The OroPress: a pilot study to examine the tool’s properties of measurement and use as a biofeedback tool for isometric tongue tasks.

By

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For the consideration of Dysphagia.
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# Table of Contents

Abstract ..........................................................................................................................4

Introduction ....................................................................................................................5-10

Method..........................................................................................................................11-18

Results ..........................................................................................................................19-29

Discussion ....................................................................................................................30-35

References ....................................................................................................................36-40

Appendices ...................................................................................................................41-51

  Appendix 1.................................................................................................................41

  Appendix 2................................................................................................................42-43

  Appendix 3................................................................................................................44

  Appendix 4................................................................................................................45-46

  Appendix 5................................................................................................................47-51
Abstract

Background: Swallowing is a trait which can be affected by variables such as tongue strength and endurance/stamina, and by biofeedback (feedback through senses). Such variables have been examined by measuring isometric (pushing against resistance) tongue strength (ITS) and tongue endurance (ITE). The effects of biofeedback on swallowing have been examined but not its effect on isometric tongue pressure (ITP).

Aim: To examine the psychometric properties of a new wireless tool, the OroPress, when used to measure (i) ITS and (ii) ITE and (iii) to assess its effectiveness as a biofeedback tool.

Method: Thirty five normal healthy adults (17 males, 18 females) across two age groups, 18-38yrs (n=21), >38yrs (n=13), were recruited. ITPs were obtained, with and without biofeedback, using the OroPress. The effect of age and gender on ITP was examined, the correlation between two independent methods of extracting data was inspected, and the effects of biofeedback on ITP were documented.

Results: Data are reported on 34 subjects- (16 males, 18 females). Males had significantly higher ITS than females (P<.05) but there was no effect for age. Neither age nor gender affected ITE. Large positive correlations (P<.0005) were found between two independent methods of data extraction, and ITS increased significantly with biofeedback (P<.005) but there was a non-significant effect for ITE.

Summary: The OroPress was a valid tool for measuring ITPs. Excellent construct validity was found for data extraction. In use as a biofeedback tool, the OroPress significantly increased ITS but had a non-significant effect on ITE.
Introduction

A qualified speech and language therapist (SLT) is able to conduct assessments, “to determine the presence, nature, and cause of a swallowing problem, current level of dysfunction ... and to develop strategies for stabilisation and rehabilitation” (Pettigrew and O’Toole 2007, p. 235). SLTs working in the area of swallowing disorders use many measurement tools to assess swallowing ability. A tool’s usefulness depends on the level to which SLTs can rely on the resulting data to give accurate and meaningful indicators of a client's swallowing (dis)ability (Portney and Watkins 2007) which is important for the accurate diagnosis of dysphagia. The term 'dysphagia' refers to any difficulty in moving food or fluid from the mouth to the stomach (Logemann 1998).

Dysphagia is a serious symptom as it may result in dehydration, malnutrition and aspiration, where solids and/or liquids enter into the airway below the true vocal folds. This in turn may result in aspiration pneumonia and even death (Murry and Carrau 2012). Such signs and symptoms, therefore, need to be carefully and accurately assessed. Having adequate control over the musculature of the tongue is crucial for the oropharyngeal phase of swallowing (Crow and Ship 1996) so it is important to consider tongue control when conducting swallowing assessments.

Many researchers have examined the relationship between tongue control and swallowing function (i.e., efficiency and safety) by measuring factors such as the isometric (pushing against a resistance) strength and/or endurance (activity for extended periods) of the tongue. Such researchers have used the Kay Swallowing Workstation (KSW)'s three-bulb tongue pressure array and/or the single-bulb of the Iowa Oral Performance Instrument (IOPI) to demonstrate the negative impact of reduced isometric tongue strength (ITS) on swallowing function.

Although such a relationship still needs to established across many patient populations (Adams et al., 2013), the contribution of adequate ITS to successful swallowing is well established (Clark and Solomon 2012; Clark et al., 2003). By contrast, an understanding of the relationship between isometric tongue endurance (ITE) and swallowing function has received little attention although this too may be an important indicator of swallowing (dys)function (Kays et al., 2010; Kays and Robbins 2009).
Some instrumental tools, such as the IOPI (Yeates et al., 2008) and surface electromyography (sEMG; van den Engel-Hoek et al., 2012; Crary and Groher 2006) have also been used to provide biofeedback on isometric tongue pressure (ITP) generation. Biofeedback is a technique of using instrumentation to display physiological events to a patient, through different sensory modes (Reddy et al., 2000) and allows a person to view, monitor and, if necessary, alter their swallowing behaviour (Huckabee 1992). It enables a patient to visualise the effects of therapeutic strategies, as well as providing quantitative data for the measurement of treatment outcome (Huckabee 1992).

Although the effect of biofeedback on tongue pressures has received little attention, it has been shown to improve recovery from dysphagia through enhancing patients’ motivation (Reddy et al., 2000). Further research into the effects of instrumental biofeedback tools on tongue pressure generation is required. It is also evident that a tool with robust psychometric properties (i.e., validity, reliability, and stability) for measuring ITS and ITE pressures and providing biofeedback on these measures is needed.

By examining the validity of a tool, the degree to which the tool measures what it is intended to measure, can be established (Portney and Watkins 2007, p.879). Two forms of validity include face validity, or the extent to which an instrument appears to test what it is intended to test; and construct validity, or the ability of a tool to measure abstract constructs and the degree to which a tool reflects its theoretical foundation (Portney and Watkins 2007). Validity is an important property, as a valid tool is also a reliable tool (Portney and Watkins 2007). A tool’s reliability refers to the extent to which, “a test or measurement is reproducible” (Polgar and Thomas 2000, p.298).

**Tongue pressure measurement tools**

Levels of psychometric testing vary considerably when ITPs are being examined. The KSW and IOPI are two popular tools used for ITP measurement (Ball et al., 2006). There are notable variations in the measurement protocols provided by researchers using these tools. This increases the opportunity for measurement error to occur, and hence may result in invalid, unreliable and/or unstable measurements being obtained.
Some variables of the KSW and IOPI affect the properties of the measurements taken with these tools, and these are described below.

**The Kay Swallowing Workstation (KSW)**

The KSW is a computerised system consisting of a three sensor array, with air-filled bulbs that can be used synchronously with a videofluoroscopic swallowing study (VFSS) and/or sEMG (White et al., 2009). Its three sensors enable the measurement of ITS at the anterior, medial, and posterior portions of the tongue.

A number of the studies by researchers investigating the KSW fixed array are limited by the use of small, heterogeneous samples (Ball et al., 2006; Pelletier and Dhanaraj 2006; Hind et al., 2005; Nicosa et al., 2000), ranging from ten (Pellitier and Dhanaraj 2006) to twenty participants (Nicosa et al., 2000). Such samples do not ensure representativeness of the population and may “decrease the power of statistical analysis” (Polgar and Thomas 2000, p.278). The KSW fixed sensor array also has a number of limitations regarding its design, described below, which may negatively affect its psychometric properties.

First, the size of its array may alter 'normal' ITS generation, as a gag reflex may be elicited, due to the invasiveness of the KSW array. Second, the use of the array in conjunction with a VFSS exposes patients to (low level) radiation (Utanohara et al., 2008) and requires a compliant patient for a successful examination (Kosta and Mitchell 1998). Finally, the KSW is expensive to purchase, resulting in its limited availability (Hewitt et al., 2008). The conflicting research about the psychometric properties of this tool suggests that further research is warranted. This is also the case for the IOPI as described below.

**Iowa Oral Performance Instrument (IOPI)**

The IOPI is another popular device for ITS and ITE measurement. It has a hand-held, portable pressure transducer, consisting of an air-filled plastic bulb (which is typically positioned on/at the alveolar ridge) (Clark et al., 2003), connected to a liquid crystal display via a plastic tube (Vanderwegen et al., 2012). It is used to measure ITP in kilo-Pascal’s (kPa), and can provide biofeedback to the user about the measures (Crow and Ship 1996).
A number of researchers have used the IOPI to measure ITP, with sample sizes ranging from ten (Solomon and Munson 2004), to 420 people (Vanderwegen et al., 2012). Some researchers have reported near-perfect inter-rater reliability (Youmans et al., 2009) with statistical significance of $p<0.001$ (Youmans and Stierwalt 2006), and ‘excellent’ test-retest reliability (ICC range .882 -.973) scores (Gingrich et al., 2012). This implies that the IOPI is a very stable measurement. Regardless, there is a dearth of research into the validity of the IOPI measurements. Without valid data, researcher cannot be sure that the IOPI is measuring ITP.

As with the KSW, some researchers have highlighted limitations in the design of the IOPI. First, the IOPI can only measure pressures at anterior portion of the tongue (Clark et al., 2003) so, unlike the KSW, it is not a complete measure of ITP (Yoshikawa et al., 2011). Second, the validity of the IOPI is limited by the (large) size of its bulb, a lack of precise fit (Kennedy et al., 2010), and a protruding tube that prevents either dental or full lip occlusion (Hori et al., 2005; Ono et al., 2004), all of which may alter ‘usual’ tongue behaviours and may affect the psychometric properties of this tool.

Finally, the IOPI is not extensively used by SLTs for clinical purposes. This may be due to the lack of research into normal and impaired ITPs (Youmans and Stierwalt 2006). The paucity of research into the validity of the IOPI measurements, along with its identified design limitations, highlights the need for further development of psychometrically robust ITP measurement tools.

**Summary**

There are acknowledged limitations with existing instrumental tools, the KSW and the IOPI. This, in turn, leads to the situation where, “currently there is a lack of methodological rigor in SLT dysphagia research” (Ball et al., 2006, p.26). Specifically there is a lack of research into the psychometric properties of the IOPI and KSW when they are used to obtain ITP measurements and into their possible uses and benefits as tools for biofeedback purposes.

**Present Study**

To address the identified shortcomings of the existing tools, a new device was designed. The OroPress is a wireless, portable, intra-oral tongue pressure sensor, with
a remarkably low profile to be minimally intrusive in the mouth, thus, reducing one aspect of measurement error. In this study the validity of the OroPress when used to measure ITS and ITE in normal healthy adults, was examined by evaluating the effects of age and gender on ITP. The effectiveness of the OroPress in providing biofeedback on ITPs was also documented.

**Aims and Hypotheses**

There were four aims and six hypotheses for the current study:

**Aim 1:** To determine the validity of the OroPress as a measurement tool of isometric tongue strength (ITS) pressures by investigating the tool’s ability to determine differences in maximum ITS pressures across males and females and between two age groups - young (18-38 years) and old (>38 years).

Hypothesis 1: The older age group will demonstrate significantly lower ITS pressures than the younger age group.

Hypothesis 2: Females will demonstrate significantly lower ITS pressures than males.

The rationale for hypotheses 1 and 2 is that age and gender have been shown to impact on ITS pressures in ‘normal’ (i.e., people without dysphagia) populations (Adams et al., 2013)

**Aim 2:** To determine the validity of the OroPress as a measurement tool of isometric tongue endurance (ITE) by investigating the tools ability to determine differences in the area of ITE pressures across males and females and between young and old age groups.

Hypothesis 3: The older age group will demonstrate significantly smaller area of ITE pressures when compared to the younger age group.

Hypothesis 4: There will be no significant difference in the area of ITE pressures across males and females.

The rationale for hypotheses 3 and 4 is that age, but not gender, has been shown to affect ITE in normal populations (Adams et al., 2013).

**Aim 3:** To determine the differences in ITS pressures obtained with the OroPress between the biofeedback and non-biofeedback conditions.

Hypothesis 5: ITS pressures will significantly increase in the biofeedback condition compared to the non-biofeedback condition.
Aim 4: To determine the differences in the area of ITE pressures obtained with the OroPress between the biofeedback and non-biofeedback conditions.

Hypothesis 6: The area of ITE pressures will significantly increase in the biofeedback condition compared to the non-biofeedback condition.

The rationale for these hypotheses is based on prior researchers who have demonstrated the positive effects of biofeedback (with tools such as sEMG) on the treatment of swallowing disorders (Crary and Groher 2006). Although the effects of biofeedback on tongue pressures has received little attention, biofeedback has been shown to improve recovery through enhancing patients’ motivation (Reddy et al., 2000) so we anticipated that biofeedback would have a positive effect on the measurements taken in this study.
Method

Preamble: This work was part of a larger study where both swallowing pressures and isometric tongue pressure’s (ITPs) were taken from a sample of normal adults. The focus of this work is on ITPs including isometric tongue strength (ITS) and isometric tongue endurance (ITE) measures and the effects of biofeedback on these measures.

Participants

Using advertising posters (see Appendix 1) and verbal request to friends and relatives of the researchers, a non-randomised, convenience sample of thirty five normal adult participants was recruited. 10 male and 11 female participants of 18-38 years and 7 male and 7 female participants of >38 years undertook the study.

Participants were excluded if they had a history of notable swallowing and/or speech disorders, a medical condition, or use of medications that may affect swallowing, any structural or functional oral peripheral abnormality, an overly sensitive gag reflex (i.e., gag reflex triggered in the middle portion of the anterior tongue), and/or an inability to give informed consent or follow oral instructions.

Materials

A newly developed wireless tool, the OroPress, was used to capture ITP data and provide biofeedback on these measures. This consisted of a pressure sensor embedded in a silicone body which is connected, via a battery operated and wireless system, to a laptop computer for data display and recording.

The OroPress pressure sensor, was sterilised using the Tristel Trio Wipes system and was adhered to each participant’s hard palate using a Poligrip ComfiSeal Strip. Disposable tongue depressors, along with latex gloves, were used for hygiene purposes. A password-embedded thumb-drive was used for data transfer and the IBM® Statistical Package for Social Sciences (SPSS ®) Version 20 software package (SPSS 2011) and a Microsoft Excel spreadsheet were employed for data entry and analysis.

Procedure

Full ethical approval from the Faculty of Education and Health Sciences Research Ethics Committee, University of Limerick was obtained before the study commenced. Prior to the trial beginning, all participants were given an information form (see Appendix 2)
and a verbal explanation of the trial by the researcher. Written informed consent (see Appendix 3) was obtained from each person before they embarked on the study.

Each participant was asked to complete a short medical information sheet containing questions about the persons’ past and present swallowing function (see Appendix 4) and was then seated in a chair at a measured distance from the facing wall. The researcher conducted an oromotor examination on each participant which involved an examination of the participants' face, lips, tongue, velum, voluntary cough and gag reflex (see Appendix 5). A yellow disc was placed on the wall at a participant’s eye-level, which s/he was instructed to look at during the trials, to control for head movement.

The OroPress sensor was calibrated before every trial, using zero and 100 mmHg datum points. The sensor was then connected, using the battery operated wireless system, to the laptop computer for data display and recording. A file containing a header with participant identification number, sensor number, and date and time stamps was established. Once data were displayed on the laptop screen (tested by lightly pressing on the sensor), the sensor was adhered to the participant’s hard palate at the alveolar ridge, using a Poligrip ComfiSeal strip (see Fig 1).

![Figure 1. The OroPress sensor in situ.](image)

To become familiar with the array in situ, the participants first practised the ITP tasks without being recorded. Once they were comfortable and confident, the trials commenced. The order of ITP trials were randomised i.e., ITS vs. ITE, as was the order of biofeedback i.e., biofeedback vs. no biofeedback, to control for the possible effect(s) of learning and/or fatigue on ITP generation.
**Isometric Tongue Strength**

Two levels of measurement- ITS with biofeedback and ITS with no biofeedback-involving one trial each (2 trials in total), were recorded. During the biofeedback condition, the participants were shown the laptop which displayed the pressure waveform and were instructed to look at the laptop when performing the trial. During the no-biofeedback condition, the participants were instructed to look at the yellow disc on the wall in front of them and keep their head steady when performing the trial.

Each participant had one (or more if needed) practice ‘push(es)’ which was not recorded. Participants were then instructed to push the tip of their tongue ‘as hard as (they) could’ against the sensor for three seconds when the researcher said, ‘go’. A second researcher timed the trial and instructed the participants to ‘stop’ once three seconds passed.

**Isometric Tongue Endurance**

The same procedure for the ITS trials was used for the ITE trials; however, for the ITE trials each participants was instructed to push the tip of their tongue ‘as hard as (they) could’ against the sensor ‘for as long as (they) could’ when the researcher said, ‘go’. A second researcher viewed the data on the laptop and instructed the participants to ‘stop ‘once a significant dip in ITP (below the 100mmHg marker) was noted.

**Data Management**

The data obtained from the OroPress were transferred to a Microsoft Excel spreadsheet, together with participant de-identified data (identification number, age and gender), which were then saved on the thumb-drive for statistical analysis.

**Data extraction**

As the OroPress is a newly developed tool, a new data extraction method was developed to manage the raw data recorded using the OroPress. To test for construct validity of the new data extraction method, the data for this study were extracted using two different methods as described below, and the results were compared.

Method 1 involved extracting data manually by scanning through the data set to identify dependent variables such as PMaxS and PMaxE (see Table 2) and the start
and finish time (of ITE pressure>100mmHg) for ITE trials. Mathematical calculations were then undertaken to derive $t_{100}$, $P_{t100}$ and rate of fatigue (ROF; see Table 2).

Method 2 involved designing a Microsoft Excel spreadsheet containing the study data and data extraction formulae specific to data recorded using the OroPress. Microsoft Excel was then used to extract and calculate data such as $P_{MaxS}$, $P_{MaxE}$, $t_{100}$, $P_{t100}$ and ROF (see table 2).

**Research Design**

This was a pilot study with three independent variables (see Table 1) and six dependent variables (see Table 2).

**Table 1**
*Independent variables and their levels*

<table>
<thead>
<tr>
<th>IVs</th>
<th>Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Young (18-38 years) vs. Old (&gt;38 years)</td>
</tr>
<tr>
<td>Gender</td>
<td>Males vs. Females</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>Biofeedback vs. No-biofeedback</td>
</tr>
</tbody>
</table>

**Table 2**
*Dependent variables and their scale of measurement*

<table>
<thead>
<tr>
<th>DVs</th>
<th>Scale of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{MaxS}$- Maximum isometric tongue pressure (ITP) during the isometric tongue strength (ITS) trials.</td>
<td>mmHg</td>
</tr>
<tr>
<td>$P_{MaxE}$- Max ITP during the isometric tongue endurance (ITE) trials.</td>
<td>mmHg</td>
</tr>
</tbody>
</table>
### t100- Max time that ITP is maintained during the ITE trials.

| Seconds |

### Pt100- Max area under curve area (i.e., pressure x time, during the ITE trials).

| mmHg x Sec |

### ROF- Rate of fatigue (i.e., average pressure at the start of the waveform (for 1 sec) – (minus) average pressure at the end of the waveform (for 1 sec) ÷ t100 during the ITE trials).

| mmHg/Sec |

*Note: The 'start' and 'cut-off point' for pressure readings obtained during the ITE trials was 100 mmHg. This was to ensure that the pressure readings selected were intentional and not due to extraneous variables e.g., the participant playing with the sensor.*

#### Statistical Analysis

Statistical analysis was conducted using the IBM® SPSS ® Version 20 software package (SPSS 2011) and the data underwent a series of steps, as described below.

**Data Screening**

Data screening prior to statistical testing involved examining various statistics (means, medians, standard deviations), analysing box plots and histograms, calculating skewedness and kurtosis, and using the Shapiro-Wilk test (Tabacknick and Fidell 2007). The data captured for ITS pressures conformed to normality; hence, parametric testing was applied. The data captured for ITE pressures did not conform to normality; hence, non-parametric testing was applied.

**Descriptive Statistics**

Descriptive statistics were used to describe the characteristics of the sample (Portney and Watkins 2009). The descriptive statistics considered for the ITS (PMaxS) and ITE (PMaxE, t100, Pt100 and ROF) data included measures of central tendency, such as the mean and median, and measures of variability, such as range and standard deviation (Portney and Watkins 2009).
**Face validity of the OroPress as a measure of isometric tongue pressure**

In ‘normal’ (i.e., people without dysphagia) populations, both age and gender have been reported to influence ITS pressure, when measured with the Kay Swallowing Workstation (KSW)’s three-bulb tongue pressure array and the single-bulb of the Iowa Oral Performance Instrument (IOPI) tools (Adams et al., 2013). For this reason, the influences of both age and gender on ITS pressures obtained with the OroPress were examined using an independent-samples t-test, to determine its face validity as a measure of ITS pressure.

Previous researchers have reported the influence of age, but not gender, on ITE pressure (Adams et al., 2013). The possible influence of age and possible (lack-of) influence of gender on ITE pressures obtained with the OroPress was therefore examined using a Mann-Whitney U test, to determine the face validity of the OroPress as a measure of ITE pressure.

**The effectiveness of OroPress as a biofeedback tool**

Prior researchers have demonstrated the positive effects of biofeedback on the treatment of swallowing disorders (Crary and Groher 2006). For this reason, the possible effect of biofeedback (using the OroPress) on ITE and ITS pressure generation was tested, in order to investigate the effectiveness of the OroPress as a tool for providing biofeedback on ITP’s.

The effect of biofeedback on ITS pressure was examined using the paired-samples t-test. Post-hoc analysis was then performed using an independent-samples t-test, to investigate the differences in ITS pressures recorded between males and females and/or the younger and older age groups, during the biofeedback and no biofeedback conditions.

A Wilcoxon Signed-Rank test was used to examine the overall effect of biofeedback on ITE pressure and post-hoc analysis was performed using the Mann-Whitney U test, to investigate the differences in ITS pressures recorded between males and females and/or across the younger and older age groups, during the biofeedback and no biofeedback conditions. Differences in ROF during the biofeedback and no biofeedback condition were examined using a Wilcoxon Signed-Rank test.
**Validity of the data extraction methods**

To test the construct validity of the new data extraction method (method 2) which was developed for use with the OroPress, the correlation between the same data extracted using the two different methods was investigated. Pearson product-moment correlation coefficient (r) (Pearson r) was used to examine the correlation between ITS data extracted through method 1 and through method 2. Spearman’s Rank order correlation (rho) (Spearman rho) was used to examine the correlation between ITE data extracted through method 1 and through method 2.

**Summary of Statistical Analysis**

A summary of the analyses and statistical methods used are listed in Table 3.

Table 3

**Summary of statistical analyses**

<table>
<thead>
<tr>
<th>Subject of Analysis</th>
<th>Statistical Method Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normality of distribution and homogeneity of variance in isometric tongue pressures obtained</td>
<td>Mean versus medians, standard deviations, visual analysis of box plots and histograms; calculations of levels of skewedness and kurtosis; Shapiro-Wilk test.</td>
</tr>
<tr>
<td>Descriptive statistics</td>
<td>Mean and median.</td>
</tr>
<tr>
<td>- Central tendency</td>
<td>Range, standard deviation, minimum and maximum pressures.</td>
</tr>
<tr>
<td>- Variability</td>
<td></td>
</tr>
<tr>
<td>Construct validity</td>
<td>Parametric- Pearson r.</td>
</tr>
<tr>
<td></td>
<td>Non-parametric - Spearman rho.</td>
</tr>
</tbody>
</table>
| **Face validity** | Parametric- Independent-samples t-test.  
Non-parametric- Mann-Whitney U test. |
|------------------|-----------------------------------|
| **Difference between biofeedback and no-biofeedback conditions** | Parametric- Paired-samples t-test.  
Non-parametric- Wilcoxon Signed-Rank tests. |
| **Post-hoc analysis** |  |
| **Differences between genders and age groups during biofeedback and no-biofeedback condition.** | Parametric- Independent-samples t-test.  
Non-parametric- Mann-Whitney U test. |
| **Differences in rate of fatigue during biofeedback and no-biofeedback condition.** | Non-parametric- Wilcoxon Signed-Rank tests. |
Results

Excluded Data

The data from one older male were excluded. Data were excluded as the qualities of the recorded pressure waveform were extremely 'poor'. It is probable that the 'poor' quality of recorded data occurred as a result of an instrumental error. Data are thus reported on 34 subjects (see Table 4).

Table 4

Participant demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Males</th>
<th>Females</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-38 Years (n)</td>
<td>10</td>
<td>11</td>
<td>21</td>
</tr>
<tr>
<td>&gt;38 years (n)</td>
<td>6</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>18</td>
<td>34</td>
</tr>
</tbody>
</table>

Descriptive Statistics

The means, standard deviations and ranges for all of the study dependent variables (see Table 2 method section) with and without biofeedback, are presented in Table 5.

Table 5

Descriptive statistics for isometric tongue pressure data.

<table>
<thead>
<tr>
<th>Task</th>
<th>Biofeedback</th>
<th>Parameter</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>Sd</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITS</td>
<td>With Bio</td>
<td>PMaxS (mmHg)</td>
<td>252.20</td>
<td>832.70</td>
<td>540.92</td>
<td>132.80</td>
</tr>
<tr>
<td>ITS</td>
<td>No Bio</td>
<td>PMaxS (mmHg)</td>
<td>197.90</td>
<td>826.70</td>
<td>516.04</td>
<td>137.02</td>
</tr>
</tbody>
</table>
For both the ITS and the ITE tasks the range of data varied considerably. There were some variations between data obtained with and without biofeedback. These differences were significant for ITS and were non-significant for the ITE task and these will be discussed in detail later.

Validity of the OroPress as a measure of isometric tongue pressure

Gender differences in PMaxS (ITS pressure) were investigated using an independent-samples t-test. This indicated that males had significantly higher ITS pressures than females (P<.05, males- 148.35 mmHg, females- 112.35 mmHg; see Fig 2); thus, the alternate hypothesis 2 (females will demonstrate significantly lower recorded ITS

<table>
<thead>
<tr>
<th></th>
<th>With Bio</th>
<th>PMaxE (mmHg)</th>
<th>t100 (seconds)</th>
<th>Pt100 (mmHg x sec)</th>
<th>ROF (mmHg/ Sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ITE</strong></td>
<td>With Bio</td>
<td>PMaxE (mmHg)</td>
<td>265.90</td>
<td>816.30</td>
<td>539.07</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>No Bio</td>
<td>PMaxE (mmHg)</td>
<td>313.00</td>
<td>1011.40</td>
<td>549.37</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>With Bio</td>
<td>t100 (seconds)</td>
<td>4.30</td>
<td>48.40</td>
<td>15.25</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>No Bio</td>
<td>t100 (seconds)</td>
<td>3.5</td>
<td>40.5</td>
<td>13.21</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>With Bio</td>
<td>Pt100 (mmHg x sec)</td>
<td>1302.00</td>
<td>12725.50</td>
<td>5121.62</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>No Bio</td>
<td>Pt100 (mmHg x sec)</td>
<td>1658.90</td>
<td>10429.80</td>
<td>4666.41</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>With Bio</td>
<td>ROF (mmHg/ Sec)</td>
<td>-18.26</td>
<td>33.80</td>
<td>12.48</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>No Bio</td>
<td>ROF (mmHg/ Sec)</td>
<td>-5.90</td>
<td>38.52</td>
<td>15.13</td>
</tr>
</tbody>
</table>
pressures than males) was accepted, and the null hypothesis 2 (there will be no significant difference in the ITS pressures across males and females) was rejected.

Figure 2. Gender differences in isometric tongue strength.

An independent-samples t-test was used to investigate the age differences in PMaxS. A difference in the opposite direction, as hypothesised, was demonstrated i.e., the older age group demonstrated higher PMaxS pressures compared to the younger age group, but the difference was non-significant (18-38 years- 121.36 mmHg, >38 years-161.32 mmHg; see Fig 3).

As a result, the null hypothesis 1 (there will be no significant difference in the ITS pressures across the older and younger age groups) was accepted and the alternate hypothesis 1 (the older age group will demonstrate significantly lower recorded ITS pressures than the younger age group) was rejected.

Figure 3. Age differences in isometric tongue strength.
A Mann-Whitney U test was used to examine the differences in PMaxE, t100 and Pt100 (ITE pressures) obtained by males compared to females. Males had 'stronger' PMaxE pressures than females (males- 19.00 mmHg, females- 16.17 mmHg) and females had 'longer' t100 durations than males (females- 19.19 seconds, males- 15.59 seconds); however, neither of these differences were significant.

On the more robust parameter Pt100 (considers area i.e., both the time and pressure obtained; thus, it provides a more detailed measure for ITE), females had 'larger' ITE pressure areas than did males (females- 17.94 mmHg/sec, males- 17.00 mmHg/sec); however, the difference was non-significant (see Fig 4). For this reason the alternate hypothesis 4 (there will be no significant difference in the area of ITE pressures between males and females) was accepted and the null hypothesis 4 (there will be a significant difference in the area of ITE pressures between males and females) was rejected.

Figure 4. *Gender differences in isometric tongue endurance.*

Age differences for PMaxE, t100 and Pt100 were investigated using a Mann-Whitney U test. The younger age group had 'stronger' PMax E pressures than the older age group (18-38 years- 19.90 mmHg, >38 years- 13.62 mmHg); the older age group had 'longer' t100 durations than the younger age group (>38 years- 21.42 seconds, 18-38 years- 15.07 seconds) and the older age group had 'larger' Pt100 pressure areas than the younger age group (>38 years- 19.92 mmHg/sec, 18-38 years- 16.00 mmHg/sec; see
Fig 5). This result was in the opposite direction as hypothesised; however, none of these differences were significant.

As a result, the null hypothesis 3 (there will be no significant difference in the area of ITE pressures for the older and younger age groups) was accepted and the alternate hypothesis 3 (the older age group will demonstrate significantly smaller areas of ITE pressures when compared to the younger age group) was rejected.

Figure 5. Age differences in isometric tongue endurance.

The effect of OroPress as a biofeedback tool

The effect of biofeedback (using the OroPress) on ITS and ITE pressure generation was tested in order to investigate whether or not the OroPress may be effective as a biofeedback tool for these measures. The group data were examined (i.e., not differentiating across ages or between gender) using a paired-samples t-test, which demonstrated that PMaxS increased significantly with biofeedback (P<.05, with biofeedback- 540.92 mmHg, without biofeedback- 516.04 mmHg; see Fig 6).

For this reason the alternate hypothesis 5 (ITS pressures will significantly increase in the biofeedback condition compared to the non-biofeedback condition) was accepted and the null hypothesis 5 (there will be no significant difference in ITS pressures obtained in the biofeedback condition compared to the non-biofeedback condition) was rejected.
A Wilcoxon Signed Rank test was used to examine the differences in PMaxE, t100 and Pt100 recorded, with and without biofeedback. This indicated an increase in PMaxE, t100 and Pt100 with biofeedback; however, these increases were non-significant (see Table 6). As a result the null hypothesis 6 (there will be no significant difference in ITE pressures obtained in the biofeedback condition compared to the non-biofeedback condition) was accepted and the alternate hypothesis 6 (ITE pressures will significantly increase in the biofeedback condition compared to the non-biofeedback condition) was rejected.

Table 6

The effects of biofeedback on isometric tongue endurance.

<table>
<thead>
<tr>
<th></th>
<th>With biofeedback</th>
<th>Without biofeedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMaxE</td>
<td>539.07 mmHg</td>
<td>549.37 mmHg</td>
</tr>
<tr>
<td>t100</td>
<td>15.25 seconds</td>
<td>13.21 seconds</td>
</tr>
<tr>
<td>Pt100</td>
<td>5121.62 mmHg/sec</td>
<td>4666.41 mmHg/sec</td>
</tr>
</tbody>
</table>
The pressure waveforms obtained during the ITS and ITE tasks were also visually analysed. A possible ‘motivation effect’ was evident across many of the ITS waveforms recorded with biofeedback. Fig 7 illustrates an ITS waveform generated with biofeedback and Fig 8 illustrates an ITS waveform generated without biofeedback, by the same participant. In Fig 7 there is a visible sharp incline in the pressure gradient, but in Fig 8 there is a more gradual incline, which is possibly caused by an increase in motivation.

Figure 7. Isometric tongue strength waveform obtained with biofeedback.

Figure 8. Isometric tongue strength waveform obtained without biofeedback.
This possible ‘motivation effect’ of biofeedback also was visible across many of the ITE waveforms recorded. Fig 9 illustrates an ITE waveform generated with biofeedback and Fig 10 illustrates an ITE waveform generated without biofeedback, by the same participant. In Fig 9 there is a visible ‘decline’ in pressure (under 125 mmHg), possibly due to fatigue, which then rapidly increases to approximately 200 mmHg. This pattern was not observed for ITE waveforms recorded without biofeedback. They demonstrated a gradual decline in the pressure gradient, with less of an incline as the recording progressed (see Fig 10).

**Figure 9. Isometric tongue endurance waveform obtained with biofeedback.**

**Figure 10. Isometric tongue endurance waveform obtained without biofeedback.**
Post-hoc analysis was then conducted to investigate the differences between males and females, and across the older and younger age groups, in ITS and ITE pressures obtained with and without biofeedback. The effect of biofeedback on the rate of fatigue (ROF) during ITE tasks was also examined. A significant increase in ITS pressures (PMaxS) with biofeedback was demonstrated by females (P<.05; with biofeedback=504.69 mmHg, without biofeedback= 471.79 mmHg) but not by males (see Fig 11). The ITS pressure of both the younger and older age groups increased with biofeedback; however, this effect was non-significant.

![Gender differences in isometric tongue strength, with and without biofeedback.](image)

Figure 11. *Gender differences in isometric tongue strength, with and without biofeedback.*

Similarly, the ITE pressures (Pt100) obtained by the females and the older age group increased with biofeedback, but the Pt100 decreased with biofeedback for the males and the younger age group. These effects were non-significant (see Table 7). Biofeedback significantly reduced the ROF (P<.05; ROF with biofeedback=12.48 mmHg/S, without biofeedback= 15.13 mmHg/S) during the ITE task (see Fig 12).
Table 7

*Age and Gender differences in isometric tongue endurance, with and without biofeedback.*

<table>
<thead>
<tr>
<th></th>
<th>With biofeedback</th>
<th>Without biofeedback</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Younger</strong></td>
<td>15.38 mmHg</td>
<td>16.00 mmHg</td>
</tr>
<tr>
<td><strong>Older</strong></td>
<td>20.92 mmHg</td>
<td>19.92 mmHg</td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td>16.75 mmHg</td>
<td>17.00 mmHg</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td>18.17 mmHg</td>
<td>17.94 mmHg</td>
</tr>
</tbody>
</table>

Figure 12. *The effect on biofeedback on rate of fatigue.*

**Validity of the data extraction methods**

Large positive correlations (P<.0005) were found between all of the data extracted by the two independent researchers, using two different methods of data extraction (see
Table 8). This demonstrates the strong construct validity for the newly developed data extraction method which was designed for use with the OroPress.

Table 8

Correlations between the data extraction methods.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test</th>
<th>Correlation</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMaxS with bio</td>
<td>Pearson r</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
<tr>
<td>PMaxS no bio</td>
<td>Pearson r</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
<tr>
<td>PMaxE with bio</td>
<td>Spearman’s rho</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
<tr>
<td>PMaxE no bio</td>
<td>Spearman’s rho</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
<tr>
<td>t100 with bio</td>
<td>Spearman’s rho</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
<tr>
<td>t100 no bio</td>
<td>Spearman’s rho</td>
<td>1 (Large)</td>
<td>.000</td>
</tr>
</tbody>
</table>
Discussion

As this was a pilot study, to test the validity of a newly developed wireless tool, the OroPress, when used to measure isometric tongue pressures (ITP) in normal adults (i.e., people without dysphagia), the findings from this study offer novel and important information about ITPs. Since evidence-based practice is considered the hallmark of clinical practice (Frattali and Worrall 2001) it is important that valid measurement tools are used in clinical practice, so understanding the psychometric properties of a new tool is important. The effects of the OroPress as a tool for providing biofeedback on ITP were also investigated in this study.

Validity of the OroPress when used to measure isometric tongue pressures

In this study, differences in isometric tongue strength (ITS) pressures obtained from males and females were demonstrated. Males had significantly higher maximum ITS pressure (PMaxS) recordings than did females. This finding supported previous reports that males have higher ITS than do females (Adams et al., 2013).

There were differences in PMaxS obtained from the younger and the older age group with the older group having higher PMaxS than the younger group, but this difference was not significant. This finding was unexpected as previous researchers have reported that younger people have higher ITS than older people (Adams et al., 2013).

One possible explanation for this finding is that there is little agreement on the categorisation of different age groups. In this study, the younger age group was from 18–38 years and the older age group was over 38 years (using the split mean difference); however, Nicosia et al., (2000) used mean ages to classify the older and younger participants as older = 81 years, and younger = 51 years. By contrast, Youmans et al., (2009) used three age categories (young: 20–39; middle: 40–59; and older: 60–79) in their published study.

Another possible explanation is that the extremely low profile of the OroPress sensor, unlike those of the more intrusive three sensors of the KSW (Hewitt et al.,
Although the findings for the differences in PMaxS for the two age groups were in the opposite direction as was hypothesised, the ability of the OroPress to detect differences between males and females and across younger and older age groups, demonstrate good face validity for the OroPress as a measure of ITS.

Three parameters of isometric tongue endurance (ITE), including the maximum ITE pressure (PMaxE), maximum ITE time (t100), and maximum areas under the ITE pressure waveform (Pt100), were examined to assess the differences in ITE between males and females across the younger and older age groups. The most robust of these parameters was Pt100 as it incorporated both time (for the first and last second of the waveform) and pressure into one datum.

Differences between the males and females were demonstrated, with female’s obtaining larger Pt100 pressure areas than that of males, but this difference was not significant. Likewise, differences across the older age group and the younger age group were demonstrated, with the older age group obtaining larger Pt100 than that of the younger age group, but again this difference was not significant.

Although there has been limited research into the relationship between age/gender and ITE (Adams et al., 2013), a possible explanation for these findings is that both the males and the younger participants exerted more effort/strength (i.e., stronger PMaxE) during the ITE trials. Consequently, the males and younger age group may have fatigued faster; thus, producing smaller Pt100 (Kays et al., 2010).

These findings provide important information about the suitability of Pt100 as a parameter for ITE. Previously, to examine ITE, researchers have relied on measures of duration, obtained with the IOPI (Youmans and Stierwalt 2006). By doing this, pressure/effort was not considered, so an inadequate measure of ITE may have been documented.
The effect of the OroPress as a biofeedback tool

The effect of using biofeedback (via the OroPress) on ITP was tested. Differences between PMaxS measures obtained with and without biofeedback were demonstrated, with significantly higher PMaxS measures being recorded in the biofeedback condition. Similar differences were demonstrated in Pt100 measures obtained with and without biofeedback with larger Pt100 measures recorded with biofeedback, but this was non-significant.

One possible explanation for these findings is that biofeedback increased participant motivation (Reddy et al., 2000). The motivation effect of biofeedback was evident across many of the ITS (see Fig 7 & 8 in results section) and ITE (see Fig 9 & 10 in results section) waveforms recorded this study. Although this pattern was not analysed statistically, it provided a useful illustration of the effects of biofeedback on ITP, specifically of the rate of fatigue (ROF) during ITE tasks.

Visible differences in the ROF during the ITE trials with, and without, biofeedback were observed across many ITE waveforms (see Fig 9 & 10 in results section). When post-hoc analysis was performed to examine the effect of biofeedback on the ROF, a significant reduction in ROF during ITE trials when recorded with biofeedback compared to those recorded without biofeedback was demonstrated. This reduction in ROF during the biofeedback trials may be a result of increased motivation levels (as a consequence of biofeedback) causing a reduction in the effects of fatigue, as keeping a person informed about their progress generally results in greater effort being exhibited (Lünenburger et al., 2007).

Post-hoc analysis was also conducted to examine the differences between males and females, and across the older and younger age groups, in ITS and ITE measures obtained with biofeedback. This analysis indicated that PMaxS increased with biofeedback for both genders and age groups; however, these effects were significant for females only. This finding indicates that biofeedback, using the OroPress, had a larger effect on the PMaxS generated by females than by males.
Similarly, the Pt100 measures increased with biofeedback for females and for the older age group. Neither of these effects were significant. As this was the first study in which the effects of biofeedback on ITP generation have been examined, the reported findings cannot be compared to previously published research. These novel findings may offer important information about the effects of biofeedback on ITP but the results need to be replicated with a larger sample size.

Validity of the data extraction method

Large correlations were demonstrated between method 1 (manual) and method 2 (computerised) for data extraction. These findings support the use of this newly developed, computerised, data extraction method, i.e., a Microsoft Excel spreadsheet containing the study data and data extraction formulae to extract and calculate PMaxS, PMaxE, t100, Pt100 and ROF, from the OroPress.

Study limitations

The findings from this study are limited by a small and possibly heterogeneous sample size (n=35). Also by using exclusionary criteria (Polgar and Thomas 2000) and convenience sampling for this study (Fraenkel and Wallen 2003), the risk of capturing non-representative population data may have increased. Regardless of these limitations, by purposefully recruiting this sample, a sound testing protocol for use with the OroPress was established.

The face validity of the OroPress as a tool for measuring ITP was examined. Face validity is sometimes regarded a subjective measure of validity, but the face validity of a tool must be first assured before its construct validity can be examined (Portney and Watkins 2009). The data provided from this pilot study therefore provides an important starting point for future researchers to build on.

Clinical implications

There are two major clinical implications from this study. First, the OroPress was shown to be a valid tool for capturing and extracting ITPs in normal healthy adults.
Second, the tool may be used to motivate normal healthy adults to increase their ITS pressures by providing biofeedback on these measures.

**Recommendations**

Although preliminary, the findings from this pilot study are promising. Further research into the psychometric properties and effectiveness of the OroPress as a tool for recording ITP and for providing biofeedback, is required. Recommendations for future research include, first, increase the number of ITE and ITS trials to three of each (and each both with and without biofeedback), so that the test-retest and inter-rater reliability of the OroPress as a tool for measuring ITP and for providing biofeedback may be better examined.

Second, compare data obtained using the OroPress with data obtained (from the same participants, during the same conditions) using the KSW and/or IOPI, so that the criterion validity of the OroPress tool for (i) measuring ITPs and (ii) providing biofeedback, may be examined. This would be a more robust measure of validity, as it would indicate if the OroPress could provide a reliable measure of ITP instead of the presently available KSW and/or IOPI (Portney and Watkins 2007), each of which has limitations.

Last, with an increase in the number of normal older participants, data obtained would be more representative of the target population. An older population is at a higher risk of muscle weakness, muscle fatigue and dysphagia (Robbins et al., 1995) so these data may contribute to the development of taxonomy of normal ITP in the older population. This taxonomy would help clinicians and/or researchers in identifying what is a normal and/or disordered ITP for this population.

**Summary**

Face validity of the OroPress as a tool for measuring ITP was demonstrated and strong construct validity was established for a newly developed computerised data extraction method, for use with the OroPress. Face validity is an important property of a new tool
as, without this, the tool will not be accepted by consumers, clinicians and/or patients (Portney and Watkins 2007, pp. 100-101).

The effectiveness of the OroPress as a biofeedback tool for ITS, but not for ITE, was established. Biofeedback significantly increased female ITS pressure, but had non-significant effect on male ITS pressure, and had a non-significant effect on the ITS and ITE pressures of both age groups. The use of the OroPress as a biofeedback tool also significantly reduced the rate of fatigue during the ITE trial, as demonstrated by all the participants.

Conclusions

To date researchers have focused on recording maximum pressure during ITS tasks and maximum duration during ITE tasks, using the KSW and/or IOPI. The newly developed wireless tongue pressure measurement tool, the OroPress, provides further scope for examining ITP such as measuring the area (Pt100) of the ITE waveform and measuring the rate of fatigue.

At present, there is a dearth of research into the effects of biofeedback on ITP so the findings from this study offer novel, important information on this topic. As biofeedback can increase patient motivation (Reddy et al., 2000), using the OroPress as a biofeedback tool may increase patient motivation and adherence to a tongue or swallowing exercise protocol which, in turn, may make for more effective swallowing rehabilitation.
References


YOU are being invited to take part in a study to examine tongue pressure 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: Joanne McCormack. Tel: 087-9729588 email: 11010878@studentmail.ul.ie

| **Tongue pressure Study Contact:** Joanne 087-9729588 11010878@studentmail.ul.ie | **Tongue pressure Study Contact:** Joanne 087-9729588 11010878@studentmail.ul.ie | **Tongue pressure Study Contact:** Joanne 087-9729588 11010878@studentmail.ul.ie | **Tongue pressure Study Contact:** Joanne 087-9729588 11010878@studentmail.ul.ie | **Tongue pressure Study Contact:** Joanne 087-9729588 11010878@studentmail.ul.ie |
Appendix 2:  

**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 and during isometric (pushing against resistance) trials 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 twice 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 twice with small intervals in between. We will then remove the sensor and answer. The study will take place at the University of Limerick 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 and isometric (pushing against resistance) 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 the UL / EHS Research Ethics Committee.

**Is There A Complaints Procedure?**
Complaints or queries about the study can be directed to the Principal-Investigator (Prof Alison Perry) or to the UL/EHS Ethics Committee Chairperson.
Appendix 3:

**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/more of the statements and I 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: __________________________

________________________________________

44
Appendix 4:  

**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 7. 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 Q9.
   _______________________________________________________________
   _______________________________________________________________
Does your medical condition affect your breathing? □ Yes □ No
If yes, please describe:
_________________________________________________________________
_________________________________________________________________

6. Does your medical condition affect your swallowing? □ Yes □ No
If yes, please describe:
_________________________________________________________________
_________________________________________________________________

7. Are you taking regular medication? □ Yes □ No
If yes, please list:
_________________________________________________________________
_________________________________________________________________

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

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

10. 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 5:

ORO MOTOR EXAMINATION

Participant No: ________________
Date: ________________
Student: ________________

<table>
<thead>
<tr>
<th>Organ:</th>
<th>Assessment of:</th>
<th>Method:</th>
<th>Outcome: (Circle as applicable)</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 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 = 10 secs) | 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.  
Say ‘oo- ee’ 3 times in a row, as quickly as you can, like | 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) | 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 |
| Elevation | 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). |  | 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 |
| Depression | Try to touch your nose with your tongue 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 |
| Lateral movements (norm=4secs) | Put your tongue down to your chin 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  
<p>| 5. Unable to undertake task |</p>
<table>
<thead>
<tr>
<th>Time in secs</th>
<th>1. 0 abnormalities noted</th>
<th>2. Mild abnormality noted</th>
<th>3. Abnormality obvious but can perform task reasonably well</th>
<th>4. Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured</th>
<th>5. Unable to undertake task</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)</td>
<td></td>
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<tr>
<td><strong>Soft Palate</strong></td>
<td>At rest</td>
<td>Elevation of Uvula on ‘ah’</td>
<td>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. Now say ‘ah’ and hold it for a few seconds</td>
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</tr>
</tbody>
</table>
|                |         |                           | 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 |
<table>
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<tr>
<th></th>
<th>Gag reflex</th>
<th>Sensitivity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Open your mouth wide please; I'm going to test your gag reflex.</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td>0 abnormalities noted</td>
</tr>
<tr>
<td>2.</td>
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