysis.

2.5 Reliability analysis

Inter-rater and intra-rater reliability of TOMASS measurements and VFSS biomechanical measurements were evaluated on 20% of the entire data set using the intraclass correlation coefficient (ICC) average measurement.

Results

3.1 Reliability

Inter-rater reliability: ICC revealed high inter-rater reliability with α= 0.99 and $p < .01$ for TOMASS measurements. For VFSS biomechanical measurements, ICC showed low inter-rater reliability with α= .57 and $p < .05$. Among all the measurements, only valleculae residue with solid bolus showed a higher inter-rater reliability with α= .97 and p=.01.

Intra-rater reliability: ICC revealed high intra-rater reliability for TOMASS measurements (α= .99, $p < .01$) and VFSS biomechanical measurements (α=.99, $p < .01$).

3.2 Comparison to normative data

The TOMASS measurements were compared to the TOMASS normative data[1]. It was found that only one participant was within the normal range for all measurements; five participants were outside the normal range on all measurements. Four participants had one measurement that was within the normal range and one participant had two normal measurements.

Using the normative values for timing, duration and displacement measures for subjects under and over age 65 years (Leonard & Kendall, 2014), 7 participant's measurements of the hyoid displacement measurements and 11 participants' measurements of UES opening duration on the 20ml liquid bolus were found within the normal range. None of participants were within normal range for oropharyngeal transit time. There were no available norms for glossopalatal approximation duration comparison.

[1] *Unpublished data in M.L. Huckabee Apprentice (2015)*

Based on the VFSS result, all participants were diagnosed with mild or mild-moderate dysphagia. Two participants aspirated on fluid boluses. None of the participants aspirated on solids.

3.3 Test of normality

The Kolmogorov- Smirnov test showed that not all data analysed were significantly different from a normal distribution (Table 3.1). This could be due to the small sample size resulting in a high level of variation in the measurements collected. In order to reduce the chancee of false positive result during data analysis, a non-parametric test was used.

3.4 Correlations

Very few significant correlations were identified between measures of swallowing from the TOMASS and biomechanical measures derived from VFSS. A strong negative correlation was found between the number of bites and oropharyngeal transit time with solid bolus (r_s = - 0.64. p= 0.01), as well as between total time taken and hyoid displacement (r_s= - .57, p= 0.02). Additionally, strong positive correlation (r_s= 0.58, p= 0.02) between the number of masticatory cycles and valleculae residue with fluid bolus was identified (Table 3.2) Appendix 4 contains correlations between all TOMASS measurements, between all TOMASS measurements and all VFSS biomechanical measurements, and between all VFSS measurements.

	Kolmogorov-Smirnov		
	Statistic	df	Sig.
Number of bites	.217	15	.057
Number of masticatory cycles	.195	15	.130
Number of swallows	.227	15	.037
Total time taken	.137	15	.200*
Fluid oropharyngeal transit time	.169	15	.200*
Solid oropharyngeal transit time	.334	15	.000
Fluid glossopalatal approximation duration	.237	15	.023
Solid glossopalatal approximation duration	.238	15	.023
Hyoid displacement	.140	15	.200*
Fluid UES opening duration	.219	15	.051
Solid UES opening duration	.205	15	.089
Valleculae residue Fluid	.429	15	.000
Valleculae residue Solid	.324	15	.000
Pyriform sinus residue Fluid	.535	15	.000
Pyriform sinus residue Solid	.535	15	.000
Presence of Aspiration	.485	15	.000

Table 3.1: *Test of normality*

<table>
<tr><td colspan="4">Spearman's rho</td></tr>
<tr><td>TOMASS measurements</td><td>VFSS measurements</td><td>Correlation Coefficient</td><td>Sig. (2-tailed)</td></tr>
<tr><td>Number of bites</td><td>Oropharyngeal transit time (Solid)</td><td>-0.643</td><td>.010</td></tr>
<tr><td>Number of masticatory cycles</td><td>Valleculae residue (Fluid)</td><td>0.581</td><td>.023</td></tr>
<tr><td>Total time taken</td><td>Hyoid displacement</td><td>-0.579</td><td>.024</td></tr>
<tr><td rowspan="2">Number of masticatory cycles</td><td>Fluid oropharyngeal transit time</td><td>-.388</td><td>.153</td></tr>
<tr><td>Solid oropharyngeal transit time</td><td>-.185</td><td>.510</td></tr>
<tr><td rowspan="3">Number of swallows</td><td>Fluid glossopalatal approximation duration</td><td>-.354</td><td>.196</td></tr>
<tr><td>Solid glossopalatal approximation duration</td><td>-.037</td><td>.896</td></tr>
<tr><td>Hyoid displacement</td><td>-.326</td><td>.235</td></tr>
</table>

Table 3.2: *Result summary of significant correlations and hypothesised correlations*

Discussion

The aim of this study was to establish the sensitivity and specificity of TOMASS for detecting pharyngeal phase dysphagia by comparing TOMASS measurements to VFSS biomechanical measurements. The hypotheses of this study were 1) that an increase in the number of masticatory cycles could predict an increase in oropharyngeal transit time, 2) that an increase in number of swallows could predict reduced glossopalatal approximation duration and 3) that an increase in number of swallows could also predict reduced hyoid movement. However, the results of this study do not support the hypotheses or the findings of previous studies that looked at the relationship between tongue, jaw and hyoid (Matsuo & Palmer, 2010; Matsuo & Palmer, 2008; Pancherz et al., 1986).

There are a few potential reasons for the discrepency between this study's findings and those of the earlier discussed studies, Firstly, despite finding strong relationship between tongue, jaw and hyoid movements, the earlier discussed studies used healthy participants whereas this study used patients with dysphagia, with varying oral and/or pharyngeal phase impairment. Those studies looked at the hyoid movement as an anatomical structure and its function to jaw and tongue movements whereas in this study, it looked at the hyoid movement as a pharyngeal response in swallowing. Secondly, the methods of data collection may have attributed to the difference in results. Ali et al. (1997) suggested that the presence of oral prostheses and dentures may affect bolus transports. The earlier mentioned studies (Matsuo & Palmer, 2010; Matsuo & Palmer, 2008) put lead markers in the oral cavity to measure specific movements of the tongue that could potentially affect the mastication behaviour whereas this study did not use any invasive methods or equipment as they could potentially affect eating and drinking behaviours.

The differences between the proposed hypothesis and the results can also be explained by some limitations of the study, namely the inclusion criteria of this study. The study stipulated that only patients who can safely ingest a cracker can participate which excluded many individuals and left only participants with mild or mild-moderate dysphagia. To complicate matters further, each participant's TOMASS and VFSS results were compared to the norms[2] (Leonard & Kendall, 2014) available. It was found that there was variation in each of their presentations, with different participants scoring normally on different parameters. These resulted in an unequal distribution in swallowing pathophysiology, making it difficult to cross compare results, especially considering the limited sample size.

Although results from the study did not support the hypothesis, there were three significant relationships found between the TOMASS measurements and the VFSS biomechanical measurements that are worth exploring. Firstly, there was the negative correlation between the number of bites in the TOMASS and oropharyngeal transit time with solid bolus in the VFSS with less number of bites correlating with higher oropharyngeal transit time. This appears contradictory to studies, as it has been documented by Taniiguchi et al. (2013) have indicated that eating harder foods would lead to a prolonged oral transit time as the timing of jaw motion cycles and the tongue movement during food transport are dependent on food textures. This study is supported by findings from Engel-Hoek et al. (2012) who also discussed that the pressure of tongue and control of bolus which are important components of the oral phase of swallowing are influenced by the consistency of bolus. A potential explanation then for this finding was that during the TOMASS, it was observed that there was a tendency for participants to take bites of different sizes and weights. As such, even if a participant took fewer bites to finish the given cracker, the size and weight of the bolus was likely to be bigger and heavier than the one taken by another participant who required more number of bites. This would then account for why there was a negative relationship with fewer bites to greater oral transit time. Based on this finding, there is then some indication that in a clinical setting, when a patient is noted to have prolonged

[2] *Unpublished data in M.L. Huckabee Apprentice (2015)*

oral phase duration, the clinician could investigate further by comparing the size of the bites and number of bites on the given solid. If the patient has fewer bites with an observed bigger bolus consumed, it could help guide clinicians to hypothesise that the patient may have muscle weakness.

Secondly, a correlation was found between increased total time taken to ingest the given cracker and decreased hyoid displacement was found. This is exciting, as it is supported by the various studies earlier discussed (Taniiguchi et al., 2013; Matsuo & Palmer, 2010; Pancherz et al., 2010), that there is a strong relationship between the tongue, jaw and hyoid movements in eating which is in turn due to the involvement of suprahyoid muscles. If the muscles were weak, the mastication duration may be increased, leading to an increase in the total time taken to ingest a cracker. As the same set of muscles governs hyoid movement, in conjunction with this increase in time taken, it would also be found that hyoid movement would be reduced. While this finding was not part of the original hypothesis, it is still an interesting finding that can prove useful in facilitating better clinical judgement when using the TOMASS. If a patient has exceeded the time taken to ingest a given cracker compared to the norms, one could have some basis to hypothesise the presence of some pharyngeal phase impairment, mainly the hyolaryngeal excursion. This could potentially affect the epiglottis deflation and/or UES opening that may lead the clinician to decide that an instrumental assessment is required.

Lastly, a correlation was found between the number of masticatory cycles and valleculae residue with fluid bolus. As there is no biomechanical justification, it is likely to be the result of the small sample size of this study.

A complicating factor that arose from this study was poor inter rater reliability of gathering VFSS measurements. Within the literature, while there has been no previous study that looks at the inter-rater reliability specifically of the techniques used by Leonard and

Kendall (2014) for biomechanical measurement, other studies by McCullough et al. (2001) and Stoeckli et al. (2003) have found poor inter-rater reliability of VFSS measurements. Butler et al. (2009) have discussed that interrater reliability varies due to various reasons such as clinician's experience, the ability to review samples frame by frame, independent versus consensus rating and the availability of pre-training in the study. To help mitigate this problem, McCullough et al. (2001) suggested that providing adequate training to clinicians can help to achieve acceptable inter-rater reliability while Stoeckli et al. (2003) discussed that poor inter-rater reliability could be due to inadequate definitions of descriptive parameters suggesting that by clearly defining parameters, inter-rater reliability should improve. To that end, during the course of this study, clear definitions were given and the participating clinicians, who have different experience in evaluating VFSS results, were given training on how to carry out biomechanical measurements before data analysis. Despite these careful arrangements the inter rater reliability of VFSS biomechanical measurements were poor. A potential reason then for this may be attributed to participating clinicians being given the freedom to analyse whichever frame in the VFSS recordings that they deemed appropriate. Based on the results of this study and previous studies (McCullough et al., 2001; Stoeckli et al., 2003), it challenges VFSS findings and question its usefulness in swallowing assessment and treatment plan as currently it is deemed the gold standard for swallowing assessment.

4.1 Limitations

Due to time constraints, the sample size for this study was small (n = 15). With a larger sample size, the study will be able to recruit participants with a wider range of medical diagnoses and wider range of severity and types of swallowing impairment. This will allow the study to make comparison of the correlation between the TOMASS measurements and VFSS biomechanical measurements within and between groups of different medical diagnoses and swallowing impairments. This would provide a better understanding of the

TOMASS in detecting impairment in the pharyngeal phase of swallowing and its reliability with different groups of patients.

And also, the issue of poor inter rater reliability during VFSS biomechanical measurement may have been influenced by participants' positioning. Occasionally, some participants would move during the session and that resulted in variation in spatial measurements.

4.2 Future direction

Further studies should consider larger sample sizes to further explore the correlation of the TOMASS and the pathophysiology of pharyngeal phase of swallowing. This is the first study to investigate the correlation between the oral and pharyngeal parameters using a clinical swallowing assessment, and there were promising preliminary findings. Further studies are warranted to continue to investigate the influence of the oral parameters to the pharyngeal parameter in swallowing.

Another area that is worthy of further study is on the issue of inter-rater reliability of VFSS evaluation. As it is the current acknowledged gold standard of swallowing assessments, it is important to decide on how to resolve issues of reliability. A potential area of research would be to look at how to include more specific definition of descriptive parameters, explore different training methods and the use of a single rater vs. group of raters.

4.3 Conclusion

Although the findings of this study do not support the hypotheses, it has provided some evidence that the TOMASS may be useful to detect pharyngeal phase impairment. Further studies are crucial in helping clinicians in obtaining a more holistic result from the TOMASS that would improve the detection of aspiration with oral feeding.

References

Ali, G. N., Cook, I. J., Laundl, T. M., Wallace, K. L., & De Carle, D. J. (1997). Influence of altered tongue contour and position on deglutitive pharyngeal and UES function *Am J Physiol, 273,* G1071-G1076.

Apperley, O., McIntosh, T., & Huckabee, M.-L. (2014). *Test of Masticating and Swallowing Solids (TOMASS): preliminary validation with oral anaesthesia.*

Athukorala, R. P., Jones, R. D., Sella, O., & Huckabee, M.-L. (2014). Skill training for swallowing rehabilitation in patients with parkinson's disease. *Archives of physical medicine and rehabilitation, 95*(7), 1374-1382.

Battel, I., & Huckabee, M.-L. (2014). *Comparison of oral phase swallowing efficiency for liquids and solids in Parkinson's disease, multiple sclerosis and health controls*. Paper presented at the Dysphagia Research Society Annual Scientific Meeting, Nashville, TN, USA.

Battel, I., & Huckabee, M.-L. (2014). *Comparison of oral phase swallowing efficiency for liquids and solids in Parkinson's disease, multiple sclerosis and health controls*. Paper presented at the Dysphagia Research Society Annual Scientific Meeting, Nashville, TN, USA.

Battel, I., & Huckabee, M.-L. (2014). *Oral phase swallowing efficiency in Parkinson's disease: on and off drug effects.* Paper presented at the Dysphagia Research Society Annual Scientific Meeting, Nashville, TN, USA.

Battel, I., & Huckabee, M.-L. (2014). *Oral phase swallowing efficiency in Parkinson's disease: on and off drug effects.* Paper presented at the Dysphagia Research Society Annual Scientific Meeting, Nashville, TN, USA.

Bulter, S. G., Stuart, A., Castell, D., Russell, G. B., Koch, K., & Kemp, S. (2009). Effects of age, gender, bolus condition, viscosity, and volume of pharyngeal and upper esophageal sphincter pressure and temporal measurements during swallowing *Journal of Speech, Language and Hearing Research, 52*, 240-253.

Daniels, S. K., & Huckabee, M.-L. (2008). *Dysphagia following stroke.* San Diego: Plural publishing inc.

Daniels, S. K., McAdam, C. P., & Brailey, K. (1997). Clinical assessment of swallowing and prediction of dysphagia severity. *American journal of speech-language pathology, 6*(4), 17-24.

Depippo, K. L., Holas, M. A., & Reding, M. J. (1992). Validation of 3-oz water swallow test for aspiration following stroke. . *Arch Nurol, 49*(12), 1259-1261.

Edmiaston, J., Connor, L. T., & Loehr, L. (2010). Validation of a dysphagia screening tool in acute stroke patients. *Pulmonary critical care 19*, 357-364.

Engel-Hoek, L. v., Groot, I. J. M. d., Esser, E., Gorissen, B., Hendriks, J. C. M., Swart, B. J. M., & Geurts, A. C. H. (2012). Biomechanical events of swallowing are determined more by bolus consistency than by age or gender. *Physiology & Behaviour, 106*, 285-290.

Huckabee, M.-L., McIntosh, T., Fuller, L., & Curry, M. (2014). *Normative data and measures of inter-rater and test-retest reliability for the Test of Masticating and Swallowing Solids (TOMASS).*

Hughes, T. A. T., & Wiles, C. M. (1996). Clinical measurement of swallowing in health and in neurogenic dysphagia. *Q J Med, 89,* 109-116.

Kahrilas, P. J., Logemann, J. A., Krugler, C., & Flanagan, E. (1991). Volitional augmentation of upper esophageal sphincter opening during swallowing. *Am J Physiol Gastrointest Liver Physiol, 260*(3), G450-G456.

Kim, Y., Park, T., Oommen, E., & McCullough, G. (2015). Upper esophageal sphincter opening during swallow in stroke survivors. *American journal of physical medicine & rehabilitation, 0*(0), 1-6.

Leonard, R., & Kendall, K. (2014). *Dysphagia assessment and treatment planning.* (Third ed.). San Diego: Plural Publishing.

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

Lucas, P. W., Ow, R. K. K., Ritchie, G. M., Chew, C. L., & Keng, S. B. (1986). Relationship between jaw movement and food breakdown in human mastication. *J Dent Res, 65*(3), 400-404.

Matsuo, K., & Palmer, J. B. (2008). Anatomy and physiology of feeding and swallowing: normal and abnormal. *Phys Med Rehabil Clin N Am, 19*, 691-707.

Matsuo, K., & Palmer, J. B. (2010). Kinematic linkage of the tongue, jaw and hyoid during eating and speech. *Archives of Oral Biology, 55*, 325-331.

McCullough, G. H., Wertz, R. T., & Rosenbek, J. C. (2001). Sensitivity and specificity of clinical/bedside examination signs for detecting aspiration in adults subsequent to stroke *Journal of Communication disorders, 34*, 55-72.

McCullough, G. H., Wertz, R. T., Rosenbek, J. C., Mills, R. H., Webb, W. G., & Ross, K. B. (2001). Inter- and intrajudge reliability for videofluoroscopic swallowing evaluation measures. *2001, 16*, 110-118.

Ono, T., Kumakura, I., Arimoto, M., Hori, K., Dong, J., Iwata, H., Nokubi, T., & Akagawa, Y. (2007). Influence of bite force and tongue pressure on oro-pharyngeal residue in the elderly. *Gerodontology, 24*, 143-150.

Palmer, J. B., & Drennan, J. C. (2000). Evaluation and Treatment of Swallowing Impairments. *Am Fam Physician, 61*(8), 2453-2462.

Pancherz, H., Winnberg, A., & Westesson, P.-L. (1986). Masticatory muscle activity and hyoid bone behaviour during cyclic jaw movements in man. A synchronized electromyographic and videofluorographic study. *Am J Orthod*, *89*, 122-131.

Pearson, W. G. J., Molfenter, S. M., Smith, Z. M., & Steele, C. M. (2013). Image-based Measurement of Post-Swallow Residue: The Normalized Residue Ration Scale. *Dysphagia, 28*(2), 167-177.

Peyron, M. A., Lassauzay, C., & Woda, A. (2002). Effects of increased hardness on jaw movement and muscle activity during chewing of visco-elastic model foods. *Exp Brain Res*, *142*, 41-51.

Peyron, M. A., Maskawi, K., Woda, A., Tanguay, R., & Lund, J. P. (1997). Effects of food texture and sample thickness on mandibular movement and hardness assessment during biting in man. *Journal of Dental Research, 76*(3), 789-795.

Shiozawa, K., Ohunki, Y., Mototani, Y., Umeki, D., Ito, A., Saeki, Y.,Hanada, N., & Okumura, S. (2016). Effects of food diameter on bite size per mouthful and chewing behaviour. *Journal of Physiological Sciences, 66*(1), 93-98.

Smithard, D. G., O'Neill, P. A., Park, C., England, R., Renwick, D. S., Wyatt, R., Morris, U., & Martin, D. F. (1998). Can bedside assessment reliably exclude aspiration following acute stroke? *Age and ageing, 27,* 99-106.

Splaingard, M. L., Hutchins, B., Sulton, L. D., & Chaudhuri, G. (1988). Aspiration in rehabilitation patients: Videofluoroscopy vs bedside clinical assessment *Arch Phys Med Rehabil, 69*, 637-640.

Steele, C. M., & Huckabee, M.-L. (2007). The influence of orolingual pressure on the timing of pharyngeal pressure events. *Dysphagia, 22,* 30-36.

Stoeckli, S. J., Huisman, T. A. G. M., Seifert, B., & Martin-Harris, B. J. W. (2003). Interrater reliability of videofluoroscopic swallow evaluation. *Dysphagia, 18,* 53-57.

Taniguchi, H., Matsuo, K., Okazaki, H., Yoda, M., Inokuchi, H., Gonzalez-Fernandez, M., Inoue, M., & Palmer, J. B. (2013). Fluoroscopic evaluation of tongue and jaw movements during mastication in healthy humans. *Dysphagia, 28*, 419-427.

Appendices

Appendix 1

Participant information sheet

Rose Centre for Stroke Recovery and Research
Telephone: +64 33642307
Email: tian.ng@pg.canterbury.ac.nz

Validation of the Test of Masticating and Swallowing Solids

Information Sheet

Introduction and aim of the project

You are invited to take part in a project that looks at the Test of Masticating and Swallowing Solids (TOMASS). The aim of this project is to see if the test can detect swallowing difficulty by matching it to your swallowing x-ray results.

Taking part in this study is your choice and you can pull out from the study at any time. Your decision will not affect your health care. This project is part of the principal investigator's Masters of Speech-Language Therapy research.

Participant selection:

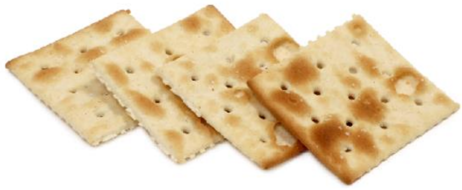
For this project, we are looking for participants who may have swallowing difficulty and need a swallowing x-ray. The speech-language therapists who carry out your swallowing x-ray will make sure that you are able to take solid food safely before asking you if you want to take part in this study.

The project will only require you to attend a twenty minute's session and will occur after your swallowing x-ray.

The research procedure

The research will take place at the Rose Centre for Stroke Recovery and Research or the Canterbury District Health Board. During the project:

1. Your speech-language therapist will briefly explain the study and ask for your consent to take part in the study after your swallowing x-ray.
2. If you have agreed, your speech-language therapist will inform the investigator.
3. The investigator will then explain the study and tell you what you need to do.
4. As signed consent is required for taking part in the study, we will also explain the consent form to you. By signing consent, you will be agreeing to take part in the project, allowing videotaping of session as well as use of your swallowing x-ray recording. We will also be answering any questions that you have.
5. When you are ready, you will be given a quarter of a single Arnott's Salada™ Cracker and asked to eat the cracker "as quickly as is comfortably possible".



6. You will need to say your name out loud once you have finished the cracker.
7. The recording of the session and a copy of your swallowing x-ray recording will be used for data analysis.

We will keep your data confidential and will not use any labels (e.g., your name or birthday) that will identify you. Data will be stored in a locked cabinet and/or password protected computer in the Rose Centre for Stroke Recovery or Research.

Risks and Benefits:

The study does not have a direct effect to your treatment. Taking part in this study will help us know more about the TOMASS that could change how speech-language therapists assessing swallowing difficulty.

Your swallowing x-ray will help to see if you can take part in the study. You will take part in the project only if your speech-language therapist has indicated that you can take solid food safely.

You will be monitored very carefully by the researchers for any possible risk during the study. Emergency equipment (e.g. suctioning) and/or medical support will be available on-site.

Participation:

If you want to pull out from the study, you can do so without giving a reason. You have up until one month after the date of participation to withdraw your data from the study. This will not affect your future care or treatment. Your participation in the study will be stopped should there be any harmful effects or if you feel it is not in your best interest to continue.

Confidentiality:

The results from the test and your swallowing x-ray may be included in the investigator's thesis. With your consent, these results may be used in future related studies and/or may be submitted to a peer-reviewed journal. However, we will ensure that there will be no information that can identify you in the report of this study. The data from this study will be kept in a locked filing cabinet or will be stored on password-protected computers. The data from this study will be stored for a period of 10 years after data collection is completed, after which all hard copies of data will be shredded and soft copies of data will be deleted by the senior researcher.

Compensation:

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Accident Compensation Act 2001 (previously known as the Injury Prevention, Rehabilitation and Compensation Act 2001). ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigator. If you have questions about ACC, contact your nearest ACC officer or the investigator.

Results:

You will be offered a copy of the final report of this project. A delay may occur between completion of data collection and the final report. You can also choose to have the results of the study discussed with you by the investigator.

Questions:

You can contact the principal investigator if you require any further information about the study. The principal investigator, Wan-Tian Ng, can be contacted during work hours at (03)3642307 or via email: tian.ng@pg.canterbury.ac.nz

If you need an interpreter, we will provide one.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate via:

Phone: 0800 555 050

Email: advocacy@hdc.org.nz

This study has been approved by the Health and Disability Ethics Committee. You can contact the committee regarding this study:

Phone: 0800 4438 442

Email: hdecs@moh.govt.nz

Appendix 2

Consent form

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Validation of Test of Masticating and Swallowing Solids

Consent Form

Declaration by participant:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I have been given a copy of the Participant Information Sheet and Consent Form to keep.

I have agree to release a copy of my swallowing x-ray recording for data analysis

I freely agree to participate in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about the project.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Appendix 3

Questionnaire

PARTICIPANT QUESTIONNAIRE

Validation of the Test of Masticating and Swallowing Solids (TOMASS)

Date of completion: ________________________

Participant ID number: _____________________ Date of birth: _____________

Ethnicity:

- ☐ New Zealand European
- ☐ New Zealand Maori
- ☐ Samoan
- ☐ Cook Island Maori
- ☐ Tongan
- ☐ Niuean
- ☐ Chinese
- ☐ Indian
- ☐ Other ______________________________

The health and disability ethics committee requests that research participants provide information about his/her ethnicity

Do you suffer from the effects of any of the following medical problems? (Please tick the most applicable)

- ☐ Stroke
- ☐ Head and/or neck injury/ cancer
- ☐ Head and/or neck surgery
- ☐ Neurological disorders (eg. Multiple Sclerosis etc.)
- ☐ Gastroesophageal Reflux Disease
- ☐ Other: _____________________________

What is the year? __________________________

What procedure are you scheduled for? _____________________________

What will you be given to eat in this study? _______________________________

Why do we need your swallowing x-ray recording? __________________________

Appendix 4a Correlation between TOMASS measurements using Spearman's correlation coefficient

		Number of bites	Number of masticatory cycles	Number of swallows	Total time taken
Number of bites	Correlation Coefficient	1	.538*	.655**	0.381
	Sig. (2-tailed)	.	0.038	0.008	0.162
Number of masticatory cycles	Correlation Coefficient	.538*	1	0.251	.729**
	Sig. (2-tailed)	0.038	.	0.367	0.002
Number of swallows	Correlation Coefficient	.655**	0.251	1	0.354
	Sig. (2-tailed)	0.008	0.367	.	0.196
Total time taken	Correlation Coefficient	0.381	.729**	0.354	1
	Sig. (2-tailed)	0.162	0.002	0.196	.

Appendix 4b Correlation between TOMASS measurements and the VFSS biomechanical measurements using Spearman's correlation coefficient

		Fluid oropharyngeal transit time	Solid oropharyngeal transit time	Fluid glossopalatal approximation duration	Solid glossopalatal approximation duration	Hyoid displacement	Fluid UES opening duration	Solid UES opening duration	Fluid valleculae residue	Solid valleculae residue	Fluid pyriform sinus residue	Solid pyriform sinus residue	Presence of Aspiration
Number of bites	Correlation Coefficient	-0.349	-.643**	-0.405	0.017	-0.458	0.017	-0.017	-0.007	-0.287	-0.191	-0.191	-0.179
	Sig.	0.203	0.01	0.135	0.953	0.086	0.953	0.953	0.98	0.3	0.495	0.495	0.524
Number of masticatory cycles	Correlation Coefficient	-0.388	-0.185	-0.095	0.507	-0.512	0.121	-0.162	.581*	0.008	-0.093	-0.093	0.232
	Sig.	0.153	0.51	0.737	0.054	0.051	0.669	0.564	0.023	0.979	0.742	0.742	0.405
Number of swallows	Correlation Coefficient	0.005	-0.172	-0.354	-0.037	-0.326	-0.192	0.477	-0.183	-0.051	-0.225	-0.225	-0.42
	Sig.	0.987	0.539	0.196	0.896	0.235	0.494	0.072	0.514	0.857	0.421	0.421	0.119
Total time taken	Correlation Coefficient	-0.36	-0.125	0.225	0.379	-.579*	0.1	0.077	0.248	0.181	-0.124	-0.124	0.077
	Sig.	0.188	0.657	0.42	0.164	0.024	0.722	0.784	0.374	0.519	0.66	0.66	0.785

Appendix 4c Correlation between the VFSS biomechanical measurements using Spearman's correlation coefficient

		Fluid oropharyngeal transit time	Solid oropharyngeal transit time	Fluid glossopalatal approximation duration	Solid glossopalatal approximation duration	Hyoid displacement	Fluid UES opening duration	Solid UES opening duration	Fluid valleculae residue	Solid valleculae residue	Fluid pyriform sinus residue	Solid pyriform sinus residue	Presence of Aspiration
Fluid oropharyngeal transit time	Correlation Coefficient	1	0.103	-0.068	-0.211	0.091	-0.215	0.324	-0.108	-0.106	-0.062	-0.062	-0.309
	Sig. (2-tailed)	.	0.715	0.81	0.45	0.746	0.442	0.239	0.702	0.708	0.826	0.826	0.262
Solid oropharyngeal transit time	Correlation Coefficient	0.103	1	0.266	0.213	0.349	-0.138	0.163	-0.126	0.237	0.248	0.248	-0.077
	Sig. (2-tailed)	0.715	.	0.337	0.447	0.203	0.623	0.563	0.654	0.394	0.373	0.373	0.784
Fluid glossopalatal approximation duration	Correlation Coefficient	-0.068	0.266	1	0.018	-0.104	0.28	0.133	-0.105	.617*	-0.309	-0.309	0.154
	Sig. (2-tailed)	0.81	0.337	.	0.95	0.713	0.312	0.637	0.708	0.014	0.262	0.262	0.583
Solid glossopalatal approximation duration	Correlation Coefficient	-0.211	0.213	0.018	1	-0.354	-0.174	-0.434	.614*	-0.215	0.309	0.309	0.154
	Sig. (2-tailed)	0.45	0.447	0.95	.	0.196	0.535	0.106	0.015	0.442	0.262	0.262	0.583
Hyoid displacement	Correlation Coefficient	0.091	0.349	-0.104	-0.354	1	-0.407	-0.147	-0.408	-0.015	0.371	0.371	0
	Sig. (2-tailed)	0.746	0.203	0.713	0.196	.	0.132	0.601	0.131	0.958	0.173	0.173	1
Fluid UES opening duration	Correlation Coefficient	-0.215	-0.138	0.28	-0.174	-0.407	1	0.339	0.196	0.189	-0.342	-0.342	0.058
	Sig. (2-tailed)	0.442	0.623	0.312	0.535	0.132	.	0.216	0.485	0.5	0.212	0.212	0.837

Solid UES opening duration	Correlation Coefficient	0.324	0.163	0.133	-0.434	-0.147	0.339	1	-0.249	0.299	-0.373	-0.373	-0.233
	Sig. (2-tailed)	0.239	0.563	0.637	0.106	0.601	0.216	.	0.371	0.279	0.171	0.171	0.404
Fluid valleculae residue	Correlation Coefficient	-0.108	-0.126	-0.105	.614*	-0.408	0.196	-0.249	1	-0.068	-0.159	-0.159	0.446
	Sig. (2-tailed)	0.702	0.654	0.708	0.015	0.131	0.485	0.371	.	0.811	0.572	0.572	0.096
Solid valleculae residue	Correlation Coefficient	-0.106	0.237	.617*	-0.215	-0.015	0.189	0.299	-0.068	1	-0.261	-0.261	0.081
	Sig. (2-tailed)	0.708	0.394	0.014	0.442	0.958	0.5	0.279	0.811	.	0.348	0.348	0.773
Fluid pyriform sinus residue	Correlation Coefficient	-0.062	0.248	-0.309	0.309	0.371	-0.342	-0.373	-0.159	-0.261	1	1.000**	-0.134
	Sig. (2-tailed)	0.826	0.373	0.262	0.262	0.173	0.212	0.171	0.572	0.348	.	.	0.635
Solid pyriform sinus residue	Correlation Coefficient	-0.062	0.248	-0.309	0.309	0.371	-0.342	-0.373	-0.159	-0.261	1.000**	1	-0.134
	Sig. (2-tailed)	0.826	0.373	0.262	0.262	0.173	0.212	0.171	0.572	0.348	.	.	0.635
Presence of Aspiration	Correlation Coefficient	-0.309	-0.077	0.154	0.154	0	0.058	-0.233	0.446	0.081	-0.134	-0.134	1
	Sig. (2-tailed)	0.262	0.784	0.583	0.583	1	0.837	0.404	0.096	0.773	0.635	0.635	.