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Title:

Using the OroPress to examine the effect of age, gender, bolus consistency and bolus volume on maximum oro-lingual swallowing pressures: a pilot study.

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Abstract

Background/Aim:

The tongue is the main organ which initiates swallowing. It generates sufficient pressure against the palate to clear bolus (food/liquid) safely through the oral cavity into the pharynx (Logemann, 1998). Previous literature on oro-lingual/tongue pressures generated during swallowing tasks have conflicted reports on how variables such as age, gender, bolus volume and consistency influence tongue pressures. The purpose of this study was to investigate the effects of these variables on maximum oro-lingual pressures generated during swallowing tasks.

Method:

35 healthy males and females from different age groups (18-28, 29-38, 39-48, 49-58 and 59-68) each performed three trials of 5ml liquid, 5ml semisolid, and 10ml liquid in random order. Each trial consisted of three swallows (nine swallows in total). The OroPress pressure sensor was adhered to the participants' hard palate which recorded oro-lingual pressures through a battery operated isolated system. This was connected to a laptop computer for data display and then recorded to file.

Results:

The results of the study yielded no significant age effect on maximum oro-lingual pressures ($p=0.773$). In terms of gender effect, women displayed higher maximum oro-lingual pressures than men during swallowing, but it was statistically insignificant ($p=0.509$). Bolus condition results revealed a significant bolus consistency effect with semisolids producing higher maximum oro-lingual pressures than liquids ($p=0.004$). In conclusion, these results will add to the database on oro-lingual pressures during normal swallowing using the new OroPress tool.

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Chapter 1: Introduction

This pilot study was designed to evaluate the psychometric properties of a new dynamic pressure measurement tool called the OroPress. This tool was used to record oral tongue pressures during isometric tasks (tongue 'pushing' against a sensor) and during the oral phase of swallowing boluses of known sizes, consistencies.
In this study information about the utility of the OroPress, when used to record swallowing pressures generated by people who do not have dysphagia (swallowing/ eating problems) were examined. Recording norm data is a necessary first step when designing a tool to measure tongue pressures with people who have dysphagia.

The aims of this study were to:

1. Examine the stability, reliability and validity (also known as psychometric properties) of the OroPress when it was used to measure dynamic tongue pressure in normal adults.
2. Determine the range and variability of the maximum tongue pressure recorded, from a sample of normal adults across age, gender, bolus consistency and bolus volume.

In order to undertake this study, the tongue and its function in swallowing needed to be understood.

The role of the tongue in swallowing:

Logemann (1998) describes the tongue's function as generating pressure against the palate to clear a bolus (food/liquid) safely through the oral cavity into the pharynx. There are four stages to swallowing which involve "fine neuromotor coordination of the upper aerodigestive tract and both cortical and brain stem control" (Miller 1982 cited in Logemann 1998, p. 39). Logemann (1984) describes the importance of tongue mobility, which assists mastication, when he states that without normal tongue range and motion, normal chewing and swallowing would be impossible.

Organisation of study:

The study was divided into three parts with each student being allocated one. This report addresses how four variables - age, gender, bolus volume and bolus consistency - affect maximum oro-lingual pressures generated during swallowing tasks. The background literature on these variables was considered and is reported on as follows.

Background:

The background studies will be discussed regarding the variables of age, gender, bolus consistency and bolus volume.

Youmans and Stierwalt (2011) studied normal swallow acoustics using an accelerometer taped to each participant's neck to record acoustic information about the pharyngeal phase of swallowing. The researchers had a large sample, with 48 males and 48 females, aged from 20 to over 60 years. Results indicated an increasing pharyngeal swallowing duration with increasing age, bolus consistency and bolus volume. In addition, an increased duration to peak intensity with advancing age was found, as well as with more versus less viscous boluses. Men and older people produced higher peak intensities and peak frequencies than did women and younger aged participants. Thin liquids were produced with more intensity than honey or more viscous boluses, and with greater intensity than soft solids. Larger volumes resulted in greater peak frequency values. Swallowing was highly variable across participants, and this difference was more pronounced in the elderly participants. In a prior study by Youmans *et al* (2009) with 96 participants of equal gender, aged 20-79 years, mean anterior tongue pressures during swallowing tasks were recorded using the Iowa Oral Performance Instrument (IOPI). There were no significant age effect or age and gender interaction, which corresponds with other researchers (Nicosia *et al* 2000; Robbins *et al* 1992). Youmans *et al* (2006) found similar results using the IOPI. However, there was a significant gender effect in the study by Youmans *et al* (2009) with women producing significantly higher pressures than men. This has not been supported by previous researchers. There were significant statistical differences found when examining the relationship across increasing oro-lingual pressures and increasing bolus volumes and consistencies (Youmans *et al* 2009).

Hind *et al* (2005) examined the effects of intraoral pressure on normal younger and older swallow patterns using the 3 bulb pressure sensors from the Kay Swallowing Workstation (KSW). There was a small sample of 12 participants and an unequal representation of each gender. The results of the study indicated that younger subjects cleared boluses from the oral cavity faster than did older subjects when swallowing semisolids and when insructed to 'swallow hard' – a result which is consistent with the work of Robbins *et al* (1992) who found that younger subjects swallowed faster than did older subjects.

Steel *et al's* (2010) study was to confirm whether tongue-palate pressures are modulated across bolus consistency. Twenty adults took five sips in a row from a cup containing approximately 150 ml of either water or nectar-thick juice water. It was demonstrated that tongue-palate pressure amplitude modulation did not occur for nectar-thick swallows compared to thin liquid swallows. Modulation did, however, occur with respect to the tongue-palate contact surface area and duration of pressure. Steel *et al* (2010) stated that this study was undertaken in order to characterise these modulations in healthy young adults as a precursor to determining whether similar patterns exist in healthy seniors or in individuals with dysphagia.

Furuya *et al's* (2012) study to examine tongue pressure production while swallowing water and pudding and during dry swallowing used a sensor sheet system, which measured five measurement points in the palate. The researchers documented ten healthy participants of both genders while swallowing pudding and during a dry swallow. The duration of tongue pressure tended to increase at all surface areas, except for the posterior-median part. The maximal tongue pressure was significantly higher when swallowing pudding compared to swallowing water at all areas, except for the posterior-median part. The integrated value of tongue pressure was significantly higher when swallowing pudding than when swallowing water at all areas, except for the posterior-median part. Effort was generally greater when dry swallowing than when swallowing water. It was reported that more effort was required for dry swallowing. From these results, it was considered the sequential order, the duration, and the tongue pressure production changed according to the swallowing conditions (liquid swallowing, semisolid swallowing, and dry swallow).

In their study on tongue-palate interactions during swallowing, Kieser *et al* (2010) reported that pressure patterns were consistent within individuals, irrespective of bolus size or consistency. The limitations to this study included a small sample size (six participants) and limited numbers of swallows per participant. They state that, "In contrast to previous studies, our work suggests that it is a combination of positive (push) and negative (pull) pressures that are involved in bolus transport towards the pharynx" (Kieser *et al* 2010, p. 99). From related studies such as that by Shaker *et al* (1988), to examine how the tongue handles different bolus sizes during the oral phase of deglutition, it was found that "the generation of lingual pressure was more influenced by bolus viscosity than bolus volume" (Shaker *et al* 1988, p. 101). Similar results have been reported by Miller and Watkin (1996), who showed that there were significant increases in tongue force when bolus viscosity was increased, but that these increases were not matched for increased bolus volume.

Conclusions:

Age has not been shown to have an effect on swallowing pressure or on the time taken to reach peak swallowing pressures. There are conflicting reports regarding gender effect. Researchers have not shown a significant bolus volume effect on swallowing pressures. For bolus consistency, researchers have demonstrated that, when bolus consistency increased, there was a corresponding significant increase in oro-lingual pressure.

Chapter 2: Research Aims and Hypotheses

Aim:

The purpose of this study was to investigate the effects of age, gender, bolus volume and bolus consistency on maximum oro-lingual pressures generated during normal swallowing

Hypotheses:

Hypothesis 1 There will be no significant differences in recorded maximum oro-lingual pressures across age groups during normal swallowing.

Rationale: No significant differences in recorded swallow pressures have been shown between younger and older participants when swallowing boluses of different sizes and consistencies (Nicosia *et al* 2000; Youmans *et al* 2009).

Hypothesis 2: There will be a significant gender difference in maximum oro-lingual pressures during normal swallowing, with women generating higher maximum swallowing pressures.

Rationale: There been conflicting reports about the effect of gender on swallowing pressures. In one study women produced significantly higher maximum swallowing pressures than men (Youmans *et al* 2009).

Hypothesis 3: There will be higher maximum oro-lingual pressures for swallowing thicker (semisolid or ss) consistency boluses compared to swallowing liquid boluses of the same size.

Rationale: Maximum swallowing pressures for thicker boluses (honey thick) have been shown to be significantly higher than for thin liquid boluses (Youmans *et al* 2006).

Chapter 3: Methods and Materials

Ethical Committee Approval:

Ethical approval was obtained from the Human Ethics Committee at the University of Limerick prior to study commencing.

Participants:

Thirty five participants were recruited from the local area surrounding the University of Limerick. The participants consisted of seventeen males from 18 to 63 years old and eighteen females, from 19 to 70 years old. These participants were divided into five decades: 18-28, 29-38, 39-48, 49-58 and 59-68 years.

Table 1

Age groups and gender of participants

	Gender	
Age Group	**Male (Total n = 17)**	**Female (Total n = 18)**
18-28	6	8
29-38	4	3
39-48	2	2
49-58	1	3
59-68	4	2

n = number of participants

Inclusion Criteria:

Participants were included if they: (i) were able to complete the required tasks and (ii) gave written informed consent to participation in the study.

Exclusion Criteria:

Participants were excluded if they had: (i) a history of swallowing and/or speech disorders (ii) a medical condition or use of medications that may affect swallowing; (iii) any structural or functional oral peripheral abnormality; (iv) an overly sensitive gag reflex (i.e., gag reflex triggered in the middle portion of the anterior tongue) or (v) an inability to follow verbal commands.

Recruitment Procedure:

Participants were recruited using any of the following procedures: (i) verbal request to friends and colleagues at UL; (ii) written letters and emails to friends and colleagues at UL.; (iii) letters and emails to presidents of volunteer groups and organisations around the Limerick area (see appendix A) or (iv) advertisement posters placed around UL and the local area (See appendix B). Participants were provided with a study information leaflet (see appendix C). The researcher verbally explained the data collection procedure during a face to face interview with the participant and then written informed consent was obtained from each participant (see appendix D).

To ensure confidentiality, data (both electronic and hard copy) from all participants were stored using a unique identification code to de-identify the participants.

Materials:

The OroPress tool consisted of a pressure sensor implanted in a silicone sheath, which is adhered to a participant's hard palate and then attached to a headset

Figure 1

Table set-up with study materials listed below.

List of materials needed:

Oropress system which contained laptop, headset, batteries and two tongue sensors.

Forms-Consent forms, information sheets, medical questionnaires, safety and utility questionnaires and pens for the participants to fill in before data collection.

Sterilisation kit- The OroPress sensor was sterilised between participants using a Tristel Trio50 system. This system has three impregnated wipes - pre-clean, sporicidal and rinse - that are used in sequence and then disposed of.

Plastic teaspoons to transfer appropriate amount of custard into syringes.

Small plastic bags- To place sensors before and after data collection.

Randomisation order of bolus conditions.

Chair-In a standardised measured position for participant and chair for researcher. This is done using measuring tape and placing sticky tape on the floor to mark appropriate spot to place chair.

Coloured Disc-Fixed on the wall at a comfortable level to reduce head movement.

Latex Gloves-for the researcher to wear throughout the data collection.

Oro-motor form for researcher to use during examination.

Pen Torch and Tongue Depressor for Oro-motor exam.

Scissors-To cut the poligrip adhesive sheets to appropriate size for sensor.

Poligrip Denture Strips-To adhere the sensor to the participant's mouth.

Mineral Water-for practice swallow.

Custard- Three 5ml syringes filled with semisolid for each participant.

Water-Three 5ml and three 10ml syringes filled with liquid for each participant.

Digital Camera-To capture level of residue present on sensor after each trial.

Tissues-To alleviate residue surrounding the participant's mouth.

Data Collection:

Three student researchers collected the data over a period of four days. There were three main activities for each researcher to complete. The sequence of data collection was as follows:

1. Setting up the computer and managing the data when recording.

2. Preparation for trials-making sure all the equipment is ready for use and all materials are set up on the data collection table.

3. Completing the oro-motor exam with the participant and carrying out the swallowing trials on the participant.

Each participant was briefed about the study using an information leaflet.

Participants were screened using a medical questionnaire and, if they met inclusion criteria, an oro-motor was completed-(see appendices E and F).

Equipment and Participant Preparation:

Trials took place in a room in the Speech and Language Therapy (SLT) clinic at the University of Limerick. The OroPress sensors were sterilised as described above. Each sensor is factory-calibrated and includes an integrated thermometer to allow for temperature compensation. Confirmation of calibration was checked on each sensor prior to its use, using zero and 100 mmHg datum points.

Equipment and method:

Three x 5 ml syringes of water, 3 x 10 ml syringes of water and 3 x 5 ml syringes of custard, tissues, gloves, pen, forms, tongue pressure sensor, poligrip strips and a cup of water were placed on a clinic table.

Participants read their study information sheet and signed their informed consent. The researcher completed an oro-motor examination on the participant and assessed his/her gag reflex. If the participant was suitable for the study, he/she completed a medical questionnaire.

A participant was then seated in a chair at a standard distance from the wall where a coloured disc was attached at the eye level of the participant, to stabilise head movement.

The headset was placed on the participant. To increase adhesion, a poligrip strip was placed in water prior to attaching it to the reverse side of the sensor. The sensor was then attached to the headset and the battery operated system was switched on. The system was then connected to a laptop computer to display and record data. Each data file was stored under a header with subject identification, date and time stamps, and other relevant test data. The sensor was then attached to the hard palate, on the alveolar ridge, behind the upper teeth.

Figure 2

Photograph of sensor attached to headset and connected to the laptop.

The researcher explained the procedure to a participant. A participant first sat in the chair, with feet flat on the ground, facing the disc on the wall. Each participant first had some practice trials using sips of water from a cup, to become familiar with the sensor in their mouth. The practice trials were not recorded.

Swallowing Trial Procedure*:*

First, a measured bolus was presented to the participant. The person was instructed to keep their head still and to focus on swallowing the (food, fluid) as normally as possible.

They were then instructed to open their mouth, to hold the presented bolus in their mouth until the researcher said 'Swallow now, as one swallow.'

Each participant completed three swallows under each condition, in a random order of bolus size and consistency. In total, each participant completed nine swallows -three under each condition, (i.e., 5ml water, 5ml custard and 10ml water).

After each trial, a digital photograph of the sensor was taken and the amount of bolus residue was rated using a 3 point rating scale (below).

Rating scale for Oral Residue:

Rating	Description
0	No residue in oral cavity post-swallow
1	Minimal residue or coating post-swallow
2	Marked pooling in oral cavity post-swallow

At completion, each participant completed a feedback form (see appendix G) and was asked whether he/she would like to receive information on the outcome of the study. This was noted for future contact.

Confidentiality:

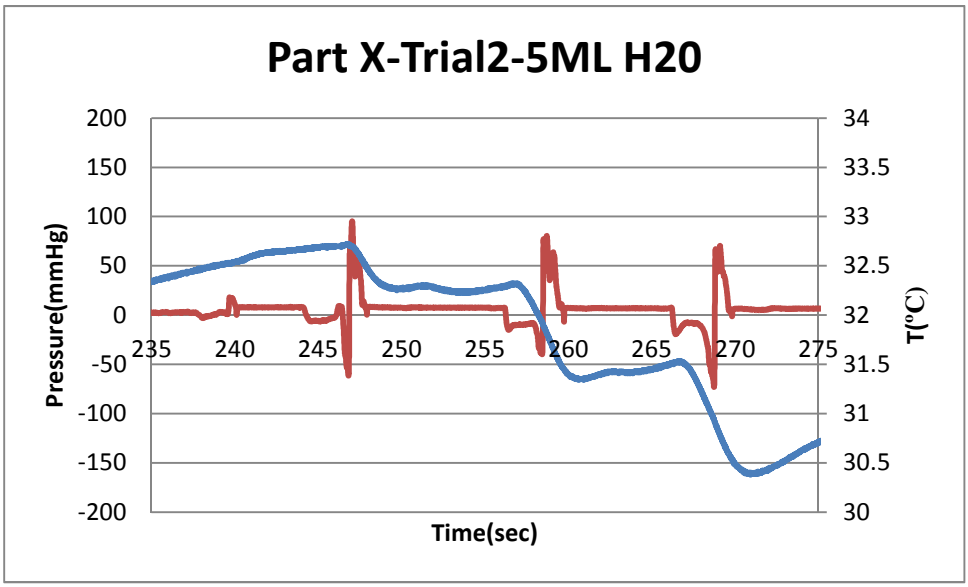
All computer data files were saved to a thumbdrive for further analyses. All participant details, trial details (bolus consistency, bolus volume, order of swallows) were documented by the researchers and hard copy data were kept in a locked filing cabinet in the office of the supervisor at the University of Limerick.

Data Management:

All raw data were uploaded from the thumbdrive to a desktop computer, where post-hoc data analyses occurred. Data were then transferred to a Microsoft Excel spreadsheet, and converted graphed. From this, maximum oro-lingual pressures were identified and displayed (see figure 3).

Figure 3

Microsoft excel spreadsheet containing graph



Examination of the oro-lingual pressure data occurred by a group of four raters. Three of the four raters independently documented the time on the screen that corresponded to the participant swallowing a specified bolus. These times were then agreed, logged and saved. The fourth rater, examined the saved data post-hoc by assessing the temperature recorded on the software programme, studying where the temperature line rose and dropped in relation to the oro-lingual pressure data/ swallowing event. These data were logged and then both sets of information were scrutinised and compared. All raters agreed on the final maximum oro-lingual pressure for each swallow for each participant.

Research Design:

This was a pilot study to examine the psychometric properties of a new tool, the OroPress. Table 2 displays the independent variables and Table 3, the dependent variables.

Table 2

Independent Variables (IVs) and their levels

Independent Variables	**Levels**

Order of swallow	First, second, third swallow of a defined bolus volume and consistency
Age group	1.(18-28) 2.(29-38) 3.(39-48) 4.(49-58) 5.(59-68)
Gender	Male vs. female
Bolus Volume	5ml vs. 10ml
Bolus Consistency	Liquid vs. Semi-solid

Table 3

Dependent Variable (DV) and scale of measurement

Dependent Variable	**Scales of Measurement**
Maximum oro-lingual pressure	Ratio (mmHg)

Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS) Student Version 20 program (IBM Corp, 2011).

Data Screening:

Data were first screened for errors. This was done using box plots and histograms, calculating skewness (indication of the "symmetry of the distribution") and kurtosis (information about the "peakedness of the distribution") (Pallant 2005, p. 51).

The data displayed abnormal distribution, so the measure of centrality used was the median, which had the advantage of being unaffected by the value of extreme scores as it is an index of 'average position in a distribution' and is a useful measure for describing a

skewed distribution (Portney and Watkins 2009, p.390). The measures of dispersion were the standard deviation and semi interquartile range, as these are used to describe a score's position within a distribution. Due to a non-normal distribution, non-parametric tests were applied. Non-parametric tests make fewer assumptions about population data (Portney and Watkins 2009), so can therefore be used very effectively with a small sample size such as in this pilot study.

Descriptive Statistics:

The descriptive statistics for the maximum oro-lingual pressures during swallowing include measures of centrality, such the mean and median, and measures of dispersion, such as semi interquartile range. This was undertaken for the pressures obtained from each swallow of differing bolus volume and consistency, across ages and gender.

Alpha Level: The alpha level, or level of significance, "represents a criterion for judging if an observed difference can be considered sampling error or real" (Portney and Watkins 2009, p. 419). For hypothesis testing in this study, the alpha level was set at 0.050. Bonferroni's correction, which adjusts the alpha level to protect against type 1 error, was applied due to the number of comparisons of swallows being carried out (Portney and Watkins 2009).

Detecting Systematic Bias: The Friedman test is the non-parametric alternative to the one-way ANOVA with repeated measures. When the Friedman test showed significance, the pairs would be tested using a multiple comparisons procedure such as the Wilcoxon Signed-Ranks test to determine the foundation of the bias (Portney and Watkins 2009).

Investigating Reliability: As this was a pilot study, establishing the reliability of the tool was necessary to ascertain whether the tool had sound properties to provide valid measures (Portney and Watkins 2009). An Intraclass Correlation Coefficient (ICC) was used to examine test-retest reliability as it is a non-parametric test.

The two way mixed effects model (ICC 3,1) was chosen to examine test-retest reliability as it reflects both "correlation and agreement" (Portney and Watkins 2009, p. 86). It allows for the testing of reliability over repeated measures made by the same rater across three swallows (Portney and Watkins, 2009). If the test is reliable, the subject's score should be similar on multiple trials of the same task.

Detecting Effects of Different Variables on Maximum Oro-Lingual Pressures:

Using an alpha level of 0.050, variables such as age, gender, bolus consistency and bolus volume were tested to see if they affected maximum oro-lingual pressures.

The effect of age on maximum oro-lingual pressures was tested using the K independent test- Kruskal Wallis test. The Kruskal Wallis test is the non-parametric alternative to the one-way between-groups analysis of variance. It allows for comparison of three or more groups. This test conveys whether there are significant differences in the median scores on the dependent variable across the age groups (Pallant 2005).

The effect of gender on maximum oro-lingual pressures were examined using the 2 Independent sample-Mann Whitney U test. This is the non-parametric alternative to an Independent-samples t-test. It is used to examine differences between two independent groups on a continuous measure. The Mann Whitney U test enables the medians to be compared, which captures more data than the mean.

The effect of bolus volume and bolus consistency on maximum oro-lingual pressures recorded were examined using the Kruskal Wallis test.

Swallow patterns were self-documented as part of the medical questionnaire. Each participant was asked to dry swallow while noting the position of the tip of their tongue at the start of that swallow. Dodds *et al* (1989, p. 1197) stated that one pattern type - 'a tipper' "is initiated with the tip of the tongue against the incisors." The other pattern type, a 'dipper' is when the tongue, "dips beneath the bolus in order to elevate the bolus above the tongue" (Dodds *et al* 1989, p. 1197). Each person reported their own pattern.

Table 4: **Summary of Statistical Analysis:**

Summary of statistical analysis displaying the subjects of distribution and the statistical measures used in the data analysis

Subject of Analysis	**Statistical Method Used**
Normality of distribution and homogeneity of variance in oro-lingual pressures obtained	Mean, median, visual analysis of box plots, line plots and histograms; calculations of levels of

	skewness and kurtosis; Shapiro-Wilk test. Non-Parametric tests were used as data did not meet parametric standards.
Descriptive Statistics	
Central tendency	Mean, median
Variability	Semi-interquartile range, standard deviation, minimum and maximum pressures.
Systematic bias across swallow trials	Friedman one way analysis of variance by ranks; Wilcoxon signed-ranks test was used if significance was detected.
Reliability	
Test-retest reliability	ICC Model (3, 1)
Effects of different variables on oro-lingual pressures:	
Age	Kruskal-Wallis test
Gender	Mann Whitney U test
Bolus Volume	Kruskal Wallis test
Bolus Consistency	Kruskal Wallis Test
Swallow Pattern	Medical questionnaire results and descriptive statistics.

Chapter 4: Results

Data Screening:

Data screening was completed using the methods described in chapter 3 and normality distribution and outliers were noted.

An abnormal distribution was noted for the maximum oro-lingual pressures data. This was shown as histograms and boxplots. The majority of the data also showed positive skewness and kurtosis. Non-parametric tests were therefore used to analyse maximum oro-lingual pressures.

To determine if there were extreme outliers (i.e. participants who were consistently three standard deviations away from the mean for all three swallowing trials), boxplots were examined and outliers were identified but they were inconsistent so they were included in the final analyses (Trabachnick and Fidell 2001).

Descriptive Statistics:

Descriptive statistics of maximum oro-lingual pressures recorded for each swallowing trial are displayed according to bolus volume and consistency in tables 5 and 6.

Table 5

Means, medians, standard deviations (SD), and minimum and maximum values of maximum oro-lingual pressures for liquid consistency.

	5ml water			**10ml water**		
	S1	**S2**	**S3**	**S1**	**S2**	**S3**
Mean (SD)	148.2	186.04	169.2	171.6	167.8	172.8
Median	81.5	115.04	151.5	156.1	158.9	167.8
(min-max)	24-398	31-559	31-348	93-338	46-396	60-334

S1 = first swallow, S2 = second swallow, S3 = third swallow

Table 6

Means, medians, standard deviations (SD), and minimum and maximum values of maximum oro-lingual pressures for semisolid consistency.

	5ml custard		
	S1	**S2**	**S3**
Mean (SD)	73.1	88.7	101.8
Median	69.04	76.4	79.5
(min-max)	28-156	20-247	55-318

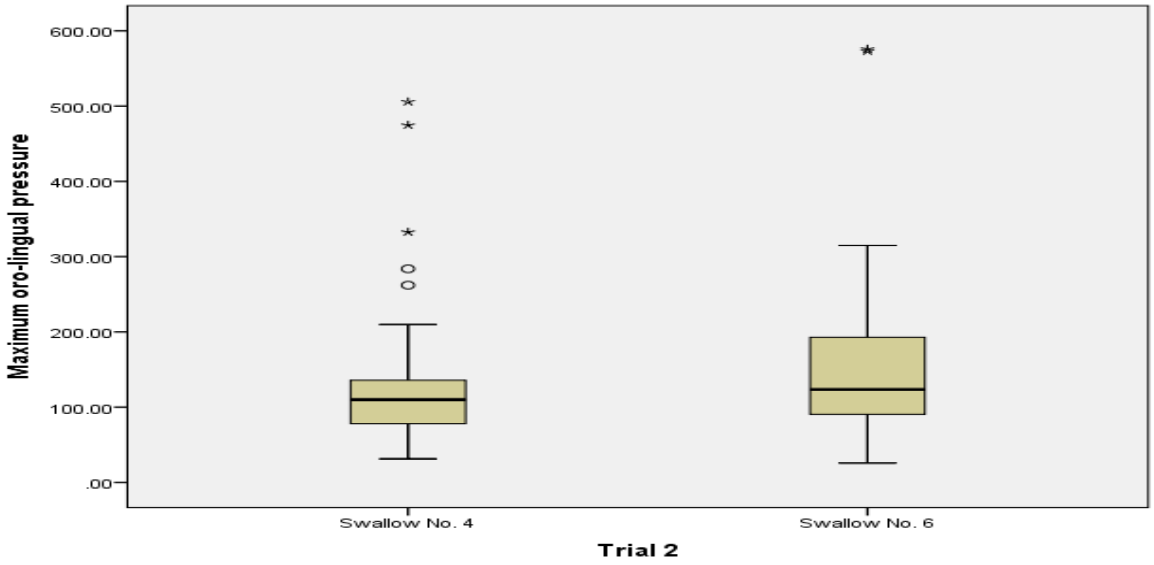
S1 = first swallow, S2 = second swallow, S3 = third swallow

From inspection of these measures, the liquid consistency produced highest oro-lingual pressure measurements. These values also display large variability in maximum pressures generated for all bolus conditions. The widest range of pressures noted was for liquids – specifically, for 5ml water swallows.

Systematic Bias: The Friedman one way analysis of variance by ranks was used to determine if any systematic bias was present in the maximum oro-lingual pressures obtained across the order of swallow. See Figure 4.

Figure 4

Maximum oro-lingual pressures for swallows four and six.



There was a statistically significant difference for trial 2 (consisting of swallows 4 to 6) from all participants (p=.011). Post-hoc analysis using the Wilcoxon signed-rank test was conducted with a Bonferroni correction applied, resulting in a significance level of (P<0.017). Median (IQR) for group swallow trial 2 were swallow 4-110 (75 to 138), swallow 5-105 (83 to 174) and swallow 6-123 (89 to 199). There was a statistically significant result between swallow 4 and swallow 6 (p=0.004), with swallow six displaying a higher mean of 160.6 than swallow four, at a mean of 136.7.

Range and Variability of Maximum Oro-Lingual Pressures:

For all second swallow trials, measures of centrality (mean and median) and dispersion (standard deviation and semi-interquartile range) were used to examine the range and variability of maximum oro-lingual pressures produced.

Table 7

Mean, standard deviations, median and semi-interquartile range values of maximum oro-lingual pressures for liquid consistency.

	5ml water			**10ml water**		
	S1	S2	S3	S1	S2	S3
Mean	114.2	157.7	151.2	115.1	151.1	184.5
SD	69.1	106.4	79.6	160.2	150.7	189.9
Median	109.9	130.7	125.6	108.8	98.5	104.5
SIQR	24.7	44.2	43.5	38.9	54.5	79.4
Min-Max	58.1-261.9	83-387.9	81.4-314.9	31.2-505.6	38.5-496.4	49.4-575.7

S1=first swallow, S2=second swallow, S3=third swallow

Table 8

Mean, standard deviations, median and semi-interquartile range values of maximum oro-lingual pressures for semisolid consistency.

	5ml custard		
	S1	S2	S3
Mean	132.8	156.6	146.9
SD	80.9	109.5	69.9
Median	118.9	112.2	137.7
SIQR	28.1	56.1	59.8
Min-max	33.7-332.7	51.6-374.1	25.7-276.9

S1=first swallow, S2=second swallow, S3=third swallow

From inspection of the semi interquartile range and minimum to maximum values, there was a wide range and variability seen in maximum oro-lingual pressures. The widest range occurred for 10ml water swallows.

Reliability:

Test-retest reliability:

Reliability of the maximum oro-lingual pressures recorded were examined using the two ways mixed effects model of the Intraclass Correlation Coefficient (ICC Model (3,1))

Table 9

ICC values, 95% confidence intervals, and p-values for maximum oro-lingual pressures for liquid and semi solid consistencies for trial two across participants.

		95% confidence interval		
	ICC (3, 1) value	**Lower Bound**	**Upper Bound**	**P-Value**
5ml water	.91	.71	.98	.001
10ml water	.96	.90	.99	.001
5ml custard	.74	.50	.89	.001

ICC values of 0.75 and 1.0 demonstrate excellent reliability (Cicchetti, 1994) and it can been seen that the above values are in this range. The highest reliability values occurred for 10ml water swallows (ICC=0.96). All of the first trials indicated good reliability values (0.61, 0.62 and 0.73). Values between (0.60-0.74) indicate ‘’good’ reliability (Cicchetti, 1994). All of the third trials displayed excellent reliability (0.68, 0.79 and 0.95). (See appendix H) for ICC values for trials 1 and 3.

The Effect of Different Variables on Maximum Oro-Lingual Pressures

Age Effect:

Descriptive statistics for maximum oro-lingual pressures by age groups are shown in table 10

Table 10

Means, medians, minimum and maximum values of maximum oro-lingual pressures for age groups

Age Group			Mean	Median	Minimum	Maximum
18-28	Swallow no. 4	5ml water	109.907	109.907	109.907	109.907
		10ml water	216.904	125.092	31.225	505.640
		5ml custard	121.339	108.159	33.670	283.764
	Swallow no. 5	5ml water	130.676	130.676	130.676	130.676
		10ml water	205.884	109.768	44.164	496.370
		5ml custard	152.740	98.048	71.631	374.072
	Swallow no. 6	5ml water	110.484	110.484	110.484	110.484
		10ml water	256.973	138.214	49.392	575.719
		5ml custard	139.179	113.035	25.720	276.879
29-38	Swallow no. 4	5ml water	61.408	61.408	58.077	64.738
		10ml water	99.219	99.219	83.280	115.157
		5ml custard	173.702	143.367	45.176	332.563
	Swallow no. 5	5ml water	110.162	110.162	83.002	137.322
		10ml water	101.150	101.150	84.217	118.083
		5ml custard	177.580	126.326	51.649	354.765
	Swallow no. 6	5ml water	103.479	103.479	81.352	125.606
		10ml water	94.872	94.872	60.710	129.033
		5ml custard	148.665	123.536	105.504	216.956
39-48	Swallow no. 4	5ml water	114.055	114.055	114.055	114.055
		10ml water	75.764	75.764	75.764	75.764
		5ml custard	171.438	171.438	132.971	209.905
	Swallow no. 5	5ml water	105.107	105.107	105.107	105.107
		10ml water	98.341	98.341	98.341	98.341
		5ml custard	144.230	144.230	139.699	148.760
	Swallow no. 6	5ml water	140.405	140.405	140.405	140.405
		10ml water	101.844	101.844	101.844	101.844

		5ml custard	202.866	202.866	174.090	231.642
49-58	**Swallow no. 4**	5ml water	.	.	.	.
		10ml water	112.195	112.195	112.195	112.195
		5ml custard	98.516	86.145	85.957	123.445
	Swallow no. 5	5ml water	.	.	.	.
		10ml water	64.093	64.093	64.093	64.093
		5ml custard	178.915	94.328	83.355	359.063
	Swallow no. 6	5ml water	.	.	.	.
		10ml water	89.483	89.483	89.483	89.483
		5ml custard	123.960	91.313	81.284	199.284
59-68	**Swallow no. 4**	5ml water	150.768	110.064	80.242	261.997
		10ml water	86.734	86.734	55.287	118.180
		5ml custard	115.105	115.105	115.105	115.105
	Swallow no. 5	5ml water	215.861	174.007	85.590	387.985
		10ml water	106.682	106.682	38.486	174.877
		5ml custard	78.772	78.772	78.772	78.772
	Swallow no. 6	5ml water	200.114	186.286	99.203	314.854
		10ml water	145.486	145.486	52.459	238.513
		5ml custard	151.903	151.903	151.903	151.903

Examining the above statistics reveals that the 39-48 year age group produced the highest pressures of all the groups for swallowing 5ml custard (median=202.9mmHg). The youngest age group (18-28 years) displayed the largest range of pressures when swallowing 10ml water (min=49.392 mmHg; max = 575.719 mmHg). The 29-38 year age group produced the smallest pressures (median=61.4mmHg). Using the Kruskal Wallis test, no significant age effect was detected (p=0.773)

Gender Effect

Descriptive statistics for maximum oro-lingual pressures by gender are shown in table 11

Table 11

Means, medians, minimum and maximum values of maximum oro-lingual pressures for gender

	Gender		Mean	Median	Minimum	Maximu
Swallow no. 4	**Males**	5ml water	114.171	95.075	58.077	261.997
		10mlwater	92.364	83.280	39.776	144.822
		5ml custard	110.648	114.756	45.176	209.905
	Females	5ml water	114.055	114.055	114.055	114.055
		10ml water	199.924	112.195	31.225	505.640
		5ml custard	146.012	124.038	33.670	332.563
Swallow no. 5	**Males**	5ml water	166.430	133.999	83.002	387.985
		10ml water	107.699	98.588	48.604	174.877
		5ml custard	166.572	157.270	51.649	359.063
	Females	5ml water	105.107	105.107	105.107	105.107
		10ml water	182.130	84.217	38.486	496.370
		5ml custard	150.647	96.188	71.631	374.072
Swallow no. 6	**Males**	5ml water	152.964	118.045	81.352	314.854
		10ml water	128.756	107.124	67.266	238.513
		5ml custard	166.200	184.309	66.861	231.642
	Females	5ml water	140.405	140.405	140.405	140.405
		10ml water	224.300	89.483	49.392	575.719
		5ml custard	135.256	118.286	25.720	276.879

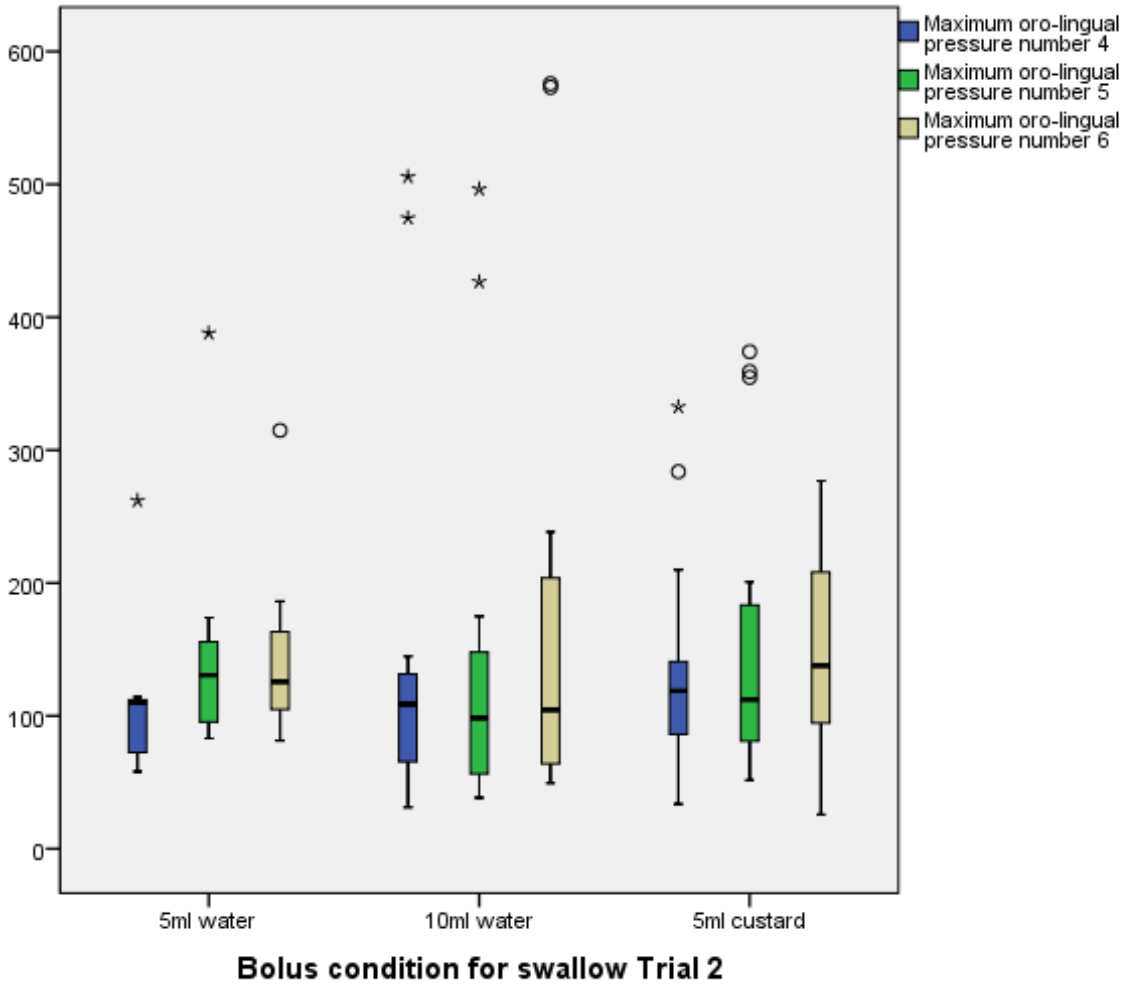
Using the Mann Whitney test, no significant gender effect for any of the bolus conditions was detected (p=0.509).

The effect of Bolus volume and consistency on oro-lingual pressures:

Maximum oro-lingual pressures for each bolus condition (5ml water, 10 ml water and 5ml custard) are shown in figure 5.

Figure 5

Maximum oro-lingual pressures for each bolus condition across swallow trial two



A significant difference was found for trial 1 across bolus conditions, with liquid consistency producing higher pressures than semisolid consistency (10 ml water, median=167.8mmHg). For trial 2, both liquid and semisolid consistencies were similar for generating maximum oro-lingual pressures, with semisolid boluses producing the highest pressure (median of semisolid swallows=137.7mmHg) whereas the median for liquid bolus swallows was (130.7 mmHg). For swallow 3 of semisolid boluses, higher pressures were recorded than for liquid

boluses of the same size (semi-solid bolus median=206.9 mmHg; liquid bolus median=137.3mmHg). (See appendix I for clustered box plots)

Swallow patterns

Table 12

Age groups according to swallow pattern

Age Group (years)	Swallow Pattern			
	Tipper (n)		**Dipper** (n)	
	Female	Male	Female	Male
18-28	6	5	2	1
29-38	2	3	1	1
39-48	1	2	-	-
49-58	2	1	-	-
59-68	2	4	-	-

n = number of participants

- = no rating provided

The majority of the participants were tippers, but in the younger age groups (18-28 years) and (29-38 years) there were participants who used a 'dipper' pattern.

Bolus Residue

Bolus residues were analysed using descriptive statistics as in Table 13

Table 13

Number of participants for each rating across bolus conditions

	Trial 1			Trial 2			Trial 3		
	5ml water	10ml water	5ml custard	5ml water	10ml water	5ml custard	5ml water	10ml water	5ml custard
No residue	10	14		7	10	3	17	9	2
Minimal residue			10		2	13	1		6
Marked pooling			1						

From the figures in table 13, semisolid boluses resulted in minimal residue. Upon closer inspection of the data, marked pooling occurred for one male in the (29-39 years) age group. Swallowing liquid boluses resulted in minimal residue. Minimal residue ratings occurred across liquid swallows, regardless of age or gender. Digital photographs were taken after every trial to augment the subjective ratings. However on inspection of the photographs, the angle and visibility of the sensor were not captured consistently, so the photographs were not used to further analyse the residue ratings.

Summary of Key Findings:

There was wide range and variability found in the maximum oro-lingual pressures generated by people in this study of normal swallowing.

Maximum oro-lingual pressures were found to be very reliable overall across bolus consistencies and volumes, with 10ml water proving to be the most reliable bolus volume/ consistency.

No significant difference was found for the effect of age on maximum oro-lingual swallowing pressures. The youngest group (18-28 years) produced the largest range of oro-lingual pressures. The middle age group (39-48 years) produced the highest oro-lingual pressures when swallowing semisolid consistency.

There were no significant differences found for gender or for bolus volume on maximum oro-lingual pressures.

Maximum oro-lingual pressures were significantly higher when swallowing semisolid boluses than liquid boluses in swallows 2 and 3.

The swallows of participants across all age groups and both genders were mainly ‘tipper’ patterns. The younger age groups (18-28 years) and (29-38years) contained participants who used a ‘dipper’ pattern.

Bolus residue was not correlated with age or gender but was dependent on bolus consistency, with semisolid boluses producing minimal residue across trials.

Chapter 5: Discussion

This pilot study had two purposes; first, to investigate the psychometric properties of a new tool, the OroPress when it was used to measure dynamic tongue pressure in normal adults and second, to document range and variability of recorded maximum oro-lingual pressures during swallowing generated by adults without dysphagia (adults with normal swallowing) with this new tool. There were many positive aspects to this pilot study, as follows:

A major strength of this study was that successful recruitment of a purposeful sample of adults across each defined age group of both sexes was achieved. The researchers were presented with recruitment difficulties, such as no response from the volunteer agencies that were initially contacted, however this obstacle was met when staff and students of the university were recruited through word of mouth. This permitted successful collection of a maximum oro-lingual pressure data set from a sample population without dysphagia. This study's sample compliments previous studies whose samples also include the same age range and equal representation of gender as well as undergoing similar procedures to determine suitability (Youmans *et al* 2009); Youmans *et al* 2011).

Excellent reliability (values exceeding 0.75) in terms of the tool's measures being repeated consistently, was achieved, so the OroPress tool was shown to be highly reliable when used for repeated measurements by the same rater across three swallows (Portney and Watkins 2009). This tool compares strongly with other tools, such as the IOPI, which also has been proven to have high test-retest reliability (Youmans *et al* 2006). The OroPress tool also compares strongly with other fixed positional tools, previous studies such as Ball *et al* (2006) have shown that the fixed version of the Kay Swallowing Workstation (KSW) displays higher reliability versus the hand held version.

Semisolid consistencies displayed the highest level of reliability across the three trials; possibly due to a strict adherence to the protocol, where each participant was asked to 'swallow as one swallow.' As minimal residue was evident after swallowing semisolid boluses, the custard consistency clearly did not affect the tongue from contacting the sensor.

Stability of the Tool:

Intra-subject variability was unstable as a systematic bias significance of (p=0.011) was present in trial 2 for all participants across bolus conditions, this signifies some bias-whether being fatigue or learned behaviour during this trial. However this systematic bias did not decrease reliability of the tool, similar to previous studies on reliability of other existing fixed position tools (Ball *et al* 2006).

Inter-subject variability of maximum oro-lingual pressures was large with the semi interquartile ranges and medians showing a wide range of documented maximum oro-lingual pressures, this corresponds with previous literature concerning the range and variability of oro-lingual pressures during swallowing (Youmans *et al* 2011).

Variable Effects on Maximum Oro-Lingual Pressures:

Age Effect:

From previous studies (Nicosia *et al* 2000; Youmans *et al* 2009), age has not been shown to effect maximum oro-lingual pressures and the results of this study corroborate those findings, supporting hypothesis number one. There was a wide range of pressures documented across age groups and bolus conditions. Although there were no specific age patterns, the 39-48 year age group produced the highest pressures when swallowing semisolid bolus, the oldest group (59-68 years) produced the lowest pressures for semisolid bolus, but the 49-58 year age group produced the lowest pressures overall across all bolus conditions. The 59-68 year age group produced the highest pressures when swallowing both smaller liquid boluses (5ml water) and larger liquid boluses (10ml water).

Gender Effect:

There have been conflicting reports regarding the effect of gender on maximum oro-lingual pressures, with one study stating a significant gender effect with women producing a higher mean maximum swallowing pressure than men (Youmans *et al* 2009) and other studies stating no significant gender effect (Nicosia *et al* 2000; Taniguchi *et al* 2008; van den Engel-Hoek *et al* 2012). Results from this current study reject hypothesis number two and therefore correspond with the studies stating no significant gender effect.

Bolus Volume and Consistency Effects:

There were no effects for bolus volume, which corresponds to previous study results (Miller and Watkin 1996). The effect of bolus consistency on maximum oro-lingual pressures showed significance (p=0.003) across the first three swallows for all participants for both liquid and semisolid consistencies, regardless of age or gender. In this study, the greater the consistency of the bolus, the higher the tongue pressures required to transport the bolus to the pharynx. Semisolid bolus swallows produced the highest pressures which supported hypothesis number three and corresponds to results from previous studies (Nicosia *et al* 2000; Taniguchi *et al* 2008; Youmans *et al* 2009; van den Engel-Hoek *et al* 2012).

Maximum oro-lingual pressure differences were significantly correlated with bolus consistencies. This is similar to the study by Youmans *et al* (2006) who stated that, in a clinical setting, a clinician would expect mean swallowing pressure scores not to be significantly different across honey-thick liquids and thin liquids. Consequently, extreme scores between those consistencies might indicate a potential tool reliability problem.

There were some limitations to this study, described below.

First, this pilot study had a small sample size, which may have an effect on statistical hypothesis testing, however the required sample size was reached in this study and Cochran 1977 (cited in Bartlett *et al* 2001) stated that pilot study results can be used to estimate population variances for determining future larger study sample sizes.

There were some issues with positioning of the tool's sensor on the hard palate of participants as this may have altered their natural swallowing behaviour, as awareness of swallowing was heightened during the trials.

Oral cavity structures were highly variable across participants, and researchers found the sensor position was more difficult to adhere on a high, arched hard palate than to a low, flat hard palate. However, the sensor was successfully positioned on each participant's hard palate and subsequently participants all commented positively on the comfort level of the sensor once in position.

From the results of this study, the OroPress tool has good capabilities and may be now used in clinical settings. Its future use could include oro-lingual pressure measurement in people

with dysphagia, assessing change over time (examining therapy or intervention to change tongue function through various oro-lingual exercises). It may also be used for biofeedback and documenting/enhancing patient adherence to tongue exercises. The OroPress is compact, of a light weight and is completely portable, thus creating opportunities for the tool to be used across many clinical settings as well as at home. With practise, the set up of the tool is timely and easily managed.

Chapter 6: Conclusions and Future Direction

This study was to document maximum oro-lingual pressures produced by healthy adults during swallowing tasks, using a new wireless tool called the OroPress. The tool showed good reliability, it was easy to use, portable and time efficient. Participants reported a good level of tolerance while the tool's sensor was in position and student researchers found the tool easy to set up and manage. Researchers may now use this valid and reliable measurement tool with clinical populations with dysphagia, assessing its usefulness for documenting baseline oro-lingual swallowing pressure measures and for measuring change over time. Further development of the tool might improve some of its features.

For example, to address the difficulty of adhering the sensor to hard palates of varying shapes and sizes, the silicone body which embeds the sensor could be expanded. Before undertaking this however, more research would be first needed to audit the range and variation of adult's hard palates and oral cavities.

A larger norm sample size in future studies would expand the database of range and variability of maximum oro-lingual swallowing pressures in healthy adults, adding to our knowledge of normal swallowing pressures.

In this current study, the OroPress tool was successfully used to obtain maximum oro-lingual pressures across a purposefully recruited sample, swallowing boluses of different sizes, consistencies, which indicated considerable promise for future research with people with dysphagia.

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Appendix A

Name of Person:
Name of Organisation:
Address:

Dear Sir/Madam

Re. OroPress: a new tool for measuring swallowing pressures in adults

I am writing on behalf of three Speech and Language Therapy (SLT) students at University of Limerick (UL) who are developing a new wireless device to measure tongue pressure in adults during swallowing. This final-year project is under the supervision of Professor Alison Perry, Head of Department of Clinical Therapies.

The purpose of this letter is to ask if/how we may approach your membership to inform them about this study in the hope that they may volunteer to assist us in this work.

We are seeking healthy adult volunteers, aged 18 years or above, who are able to attend the SLT clinic at the UL campus for approximately one hour. We hope you will enable us to give a 5 minute presentation about the study to your membership, to inform them about the study, explaining how they might volunteer and what would be involved.

If travelling to the SLT clinic is not feasible, then arrangements could be made to undertake the measurements at your organisation, if you were in agreement and if a quiet room could be provided for us.

We would be grateful if you would also display the enclosed poster in a prominent position at your organisation's offices to inform your membership about our study and that we are recruiting volunteers.

Please could you let me know as soon as possible if/when a presentation will be feasible. I can be contacted as per below.

Many thanks for your assistance,
Catraoine Hickey
Email: catraoinehickey@yahoo.ie
Mob: 0857809500

Appendix B

UNIVERSITY of LIMERICK
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Measurement of Tongue Pressure in Normal Swallowing

- Interested in finding out more about the tongue and swallowing?
- Like to help us understand swallowing better?

YOU are being invited to take part in a study to examine tongue pressure during swallowing in normal people. This will be done using a newly developed measurement tool.

Are you a healthy person, 18 years or above, without swallowing difficulties?

You should have no known medical conditions, nor use medicines that may affect swallowing.

Volunteers will undertake a swallowing study, lasting about 1 hour, at the University of Limerick (UL) Clinical Therapies' Building or at a convenient location depending on volunteer numbers at that location. This study will be carried out at a time convenient to yourself.

This involves looking inside your mouth, and then attaching a small pressure sensor to the roof of your mouth (just behind your front teeth). You will then swallow small, measured amounts of water and of custard. Your tongue swallowing pressures and tongue strength will be recorded each time.

If you would like to participate, or want more information about the study, please contact: Catraoine Hickey. Tel: 0857809500 email: catraoinehickey@yahoo.ie

Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**	**Tongue pressure study: Contact Catraoine 0857809500 11010223@studentmail.ul.ie**

Appendix C

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The OroPress in normal healthy adults: a pilot study of clinical utility and the properties of the tool.

Study Information Sheet:

What Is The Purpose Of This Study?

The purpose of the study is to examine a new tool, the OroPress, when used to record tongue pressures during swallowing in adults.

What Does The Study Involve?

The study involves you attending a one hour session at the Speech and Language Therapy Clinic, University of Limerick at a convenient time to yourself.

First: You will be asked to participate in a short interview at the given date. We will look inside your mouth to note your gag reflex and tongue movements (you will be asked to poke your tongue out, and in, and side to side). We will make a note of your age and gender. You will be asked to complete a short questionnaire about your swallowing and eating patterns. Such questionnaires are routinely used across the world by people working with those who have a swallowing disability. A member of the research team will help you in filling out any forms. This part should take no more than 10 minutes.

Second: We will record how much pressure your tongue exerts against the roof of your mouth when you swallow first some water, and then custard. A small sensor will be temporarily stuck inside your mouth, behind your teeth.The sensor will then be connected to a laptop computer to record your tongue pressures. You will then swallow, singly, 3 x teaspoons of tap water and then 3 x teaspoons of custard consistency. While you do this, we will record the 'pushing pressure' that your tongue makes against the sensor each time.

We will then ask you to push the tip of your tongue against the sensor as hard as you can for three seconds. This will be repeated three times with small intervals in between. Finally we will ask you to push the tip of your tongue against the sensor for as long as you can. This will also be repeated three times with small intervals in between. We will then remove the sensor and ask you to complete a short questionnaire about the comfort of the OroPress and your views about it. The whole study will take place at the University of Limerick. All in all, the study time will last approximately one hour.

What will I need to do next?

Once you express your interests, a member of the research team will contact you to organise a time and date that is suitable for you to attend the study.

What Are The Benefits Of Participating In The Study?

The study will provide us with information about the swallowing pressures that are generated by people who do not have swallowing/eating problems.

Is There Any Risks If I Participate In The Study?

There are no risks associated with participating in this study.

Do I Have to Participate In The Study?

Your participation in the study is purely voluntary.

Will I Receive Any Compensation?

No compensation will be offered to any of the study participants.

What Will The Information I Give Be Used For?

The information you provide will be analysed as part of a larger study. The results of the study will be written up for a Final Year Project by students at the University of Limerick and will be presented at a conference and in a scientific journal.

What About My Confidentiality?

Good research practice involves maintaining confidentiality. You can be assured that the information you provide will be kept confidential at all times. Only members of the research team will have access to the information you give.

What If I Want To Leave The Study?

You may withdraw from the study at any time without giving a reason and you will not be penalised in any way.

Is There Ethical Approval For This Study?

Ethical approval has been given from theUL / EHS Research Ethics Committee.

Is There A Complaints Procedure?

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Complaints or queries about the study can be directed to the Principal-Investigator (Prof Alison Perry) or to the UL/EHS Ethics Committee Chairperson.

Whom Do I Contact If I Want Further Information About The Study?

If you have any concerns or queries about the study please contact:

Principal Investigator: Professor Alison Perry (HOD, Clinical Therapies)

Address: Dept. of Clinical Therapies, Faculty of Education and Health Sciences, University of Limerick. **Phone**: 087-7854987.**Email**: Alison.Perry@ul.ie

Appendix D

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The OroPress in normal healthy adults: a pilot study of clinical utility and the properties of the tool.

Consent Form

Please read the statements below and tick the appropriate box.

- I have read and clearly understand all the details provided on the subject information sheet attached. ☐
- I know that my participation is voluntary and that I can withdraw from the project at any stage without giving any reason ☐
- I understand what the project is about, and what the results will be used for. ☐
- I am fully aware of all of the procedures involving myself, and of any risks and benefits associated with the study. ☐
- I am aware that my results will be kept confidential. ☐
- I agree to participate in this study. ☐

I agree with all the above statements and I consent to participate and have my tongue pressure measured during swallowing tasks. ☐

I disagree with one or more of the above statements and I will need further information before I consent. ☐

Signed: _____ Date: _____

(Print Name): _____

I consent to have my data used for analysis and for the data to be written up in a way that will not identify me (for a professional publication or/and a student project) ☐

Signed: _____ Date: _____

(Print Name): _____Phone Number: _____

Email Address: _____

Appendix E

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The OroPress in normal healthy adults: a pilot study of clinical utility and the properties of the tool.

Participant Details

ID Number _____

Sex: Male ☐ Female ☐

DOB: _____ Age: _____

Address: _____

Ph No: _____ (house) _____ (mob)

Medical History

Please tick the appropriate boxes:

1. How is your general health today? ☐ Good ☐ Not Good
   If not good, please describe:
   _____
   _____
   _____
2. Do you have any swallowing problems? ☐ Yes ☐ No
   If yes, please describe:
   _____
   _____
   _____
3. Have you had any swallowing problems in the past? ☐ Yes ☐ No
   If no, go to Q 5. If yes, please describe below and then continue to Q4.

4. Are you currently receiving any help with swallowing? ☐ Yes ☐ No
   If yes, please describe:

5. Do you have any major medical problems? ☐ Yes ☐ No
   If yes, please describe below. If no, go to Q8.

6. Does your medical condition affect your breathing? ☐ Yes ☐ No
   If yes, please describe:

7. Does your medical condition affect your swallowing? ☐ Yes ☐ No
   If yes, please describe:

8. Are you taking regular medication? ☐ Yes ☐ No
   If yes, please list:

9. Is there anything about your eating or swallowing that causes you difficulty? If so, please detail below:

_____

_____

10. Do you have any special dietary requirements or any known food allergies?
    e.g. diabetic/celiac. If so, please detail below:

    _____

    _____

    _____

11. I now want you to dry swallow.
    When you started that swallow, was your tongue tip raised up, behind your top set of teeth, or pushed down, behind your lower set of teeth?
    (If unsure, try again and/or ask for a drink of water. Take a sip and note below where you think you placed your tongue for the start of that swallow.)

    My tongue tip is UP/ DOWN (circle as applies) at the start of a swallow

Appendix F

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ORO MOTOR EXAMINATION

Participant No: _____
Date: _____
Student: _____

Organ:	**Assessment of:**	**Method:**	**Outcome: (Circle as applicable)**	**Comments**
Face	Symmetry	Observe participant's face and note any abnormalities of symmetry/tone	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured **5)** Unable to undertake task	
Lips	Lip seal (norm=15 secs) Range and speed of movement (norm =	Hold your lips firmly closed while puffing up your cheeks like this (demo). Hold the air in your cheeks for as long as you can.	Time in secs: _____ 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	

	10 secs)	Say 'oo- ee' 3 times in a row, as quickly as you can, like this; (demo)	Time in secs: _____ 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Tongue	Protrusion/retraction (Norm=4 secs) Elevation Depression	Poke your tongue in and out quickly like this; (demo). Do that 5 times in a row, as quickly as you can, like this (demo). Try to touch your nose with your tongue like this (demo)	Time in secs _____ 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	

	Lateral movements (norm=4secs)	Put your tongue down to your chin like this (demo). Put your tongue to the outside corner of your mouth, first to the right and then left, like this (demo). Do this it 3 times in a row as quickly as you can, like this. (demo)	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task Time in secs _____ 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Soft Palate	At rest	Open your mouth as wide as you can as I'm going to hold your tongue down with a wooden spatula to look at the back of your throat, with a torch.	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to	

	Elevation of Uvula on 'ah'	Now say 'ah' and hold it for a few seconds	undertake task: 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Voluntary Cough	Strength	Cough/clear you throat for me please	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Gag reflex	Sensitivity	Open your mouth wide please, I'm going to test your gag reflex.	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	

Residue Rating

Please circle accurate rating

Rating	Description
0	No residue in oral cavity post-swallow
1	Minimal residue or coating post-swallow
2	Marked pooling in oral cavity post-swallow

Appendix G

Safety and Utility Questionnaire

Participant Number: _____

Date of Assessment: _____

Place if Assessment: _____

*NOTE- Some of the questions may look the same; however, you should answer all the questions required.

Section A: Safety (to be completed by the participant)

*Please check ✓only one:	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
1. The sensor felt uncomfortable in my mouth:					
2. The sensor felt secure in my mouth:					
3. The sensor changed the way I normally swallow:					
4. I felt safe with the sensor in my mouth:					
5. The sensor made me gag when swallowing:					
6. The headset was comfortable on my head:					
7. I did not like the sensor being put in my mouth:					
8. I felt uncomfortable during the tongue pushing task:					

9. It was helpful to see the screen during the tongue pushing task:

10. The sensor felt comfortable in my mouth:

11. The sensor did not change the way I normally swallow:

12. The sensor was not secure in my mouth:

13. The sensor did not make me gag when swallowing:

14. I felt un-safe with the sensor in my mouth:

15. The headset felt uncomfortable on my head:

16. I felt comfortable during the tongue pushing task:

17. It was not helpful to see the screen during the tongue pushing task:

Overall was taking part in this study a positive or negative experience for you? (**Please check ✓only one)* Positive Negative

Please explain: _____

_____

_____

Section B: Utility (to be completed by the experimenter)

*Please check ✓ only one:

	Strongly disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
1. The sensor was easily applied:					
2. It was difficult to locate the alveolar ridge:					
3. The sensor easily adhered to the alveolar ridge:					
4. The sensor was difficult to sterilise:					
5. The headset was easily placed on the participant:					
6. The computer software was difficult to use:					

7. The alveolar ridge was easily located:

8. The sensor was difficult to apply:

9. The sensor was easily sterilised:

10. The sensor did not adhere easily to the alveolar ridge:

11. The computer software was easy to use:

12. The headset was difficult to place on the participant:

*Please check ✓ only one:

1	2	3-4	5-10	10+

How many attempts did it take to apply the sensor?

If you have any further comments please do so in the space provided: _____

_____

_____

_____

Appendix H

Trial 1

ICC values, 95% confidence intervals, and p-values for maximum oro-lingual pressures for liquid and semi solid consistencies for trial two across participants.

		95% confidence interval		
	ICC (3, 1) value	**Lower Bound**	**Upper Bound**	**P-Value**
5ml water	.62	.25	.87	.001
10ml water	.73	.48	.90	.001
5ml custard	.61	.26	.86	.001

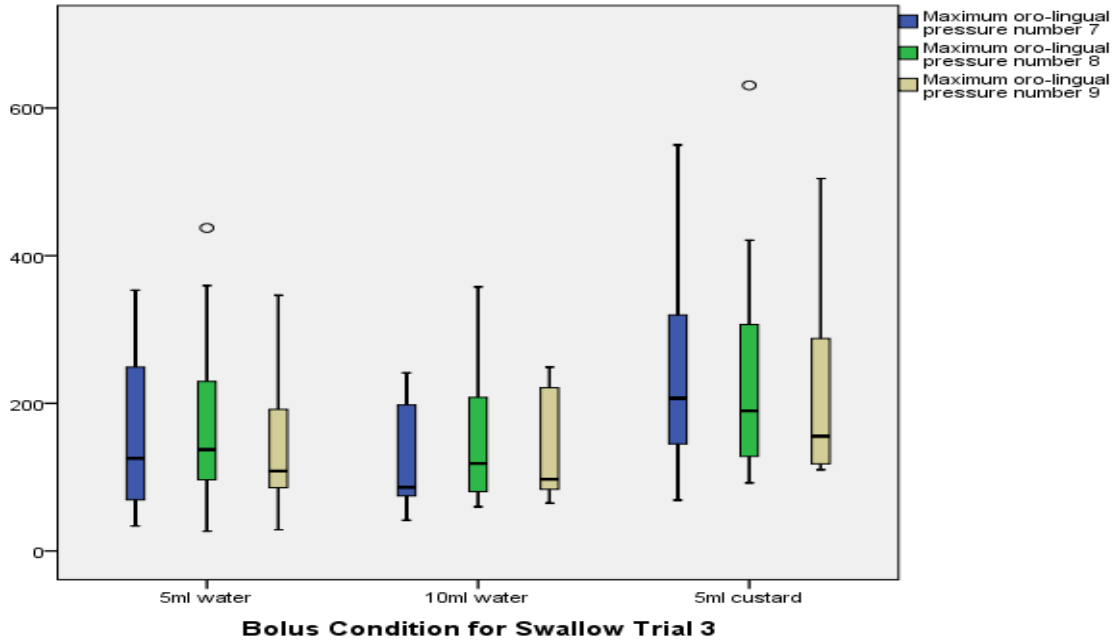
Trial 3

ICC values, 95% confidence intervals, and p-values for maximum oro-lingual pressures for liquid and semi solid consistencies for trial two across participants.

		95% confidence interval		
	ICC (3, 1) value	**Lower Bound**	**Upper Bound**	**P-Value**
5ml water	.68	.44	.85	.001
10ml water	.79	.50	.94	.001
5ml custard	.95	.85	.99	.001

Appendix I

Bolus Condition for Swallow Trial 1



Bolus Condition for Swallow Trial 3