Investigating the usefulness of the OroPress as a biofeedback tool

By

Tríona O’ Brien

12011991

Word Count: 7770

14/05/2014
Contents
Abstract.................................................................................................................................................. 2
Introduction ............................................................................................................................................. 3
Methods ................................................................................................................................................ 9
Results .................................................................................................................................................. 16
Discussion ............................................................................................................................................ 29
References .......................................................................................................................................... 35
Appendix 1 .......................................................................................................................................... 37
Appendix 2 .......................................................................................................................................... 41
Abstract

**Background:** The OroPress is a valid and reliable tool for measuring ITS and ITE but further investigation is needed to establish the usefulness of the OroPress as a biofeedback tool. Biofeedback is used to provide individuals information about a task being performed. Robbins et al. (2005) found that when participants carried out ITS and ITE tasks with biofeedback they generated greater pressures than at baseline.

**Objectives:** To determine whether participants produce greater maximum ITS (PmaxS), maximum ITE (PmxE) and longer ITE durations (t100) when presented with visual biofeedback from the OroPress. To investigate the relationship between PmaxE and t100 in ITE tasks.

**Methods:** 54 participants were recruited to this study. During trials, participants produced 3 ITS tasks (pushing the tongue against the hard palate with as much force as possible for 3 seconds) and 3 ITE tasks (ITS for as long as possible). Data was collected using OroPress and results were analysed to determine the effect of biofeedback on ITS and ITE.

**Results:** PmaxS increased significantly for the male and >50 years groups, with biofeedback (p< 0.05). PmaxE predicts t100 to a greater extent after biofeedback than at baseline, for participants >50 years.

**Conclusions:** The increase in PmaxS, indicates that biofeedback from the OroPress is useful for encouraging both males and >50 years to produce greater tongue strength. Biofeedback provided by the OroPress may have more motivational impact on participants >50 years.
Introduction

The tongue has an important role in swallowing as it propels a bolus (a ball of fluid or food) from the oral cavity through the pharynx, towards the oesophagus (Mendell & Logemann, 2007). Bolus propulsion requires coordination of the muscles of the tongue, which produce force (strength) to squeeze the bolus against the roof of the mouth (hard palate) and transport it posteriorly, towards the faucal arches (Fuller, Pimentel & Peregyo, 2012; Lazarus, Logeman, Huang & Rademaker 2003).

Tongue strength decreases across the life span due to sarcopenia, a “…reduction in skeletal muscle mass in the elderly” (Block, Borer, Bruce, Christopher, Drake, Jangid, John, Pucci, Silver, Vogl & Whitman, 2007, pp.1692) which causes presbyphagia (physiological changes related to normal aging that affect swallowing, such as slower oral bolus transfer) (Robbins, Gangnon, Theis, Kays, Hewitt, & Hind, 2005). Reduced tongue strength in elderly individuals has also been linked to dysphagia (swallowing impairment) (Yoshida, Kikutani, Tsug, Utanohara, Hayashi & Akagawa, 2006) which is associated with aspiration pneumonia and poses a serious risk to an individual’s health (Robbins et al., 2005).

Speech and language therapists (SLTs) often employ swallowing rehabilitation programmes when working with clients who have dysphagia. Swallowing rehabilitation programmes are based on findings which suggest muscle training (muscle exercise) has reduced the effects of sarcopenia in the limbs (Steele, Bailey, Cliffe Polacco, Hori, Molfenter, Oshalla & Yeates, 2013). These findings led SLT researchers to posit individuals could be taught lingual exercises to increase tongue strength (Yeates, Molfenter & Steele, 2007). The idea was supported when lingual isometric\(^1\) exercises combined with biofeedback\(^2\), had positive outcomes for increasing tongue strength in healthy young adults (Lazarus et al., 2003); and improving swallowing function in healthy older adults at risk of developing dysphagia (Robbins et al., 2005).

Biofeedback provides users with, “…additional information, above and beyond the information that is naturally available to them” (Giggins, Mc Carthy- Perssson & Caulfield, 2013, pp. 1). Clinicians use biofeedback to educate clients during rehabilitation

\(^1\) Isometric exercises refer to muscle contraction against constant resistance (Block et al., 2007).\n
\(^2\) Biofeedback is “…the process of furnishing an individual information, usually in…visual mode, on the state of one or more physiological variables…” which enables “…the individual to gain some voluntary control over the…variable being sampled” (Block et al., 2007, pp.220)
programmes, as it facilitates voluntary control over physiological functions, (Patel & Carruthers, 1977).

Yoshida et al. (2006) showed that maximum lingual pressures were related to “…the ability to perform tongue movements” (pp. 62) and to coughing during meals, a major symptom of dysphagia, in 145 elderly nursing home residents. This led them to conclude, “…tongue pressure measurement...is a useful technique for evaluating swallowing in elderly people” (Yoshida et al., pp. 64). This conclusion along with the findings of Robbins et al. (2005) that lingual isometric exercises with biofeedback increase tongue strength highlight the need for reliable tools to measure and display lingual isometric pressures.

Lingual isometric exercises include isometric tongue strength (ITS) tasks (when an individual pushes his/ her tongue against the hard palate, with as much force as possible, for a brief duration, described by Gingrich, Stierwalt, Hageman & LaPointe, (2012)); and isometric tongue endurance (ITE) tasks (the length of time an individual can continue to push his/ her tongue as hard as possible against the hard palate, defined by Smith, 2000)). ITS and ITE are measured, recorded and displayed by use of oral manometry\(^3\) devices, which measure the pressure produced for ITS and ITE tasks and the duration lasted in ITE tasks.

Robbins, Kays, Gangnon, Hind, Gentry and Taylor (2007) and Lazarus et al. (2003) used the Iowa Oral Performance Instrument (IOPI) to measure lingual isometric pressures and provide biofeedback. Although a large body of research has been conducted using the IOPI there are problems associated with this tool (Table 1). First, the IOPI sensor is a large intrusive bulb used in the mouth. Second, the IOPI is hand-held by either the participant or the clinician so it is not stable during pressure recordings (Shaker, Easterling, Belafsky, & Potsma, 2013). Third, the IOPI sensor is air- filled, which means the tongue pushes against this, rather than directly against the hard palate, producing an artefact of measure when recording oro-lingual pressures (Shaker et al., 2013). Last, the IOPI provides biofeedback by use of a liquid-crystal-display (LCD) of red and green lights presented vertically on its control device (Youmans, Youmans & Steirwalt, 2009). A green light indicates that the user is producing a target pressure, but it does not allow the user to visualise the pressure produced across time.

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\(^3\) Manometry refers to the measurement of pressure (strength, force)
In contrast, the OroPress wireless sensor is small and adhered to the hard palate with a Poligrip ComfiSeal Strip, making it minimally intrusive and stable during pressure measurement. The user pushes his or her tongue directly against the flat sensor attached to the hard palate, allowing for lingual pressures to be reliably recorded (McCormack et al., 2013). The OroPress is used to measure lingual pressures in millimetres of mercury (mmHg) in real-time and this information is displayed as an on-screen line graph which is shown to users to provide them with biofeedback, i.e. the user sees the level of pressure they are producing which rises or falls over time as they exert more or less force. This is termed biomechanical, transformed biofeedback (when pressure is recorded and displayed visually to the user) (Giggins et al., 2013). The IOPI and the OroPress are compared and contrasted in Table 1 below.

McCormack et al. (2013) found that the OroPress was valid and reliable for measuring ITS andITE in a healthy adult population, but they concluded that further investigation was necessary to determine the usefulness of the OroPress as a biofeedback tool. This is an important consideration which indicates that before the OroPress can be used to provide biofeedback within clinical settings, the tool must be deemed valid and reliable to perform such a task.
**Table 1**

A *Comparison of the IOPI and OroPress for lingual isometric pressure measurement*

<table>
<thead>
<tr>
<th>Feature</th>
<th>IOPI</th>
<th>OroPress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe &amp; easy to use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sensor intrusiveness</td>
<td>Large air filled bulb is intrusive in oral cavity</td>
<td>Small, flat sensor is minimally intrusive in oral cavity</td>
</tr>
<tr>
<td>Visual display of pressure (for biofeedback)</td>
<td>Good: Liquid-crystal-display (LCD) of red and green lights presented vertically.</td>
<td>Very good: On-screen line graph displays pressure produced in real time making it easy to visualise</td>
</tr>
<tr>
<td>Wireless system</td>
<td>No: Sensor connected to the control device</td>
<td>Yes: Headpiece with sensor and microcontroller attached, are separate from the computer</td>
</tr>
<tr>
<td>Stable during recording</td>
<td>The sensor is hand-held, therefore unsecured and unstable during recording</td>
<td>The sensor is adhered to hard palate using a Poligrip ComfiSeal Strip and is stable during recording</td>
</tr>
<tr>
<td>Provides accurate measure of pressure</td>
<td>Participants push against the air filled bulb producing an artefact of measure</td>
<td>Participants push directly against the flat sensor adhered to hard the palate providing accurate pressure reading</td>
</tr>
<tr>
<td>Can be used in both clinic and laboratory settings</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Portable</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cost effective</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
The purpose of this study was to investigate the usefulness of the OroPress for providing visual biofeedback to participants. Research was conducted to determine the effects visual biofeedback from OroPress had on maximum ITS pressures (PmaxS), maximum ITE pressures (PmaxE) and ITE durations (t100).

Aims and Hypotheses

The aims, associated hypotheses and rationales are presented below

Aim 1: To determine the differences in maximum ITS (PmaxS) obtained from the OroPress, between non-biofeedback and biofeedback conditions, for the whole group, across males and females and between the older and younger age groups.

Hypothesis 1: Participants will generate greater PmaxS when presented with visual biofeedback from the OroPress.

Hypothesis 2: Males will generate greater PmaxS than females when presented with visual biofeedback from the OroPress.

Hypothesis 3: The younger age group (< 50 years) will generate greater PmaxS than the older age group (> 50 years) when presented with visual biofeedback from OroPress.

Rationale: Lazarus et al. (2003), stated that participants’ ITS were greater after receiving visual biofeedback than at baseline, McCormack et al. (2013) showed that males produced greater PmaxS than females and Youmans and Stierwalt (2006) showed that a younger group produced greater PmaxS than an older age group.

Aim 2: To determine the differences in maximum ITE (PmaxE) obtained from the OroPress, between non-biofeedback and biofeedback conditions.

Hypothesis 4: Participants will generate greater PmaxE when presented with visual biofeedback from the OroPress.

Hypothesis 5: Males will generate greater PmaxE than females when presented with visual biofeedback from the OroPress.

Hypothesis 6: The younger age group (< 50 years) will generate greater PmaxE than the older age group (> 50 years) when presented with visual biofeedback from OroPress.
Rationale: McCormack et al. (2013) showed that participants produced greater ITE pressures after receiving visual biofeedback from the OroPress. The differences between groups for PmaxE were not discussed in that study. Branzino (2000) suggests that ITE and ITS are strongly related, therefore it was hypothesised that PmaxE would follow the same pattern as PmaxS where males would produce greater PmaxE than females and younger participants would produce greater PmaxE than older participants:

**Aim 3:** To determine the differences in ITE durations (t100) obtained from the OroPress, between non-biofeedback and biofeedback conditions.

**Hypothesis 7:** Participants will sustain longer t100 when presented with visual biofeedback from the OroPress.

Rationale: McCormack et al. (2013) found that the OroPress was useful for motivating participants to produce greater pressures. Although they did not investigate the differences in t100 before and after biofeedback, researchers in this study hypothesised that the OroPress would also motivate participants to produce greater t100

**Aim 4:** To investigate the relationship between PmaxE and t100 obtained from the OroPress, between the non-biofeedback and biofeedback trials.

**Hypothesis 8:** PmaxE will predict t100 in ITE trails and the effect will be a larger in the biofeedback (rather than non-biofeedback) trials.

Rationale: Bronzino (2000) states that, “when resistance is adjusted to the person’s strength, a weaker person tends to demonstrate more endurance than a stronger person” (pp. 148.16). This implies PmaxE predicts t100 in ITE trials, whereby greater PmaxE equals shorter duration and vice versa.
Methods

Ethical approval for this study was obtained prior to commencement from the University of Limerick’s Research Ethics Governance Committee (ULREGC).

Study design

This was a within-subjects, quantitative design to test eight hypotheses with a cohort of healthy adult volunteers. There were three independent variables (IVs), biofeedback, age and gender. Each IV had two levels, i.e. biofeedback consisted of with, and without, biofeedback, age was divided into a younger age group (age 18 – 50 years) and an older age group (50 – 74 years); gender was classified as males or females. There were three dependent variables (DVs): $P_{maxS}$ - the maximum pressure recorded during a 3 second ITS task; $P_{maxE}$ - the maximum pressure point recorded during one ITE task and $t_{100}$ - the length of time pressure was sustained above 100mmHg during one ITE task.

Participants

Fifty-four volunteers aged 18 to 74 years gave their informed consent to participate in this study. Participants were recruited from the University of Limerick (UL) campus by personal invitation and through letters to local voluntary organisations. Each volunteer had sufficient English and hearing ability to understand instructions. Volunteers were given detailed information about the study (Appendix 1) and once they agreed to participate, they were given an appointment time to attend the university speech and language therapy (SLT) clinic for data collection. In order to examine the effects of age and gender on the dependent variables, participants were divided into four groups (less than 50 years, more than 50 years and males and females).
Materials

This study was conducted to examine the effects of biofeedback, age and gender on oro-lingual pressures. Oro-lingual pressures were recorded and measured using OroPress. OroPress includes a sensor embedded in silicone, a headpiece which stabilises the sensor and houses a zero insertion force connector (ZIF), to which the sensor is inserted; a battery-operated, wireless control module; and a USB transmitter/receiver inserted into a laptop computer (Asus Eee PC NetBook) (FIGURES 1 – 5).

Figure 1. Sensor & ZIF connector
Figure 2. Headpiece
Figure 3. OroPress control module
Figure 4. Asus Eee PC NetBook with USB transmitter/receiver attached
Figure 5. Line graph representing pressure in real time
The sensor is small and flat, so minimally intrusive inside the mouth. It is adhered to the roof of the mouth with a Poligrip ComfiStrip Seal, to record either lingual isometric or lingual swallowing pressures.

OroPress is used to record information about temperature in Celsius (°C), pressure in millimetres of mercury (mmHg) and time in seconds (tS). Signals from the sensor are sent via the ZIF connector to the wireless control module where they are interpreted and then sent to the USB transmitter/ receiver. From here, signals are forwarded to the computer, where they are displayed as a 2 dimensional line graph in real-time (x-axis = time; y-axis = pressure in mmHg).

This online graph was shown to the participants in one condition of their trials to provide them with visual information (biofeedback) about the pressures they were producing. A stopwatch was used during trials to record time in seconds (ts) and a Nikon D3100 camera was used to photograph the sensor in situ.

**Procedure**

Before data collection began, a medical questionnaire and an oro- motor examination were conducted to determine whether each participant met the criteria for inclusion in the study (Appendix 2). The researchers asked the participants to fill in the medical questionnaire, specifying whether they were taking any medications, or had medical conditions which could affect swallowing. An oro- motor examination was designed to test lingual function, lip seal, palatal elevation and a gag reflex to ensure all were within normal limits. Exclusion criteria for the study included presenting with a tongue piercing and/or a history of language difficulties, which would have impeded the participant’s ability to give informed consent.

OroPress trials were conducted in a quiet room of the SLT clinic by two student researchers. After the medical questionnaire and oro-motor examination had been administered and inclusion criteria were established, participants were counterbalanced to one of two conditions – ITS first or ITE first - to control for any order effect on results. Biofeedback was not randomised, as the sample was too small to support this, so biofeedback always proceeded non- biofeedback.
Each participant was seated at a table, at a right angle from the researcher, facing a wall where a disc was placed at participant’s eye level. They were asked to gaze at it, in order to minimise their head movements during the non-biofeedback condition.

During the biofeedback condition, participants looked at the computer to monitor their generated lingual pressures.

A student researcher calibrated the OroPress to ensure correct measurement of the data; i.e. the microcontroller was switched on to receive information from the sensor and to transport the information to the USB transmitter/receiver and computer. The on-screen graph was then ‘zeroed’ - i.e. the pressure level was set at zero mmHg, rather than at the level of atmospheric pressure, for easier interpretation of results.

Once calibration was complete, a file name was set. The student researcher showed the participant the OroPress sensor, on which a Polygrip ComfiSeal Strip was stuck.

Each participant was instructed to open their mouth wide, and the OroPress sensor was secured to their hard palate, behind the alveolar ridge, in the midline. A second student assisted by stabilising the headset. Once the sensor was firmly set in place a photograph was taken to verify adequate positioning (Figure 6).

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

Participants in the ‘ITS first’ condition practised one ITS task, in order to become accustomed to the sensor in situ. They were then recorded as they produced six trials (three ‘tongue pushes’ without biofeedback, three with biofeedback). The ITE task then followed, again with one practice and then 6 recorded trials; 3 without biofeedback and 3 with
biofeedback. Each participant was given the following instructions by the student researcher before each task:

**ITS** – “*when I say ‘go,’ push the tip of your tongue against the sensor, as hard as you can, for 3 seconds. I’ll tell you when to stop.*”

**ITE** – “*when I say ‘go,’ push the tip of your tongue against the sensor, as hard as you can for as long as you can. I’ll tell you when to stop.*”

These instructions served two purposes; first, to remind participants what they were required to do and second, to give participants a short break between tasks to avoid fatigue affecting recordings.

During ITE trails, participants were allocated an additional 15 seconds of rest, as these tasks require more effort and create more fatigue (Lazarus et al., 2003).

The first student researcher timed the 3 second ITS trials using a stopwatch while the second researcher watched the screen to determine the time point at which the task began. This role was reversed during ITE trials, when the first student researcher looked at the screen and told the participant to “stop” once the pressure level dropped below 100mmHg.

After participants had completed all trials, one student researcher examined the computer database to ensure files had been successfully saved, while another completed a Microsoft Excel spreadsheet with participant data (Appendix 3). Finally, the area was cleaned and prepared for the next participant’s arrival.

**Data Analyses**

Before statistical analyses were conducted, graphs representing ITS and ITE were created and analysed within Microsoft Excel (Microsoft 2010). There were twelve graphs for each participant; three ITS without biofeedback, three ITS with biofeedback, three ITE without biofeedback and three ITE with biofeedback. Each graph was visually inspected to extract the DVs. ITS graphs were examined for the PmaxS and the ITE graphs for the PmaxE and the t100 data (Figure 7). A percentage agreement calculation was subsequently conducted to determine the inter-rater reliability on a sample of graphs analysed by two student researchers.
Statistical Analyses

Data extracted from the graphs were entered into the Statistical Package for Social Sciences (SPSS) (IBM, 2012) for further analyses.

Before descriptive statistics could be examined, an Intraclass Correlation Coefficient (ICC) (model 3, 1 - two way mixed single measure) was conducted to determine whether there was a statistically significant relationship for the 3 trials of ITS, the 3 trials of ITE (pressure) and the 3 trials of ITE (duration). Each participant undertook 3 ITS trials and ICCs were used to determine whether the group’s first ITS trials were stable (reliable) when compared to their second and their third ITS recordings and, if not, which of the three recordings was the source of variance.

Descriptive statistics on the average results for PmaxS, PmaxE and t100, before and after use of biofeedback, were undertaken and means, standard deviations, skewness and kurtosis were examined. Normality was assessed by interpreting the statistical significance from the Shapiro-Wilk test and inspecting histograms, Q- Q plots and boxplots to determine the shape of the data and identify outliers (Pallant, 2007; Portney & Watkins, 2009). Each variable was found to be normally distributed, therefore parametric tests were applied. The tests undertaken are outlined in Table 2.
Table 2

*Summary of statistical analyses*

<table>
<thead>
<tr>
<th>Subject of analysis</th>
<th>Statistical Method Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Determine statistically significant relationship between 3 trials of ITS, ITE pressure &amp; ITE duration (in order to obtain averages for each variable)</td>
<td><em>Intraclass correlation coefficient (3,1)</em></td>
</tr>
<tr>
<td>2. Summarise important information about variables</td>
<td><em>Descriptive statistics</em> – means, standard deviations, skewness, kurtosis</td>
</tr>
<tr>
<td>3. Assess whether variable is symmetrical with bell shaped curve, i.e. normally distributed</td>
<td><em>Normality testing</em> - Descriptive statistics, plus, analyse histograms, QQ plots, box plots and Shapiro- Wilk test</td>
</tr>
<tr>
<td>4. Determine the impact of biofeedback on PmaxS, PmaxE and t100</td>
<td><em>Paired-samples t-test</em></td>
</tr>
<tr>
<td>5. Determine group differences in PmaxS, PmaxE and t100</td>
<td><em>Independent-samples t- test</em></td>
</tr>
<tr>
<td>6. Visually explore the relationship between 2 continuous variables</td>
<td><em>Scatterplots</em></td>
</tr>
<tr>
<td>7. Determine the strength and direction of a linear relationship between 2 variables</td>
<td><em>Pearson’s r correlations</em></td>
</tr>
<tr>
<td>8. Determine whether one variable within a linear relationship predicts the other variable (investigate whether PmaxE predicts t100 in ITE)</td>
<td><em>Linear regression</em></td>
</tr>
</tbody>
</table>
Results

Data from two females under 50 years and one female over 50 years were removed from the sample because of recording errors, so statistical analyses are reported for fifty-one participants. Subjects were assigned to one of four groups to determine any significant differences in lingual pressures between older and younger participants or between males and females (Table 3).

Table 3
Participant demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Males</th>
<th>Females</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 49 years</td>
<td>16</td>
<td>14</td>
<td>30</td>
</tr>
<tr>
<td>50 – 74 years</td>
<td>10</td>
<td>11</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>26</td>
<td>25</td>
<td>51</td>
</tr>
</tbody>
</table>

Inter-rater reliability

Percentage agreement calculation was conducted to determine the inter-rater reliability for a sample of graphs (generated from OroPress recordings) analysed by two student researchers. Raters analysed the same ITS and ITE graphs in order to produce results for PmaxS, PmaxE and t100, without and with biofeedback, with no more than one second or one mmHg of difference.

Inter-rater reliability was conducted for 10% of the overall sample. Table 4 shows inter-rater reliability for one participant.

Both raters consistently described the data within one second or one mmHg of difference, so each measure was 100% reliable.
Table 4

*Percentage agreement for inter-rater reliability*

<table>
<thead>
<tr>
<th>Participant 31</th>
<th>Rater 1</th>
<th>Rater 2</th>
<th>% Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PmaxS without BF 1</td>
<td>456mmHg</td>
<td>456mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxS without BF 2</td>
<td>502mmHg</td>
<td>502mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxS without BF 3</td>
<td>468mmHg</td>
<td>468mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxS with BF 1</td>
<td>461mmHg</td>
<td>461mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxS with BF 2</td>
<td>411mmHg</td>
<td>411mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxS with BF 3</td>
<td>355mmHg</td>
<td>356mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE without BF 1</td>
<td>387mmHg</td>
<td>387mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE without BF 2</td>
<td>453mmHg</td>
<td>453mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE without BF 3</td>
<td>477mmHg</td>
<td>477mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE with BF 1</td>
<td>424mmHg</td>
<td>424mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE with BF 2</td>
<td>534mmHg</td>
<td>534mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>PmaxE with BF 3</td>
<td>412mmHg</td>
<td>412mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 without BF 1</td>
<td>5 seconds</td>
<td>5 seconds</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 without BF 2</td>
<td>23 seconds</td>
<td>23mmHg</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 without BF 3</td>
<td>23 seconds</td>
<td>24 seconds</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 with BF 1</td>
<td>11 seconds</td>
<td>12 seconds</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 with BF 2</td>
<td>16 seconds</td>
<td>17 seconds</td>
<td>100%</td>
</tr>
<tr>
<td>ITE t100 with BF 3</td>
<td>10 seconds</td>
<td>11 seconds</td>
<td>100%</td>
</tr>
</tbody>
</table>
Determining the strength of the relationship between 3 trials of PmaxS, PmaxE and t100

An intraclass correlation coefficient (ICC) model 3,1, was undertaken to determine the stability of results from three repeated trials of ITS and ITE (without and with biofeedback). ICCs greater than 0.7 indicate moderate associations between repeated measures while ICCs greater than 0.75 indicate strong relationships (Sanchez & Binkowitz, 1999).

The level of ICC statistical significance for trials one, two and three were compared.

There was a strong, statistically significant agreement across the three trials of PmaxS and PmaxE without and with biofeedback. For each trial p<0.001 and there was a 95% confidence interval (CI).

There was a strong, statistically significant relationship between trials one and two of t100 without biofeedback (ICC 0.78, p< 0.001, 95% CI) and there was a moderate statistically significant relationship between trials one and two of t100 with biofeedback (ICC 0.7, p<0.001, 95% CI).

There was a poor association between trial three with trials one and two for t100, both without and with use of biofeedback. Results are in Table 5.

Table 5

Level of agreement between repeated ITS and ITE trials

<table>
<thead>
<tr>
<th>Variables</th>
<th>Trials 1 - 2</th>
<th>Trials 2 – 3</th>
<th>Trials 1 - 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>PmaxS without BF</td>
<td>.94</td>
<td>.94</td>
<td>.93</td>
</tr>
<tr>
<td>PmaxE without BF</td>
<td>.9</td>
<td>.88</td>
<td>.89</td>
</tr>
<tr>
<td>t100 without BF</td>
<td>.78</td>
<td>.61</td>
<td>.56</td>
</tr>
<tr>
<td>PmaxS with BF</td>
<td>.96</td>
<td>.94</td>
<td>.93</td>
</tr>
<tr>
<td>PmaxE with BF</td>
<td>.8</td>
<td>.81</td>
<td>.93</td>
</tr>
<tr>
<td>t100 with BF</td>
<td>.7</td>
<td>.67</td>
<td>.56</td>
</tr>
</tbody>
</table>
Descriptive statistics

The means, ranges and standard deviations for all of the study variables, with and without biofeedback, are represented in Table 6.

The range of data varied considerably for the DVs, PmaxS, PmaxE and t100, without and with biofeedback. Participants produced greater PmaxS and PmaxE when presented with biofeedback from the OroPress. In contrast, participants sustained shorter t100 when presented with biofeedback from the OroPress. Results will be discussed in further detail later.

Table 6

Descriptive Statistics

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>Confidence level</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PmaxS without BF</td>
<td>51</td>
<td>95%</td>
<td>123</td>
<td>891</td>
<td>527.31</td>
<td>150.77</td>
</tr>
<tr>
<td>PmaxE without BF</td>
<td>51</td>
<td>95%</td>
<td>159</td>
<td>943</td>
<td>515.05</td>
<td>139.37</td>
</tr>
<tr>
<td>t100 without BF</td>
<td>51</td>
<td>95%</td>
<td>2</td>
<td>48</td>
<td>21.54</td>
<td>12.26</td>
</tr>
<tr>
<td>PmaxS with BF</td>
<td>51</td>
<td>95%</td>
<td>176</td>
<td>933</td>
<td>551.71</td>
<td>165.98</td>
</tr>
<tr>
<td>PmaxE with BF</td>
<td>51</td>
<td>95%</td>
<td>150</td>
<td>893</td>
<td>536.64</td>
<td>146.17</td>
</tr>
<tr>
<td>t100 with BF</td>
<td>51</td>
<td>95%</td>
<td>1</td>
<td>45</td>
<td>19.79</td>
<td>11.16</td>
</tr>
</tbody>
</table>
Assessing normality

Shapiro-Wilk tests were examined to assess the normality of the data set. The significance value of a Shapiro-Wilk test must be greater than 0.5 for normal distribution (Pallant, 2007) therefore each DV met the criteria for normal distribution. Results are outlined in Table 7.

Table 7
Shapiro-Wilk test of normality

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Statistic</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PmaxS without BF</td>
<td>.99</td>
<td>.97</td>
</tr>
<tr>
<td>PmaxE without BF</td>
<td>.98</td>
<td>.69</td>
</tr>
<tr>
<td>t100 without BF</td>
<td>.97</td>
<td>.24</td>
</tr>
<tr>
<td>PmaxS with BF</td>
<td>.99</td>
<td>.83</td>
</tr>
<tr>
<td>PmaxE with BF</td>
<td>.98</td>
<td>.34</td>
</tr>
<tr>
<td>t100 with BF</td>
<td>.97</td>
<td>.14</td>
</tr>
</tbody>
</table>

Researchers examined the level of skewness for each DV and found that all of the DVs had statistically significant positive skewness, indicating normal distribution of the data set.

Examination of histograms and boxplots identified one outlier (outside 1.5 times the interquartile range for the data set) for PmaxS (participant 16) without biofeedback and one outlier for PmaxE with biofeedback (participant 16). Two outliers were identified for PmaxE without biofeedback (participants 16 & 19; see Figure 8 below). Participant 16 was identified as an outlier on three occasions. This was a female participant >50 years of age who consistently produced ITPs below the normal distribution. Participant 19 (male <50) was identified as an outlier, producing greater force than the normal distribution on one occasion. These outliers were retained within the data set to maintain validity and representativeness of the sample to a larger population (Pallant, 2007).
The impact of biofeedback on ITS

Differences in PmaxS without and with biofeedback

A paired-samples t-test was conducted to investigate the impact of biofeedback on ITS (PmaxS). There was a statistically significant increase in PmaxS from level one (without biofeedback) to level two (with biofeedback), \( p<0.05 \). The mean increase in PmaxS was 26.68 mmHg with a 95% CI. Eta squared was calculated to determine the effect size (eta squared = 0.14). Eta squared larger than 0.14 indicates a large effect size (Pallant, 2007). Results are represented in Table 8 and Figure 9.

Table 8
**Paired-samples t-test outlining the impact of biofeedback on PmaxS**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. error mean</th>
<th>Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>PmaxS without BF</td>
<td>527.31</td>
<td>51</td>
<td>150.77</td>
<td>21.11</td>
<td>95%</td>
</tr>
<tr>
<td>PmaxS with BF</td>
<td>553.99</td>
<td>51</td>
<td>164.4</td>
<td>23.02</td>
<td>95%</td>
</tr>
</tbody>
</table>
Group differences in PmaxS without and with biofeedback

Additional paired-samples t-tests were conducted on each of the four participant groups. Researchers found a statistically significant increase in PmaxS with biofeedback for the male group (mean increase = 31.03 mmHg, p<0.05, 95% CI) with a large effect size (eta squared = 0.19); and for the older age group (mean increase = 23.86 mmHg, p<0.05, 95% CI) with a large effect size (eta squared = 0.18).

Comparing group differences in PmaxS without and with biofeedback

Independent-samples t-tests were subsequently undertaken to determine the effect of gender and age, without and with biofeedback, on mean PmaxS.

**Gender**

Independent-samples t-tests confirmed males produced significantly greater PmaxS than females for both levels (without biofeedback from the OroPress mean difference = 84.62 mmHg, p<0.05, with biofeedback from the OroPress, mean difference = 98.18 mmHg, p<0.05). The magnitude of the differences in the means was moderate for both levels but was larger with biofeedback (eta squared without biofeedback = 0.08, eta squared with biofeedback = 0.1).

**Age**

The younger group (<50 years) produced significantly greater PmaxS than the older group (>50 years) for both levels (without biofeedback mean difference = 126.28 mmHg, p<0.01,
with biofeedback mean difference = 127.19mmHg, p< 0.01). There was a large effect size in the differences between means for both levels (without biofeedback eta squared = 0.17, with biofeedback eta squared = 0.15). The effect was greater without biofeedback from the OroPress. The results of group differences in PmaxS are in Table 9.

Table 9
*Independent-samples t-tests identifying differences between (i) gender groups and (ii) age groups*

<table>
<thead>
<tr>
<th></th>
<th>T</th>
<th>Sig. (2-tailed)</th>
<th>Mean Difference</th>
<th>Std. Error Difference</th>
<th>95% C.I. Lower</th>
<th>95% C.I. Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PmaxS without BF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males 568.79</td>
<td>2.07</td>
<td>.04</td>
<td>84.62</td>
<td>40.91</td>
<td>2.4</td>
<td>166.84</td>
</tr>
<tr>
<td>Females 484.17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50 years 579.31</td>
<td>3.21</td>
<td>.002</td>
<td>126.28</td>
<td>39.4</td>
<td>47.1</td>
<td>205.46</td>
</tr>
<tr>
<td>&gt;50 years 453.03</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PmaxS with BF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males 599.83</td>
<td>2.19</td>
<td>.03</td>
<td>98.18</td>
<td>44.82</td>
<td>8.1</td>
<td>188.25</td>
</tr>
<tr>
<td>Females 501.65</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50 years 604.08</td>
<td>2.88</td>
<td>.006</td>
<td>127.19</td>
<td>44.1</td>
<td>38.55</td>
<td>215.83</td>
</tr>
<tr>
<td>&gt;50 years 476.89</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The impact of biofeedback on ITE pressure (PmaxE)

Differences in PmaxE without and with biofeedback
A paired-samples t-test was conducted to investigate the impact of biofeedback from OroPress on PmaxE.
There was a mean increase of 21.6mmHg from PmaxE without biofeedback to PmaxE with biofeedback from the OroPress, but the difference was not significant.

Group differences in PmaxE without and with biofeedback
Paired-samples t-tests were conducted for the four groups.
There was a mean increase in PmaxE for each group; males mean increase = 22.6mmHg, females mean increase = 20.5mmHg, <50 years mean increase = 30.2mmHg, >50 years mean increase = 9.3mmHg; but the difference was not statistically significant for any group.

Comparing group differences in PmaxE without and with biofeedback
Independent-samples t-tests were analysed to determine the effect of gender and age with and without biofeedback on mean PmaxE.

Gender
Males produced greater PmaxE than females without biofeedback (mean difference = 63.43mmHg) and with biofeedback (mean difference = 65.49mmHg) but these results were not significant.

Age
The younger age group produced significantly greater PmaxE than the older age group without biofeedback from the OroPress (mean difference = 105.53mmHg, P<0.01, 95% CI) and with biofeedback from the OroPress (mean difference = 126.4mmHg, p<0.01, 95% CI). The magnitude of the differences between the means was large for both levels but was greater with biofeedback (eta squared = 0.18) compared to without biofeedback (eta squared = 0.14). Figure 10 highlights differences in PmaxE between the younger and older age groups without and with biofeedback.
Figure 10. The effect of age on PmaxE without and with biofeedback from OroPress.

The impact of biofeedback on ITE duration (t100):

Differences in t100 without and with biofeedback

A paired-samples t-test was undertaken to investigate the impact of biofeedback from OroPress on t100. Researchers found that there was a mean decrease of 1.7 seconds from t100 without biofeedback, to t100 with biofeedback. This was not significant.

Group differences in t100 without and with biofeedback

Researchers conducted further paired-samples t-tests and found mean decreases in t100 from without biofeedback to with biofeedback for each of the four groups; males mean decrease = 1.3 seconds, females mean decrease = 2.2 seconds, <50 years mean decrease = 2.5 seconds, >50 years mean decrease = 0.7 seconds. Mean decreases were not statistically significant.

Comparing group differences in t100 without and with biofeedback

Independent-samples t-tests were examined to establish the effects of gender and age on t100.

Gender

Males sustained t100 for longer than females without biofeedback (mean difference = 2.62 seconds) and with biofeedback (mean difference = 3.44 seconds). The results were not significant.
**Age**

The younger age group sustained t100 for longer than the older age group without biofeedback from the OroPress (mean difference = 0.7 seconds) but they sustained t100 for shorter than the older group with biofeedback from the OroPress (mean difference = -1.73 seconds). The results were not significant.

**The impact of biofeedback on the relationship between PmaxE and t100**

Scatterplots, Pearson’s r correlations and linear regressions were conducted to examine the relationship between PmaxE and t100 in ITE tasks for each of the four groups. Results for Pearson’s r correlations and linear regressions are outlined in Table 11.

**Table 11**

*Group differences in the relationship between PmaxE and t100 in ITE tasks*

<table>
<thead>
<tr>
<th>Group</th>
<th>Pearson’s r correlation</th>
<th>Linear regression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>F</td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without BF</td>
<td>.67</td>
<td>19.64</td>
</tr>
<tr>
<td>With BF</td>
<td>.65</td>
<td>17.51</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without BF</td>
<td>.14*</td>
<td>.45*</td>
</tr>
<tr>
<td>With BF</td>
<td>.25*</td>
<td>1.49*</td>
</tr>
<tr>
<td><strong>&lt;50 years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without BF</td>
<td>.51</td>
<td>9.6</td>
</tr>
<tr>
<td>With BF</td>
<td>.46</td>
<td>7.5</td>
</tr>
<tr>
<td><strong>&gt;50 years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without BF</td>
<td>.43*</td>
<td>4.18*</td>
</tr>
<tr>
<td>With BF</td>
<td>.7</td>
<td>18.41</td>
</tr>
</tbody>
</table>

*Not statistically significant

**Males**

There was a strong positive relationship between PmaxE and t100 for the male group. The association was larger without biofeedback ($r=0.67$, $p<0.001$, 95% CI) than with biofeedback ($r=0.65$, $p<0.001$, 95% CI) from the OroPress. Similarly, PmaxE was found to successfully predict t100 for both levels and the prediction was greater without biofeedback ($F=19.64$, $p<0.001$, $R\ square=0.45$) than with biofeedback from the OroPress ($F=17.51$, $p<0.001$, $R\ square=0.42$).
**Females**

The association between PmaxE and t100 was neither strong nor significant in the female group, without or with biofeedback.

**<50 years**

There was a strong positive correlation between PmaxE and t100 for the younger group without biofeedback (r=0.51, p<0.005, 95% CI) and a moderate positive correlation between the variables with biofeedback (r=0.46, p<0.02, 95% CI). PmaxE successfully predicted t100 for both levels. The prediction was greater without biofeedback (F=9.6, p<0.005, R square=0.26) compared to with biofeedback (F=7.5, p<0.02, R square=0.21).

**>50 years**

There was a moderate correlation between PmaxE and t100 for the older group without biofeedback but this was not significant. In contrast, there was a strong positive correlation between PmaxE and t100 with biofeedback from the OroPress (r=0.7, p<0.001, 95% CI) and PmaxE successfully predicted t100 when participants were presented with biofeedback from the OroPress (F=18.41, P<0.001, R square=0.49). Scatterplots of the relationship between PmaxE and t100 in the older group without biofeedback (Figure 13) and with biofeedback (Figure 14) are shown below.
Figure 13. Scatterplot representing the linear relationship between $P_{\text{maxE}}$ (x-axis) and $t_{100}$ (y-axis) without biofeedback for the older group.

Figure 14. Scatterplot representing the linear relationship between $P_{\text{maxE}}$ (x-axis) and $t_{100}$ (y-axis) with biofeedback for the older group.
Discussion

The impact of biofeedback on ITS

The results of this study are in line with previous findings that participants produce greater PmaxS when presented with visual biofeedback from the IOPI (Lazarus et al., 2003) and the OroPress (Mc Cormack et al., 2013).

Findings from this study support the hypothesis that males produce greater PmaxS than females. The gap between PmaxS produced by males and females increased when males were presented with visual biofeedback from the OroPress.

When the groups were not compared, the male group still produced significantly greater PmaxS in the biofeedback level, than in the non-biofeedback level. The female group produced greater PmaxS with biofeedback but the results were not significant.

The results suggest biofeedback had greater motivational impact on males than on females. This may be explained by male competitiveness. Gill (1986) showed that males who engaged in competitive activities had a strong desire to “win”. This idea is mirrored by the comments of one male participant from this study who stated;

“when you see the line (graphic display of tongue pressure displayed on the OroPress computer), you just want to make it go higher”

Female participants are also competitive but they are “goal” rather than “win” oriented (Gill, 1986). This suggests the goal of females may be to successfully complete ITS tasks rather than push harder to produce higher on-screen graphs.

As expected from previous studies (Adams, Mathisen, Baines, Lazarus & Callister, 2013) the younger group produced greater PmaxS than the older group for both biofeedback levels; yet when paired-samples t-tests were conducted, researchers found the older group produced significantly greater PmaxS with biofeedback, while the younger group did not.

These findings suggest biofeedback from the OroPress may be more beneficial for encouraging older participants to produce greater tongue strength. This has important clinical implications, as reduced tongue strength is more common in older individuals (Youmans et al., 2009). Consequently, individuals over 50 years of age are more likely to require tongue strength training programmes to counter the effects of presbyphagia or to reduce symptoms of dysphagia (Robbins et al., 2005).
The findings from this study suggest that normal older individuals (those without swallowing difficulties) presenting with presbyphagia may benefit from the inclusion of biofeedback in a tongue strength training programme. Further research is indicated to examine the effects of biofeedback on PmaxS for individuals presenting with dysphagia.

**The impact of biofeedback on ITE**

**PmaxE**

Smith (2000) states endurance is directly related to strength such that if an individual produces greater strength, he/she will produce greater endurance. This idea was reflected in results from this study which showed that participants produced greater PmaxE when they were presented with visual biofeedback from the OroPress but these results were not significant.

When the groups were compared researchers found that males produced greater PmaxE than females with and without biofeedback but the results were not significant. The younger group produced significantly greater PmaxE than the older group without and with biofeedback from the OroPress, as predicted. This supports findings by Clark and Solomon (2012) that younger participants generate greater tongue strength than older participants. The effect was larger with biofeedback which reflects overall findings from this study that participants produce greater lingual force when they are presented with biofeedback from the OroPress. This subsequently indicates that visual biofeedback from the OroPress can be used to prompt users, particularly younger adults, to produce greater PmaxE.

**t100**

Participants sustained shorter t100 when they were presented with biofeedback from the OroPress but the results were not significant. When the participants were grouped researchers found the male group sustained longer t100 than the female group with and without biofeedback but the results were not significant.

The younger group sustained longer t100 than the older group without biofeedback but the older group sustained longer t100 than the younger group with biofeedback. These results were not statistically significant.

The results suggest visual biofeedback from the OroPress does not promote maintenance of t100. Interestingly, the older group sustained longer t100 than the younger group when
they were presented with visual biofeedback from the OroPress. Although these results were not significant they indicate biofeedback may have greater motivational influence over the older group than the younger group. This has important clinical implications outlined in the previous section.

**The relationship between PmaxE and t100 with biofeedback from the OroPress**

When PmaxE and t100 were analysed in conjunction with one another it appeared PmaxE increased with biofeedback from the OroPress as t100 decreased. One possible explanation is that there is a dependent relationship between the variables so when participants are presented with biofeedback from the OroPress they produce greater PmaxE (IV) and they cannot sustain t100 (DV) for as long (as when they produce less force) (Kays, Hind, Gnagnon & Robbins, 2010).

Statistical analysis confirmed that there is a strong association between PmaxE and t100 in ITE tasks but that the association is weaker with biofeedback, i.e. when participants are presented with biofeedback they produce greater PmaxE and sustain shorter t100. This supports the proposal of a dependent relationship between PmaxE and t100 and echoes previous findings that biofeedback from the OroPress is useful for motivating participants to produce greater tongue pressures but not for sustaining longer t100.

One exception is the finding that the association between PmaxE and t100 increased to a statistically significant level when older participants were presented with biofeedback from the OroPress. This indicates that when the older group were presented with biofeedback they produced greater PmaxE and sustained longer t100. This finding was not expected considering older participants produce longer endurance when the amount of force required is adjusted to their ability, but not during maximal pressure task (Smith, 2000).

A possible explanation is that older participants may not have been exerting maximal force during ITE tasks instead; they may have been producing submaximal pressures which they were able to sustain for longer (Crow & Ship, 1996).

There has been limited research into the effects of biofeedback on ITE and no previous investigations into the relationship between PmaxE and t100 during ITE tasks. Further research is warranted to replicate these findings and analyse the clinical utility of the OroPress for providing biofeedback to participants about ITE tasks.
Nevertheless, the current findings highlight the fact that the OroPress may be used to present visual biofeedback to older adults in order to encourage them to produce greater PmaxE and longer t100.

**Study limitations**

The findings from this study are limited by the small sample size (n=51) yet, White, Cotton, Hind, Robbins and Perry (2009) suggest a sample size of fifty participants provides adequate estimation of the reliability of a measurement tool. The study was limited by a smaller representation of older participants (n=21) compared to younger participants (n=30) although normal distribution of data captured from the OroPress indicates that findings significantly represent a larger healthy adult population. During data collection biofeedback always proceeded non-biofeedback which is another possible limitation of the study. Participant performance for PmaxS and PmaxE may have been subject to a learning effect (each time a participant produced an isometric task he/she became more familiar with the activity leading to increased pressure production). The study was too small to support counterbalancing of biofeedback yet the inclusion of biofeedback after non biofeedback trials was an important consideration which ensured participants were not influenced by biofeedback during non-biofeedback trials. Other researchers have identified the benefits of providing participants with biofeedback (Robbins et al., 2005) which suggests this study does not represent an isolated effect and that findings did not solely result from a learning effect.

**Clinical significance**

There are four major clinical implications from this study.

First, inter-rater reliability of OroPress graph analyses highlights that when two individuals examine the same OroPress graphs, they produce the same results, indicating graphs are clear and easy to read. These are important assets for the OroPress as a clinical tool.

Second, SLTs were able to measure baseline isometric pressures and determine differences in tongue pressures for both tasks with and without biofeedback, which again are important clinical assets for the OroPress.
Third, participants in this study were motivated to produce greater PmaxS when presented with biofeedback from the OroPress. This suggests larger populations may be educated to produce the same results.

Fourth, older adults may benefit from biofeedback provided in clinical settings to a greater extent than younger adults.

**Recommendations**

The findings of this study suggest visual biofeedback from the OroPress can be used to encourage participants to produce greater PmaxS. Although findings were significant, a small participant sample was used which may indicate poor transfer of results to a larger population; it is therefore recommended that more participants are recruited to represent a larger population.

It is also recommended that greater numbers of older adults are recruited in the future to verify whether findings from this study, that biofeedback was particularly useful for the >50 years group, are consistently reported.

It is advised that researchers investigate the usefulness of OroPress for providing biofeedback to dysphagic populations. Although the results from this study suggest biofeedback is useful for older adults, dysphagic populations may have additional complications which override the benefits of the OroPress as a biofeedback tool, e.g., dysphagic stroke patients may have language or cognitive impairments which reduce their ability to understand instructions. Alternatively, visual displays of biofeedback from the OroPress may counter the lack of verbal understanding, meaning biofeedback is useful for this population. Further analysis is required before either of these conclusions can be drawn.

Finally, future studies should target tongue strength training in normal and dysphagic populations in order to determine whether the OroPress can be used to train participants to produce greater lingual isometric pressures and greater tongue strength. Such studies would allow researchers to make conclusions about the clinical application of the OroPress.

**Summary**

The overall results indicate that the OroPress is useful for providing biofeedback about lingual pressures to a sample of healthy adults aged between 18 and 74 years.
Males and older participants (>50 years) produced significantly greater PmaxS when presented with visual biofeedback from the OroPress.
Younger participants (<50 years) produced significantly greater PmaxE than older participants.

There is a strong association between PmaxE and t100 in ITE tasks and the association decreases when a participant is presented with biofeedback from the OroPress. This reiterates findings that participants produce greater tongue pressures but not greater durations when presented with biofeedback from the OroPress.
The association between PmaxE and t100 in older participants was found to increase when those participants were presented with biofeedback from the OroPress. This finding suggests biofeedback provided by the OroPress may have a stronger motivational impact on older adults to produce greater force and longer durations in ITE tasks compared to younger adults.

**Conclusions**
The results from this study indicate that biofeedback provided by the OroPress encourages users to produce greater lingual pressures. Results from ITS and combined ITE (PmaxE and t100) for the older participant group (>50 years) were of particular significance as this age group are more likely to require tongue strength training. The results imply older participants may be more motivated to adhere to a lingual exercise programmes including visual biofeedback provided by the OroPress.
References


Appendix 1

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

What are the purposes of this study?

1. To measure tongue pressures (the pressure produced when the tongue contacts the roof of the mouth) in a sample of healthy adults using a recently developed tool: the OroPress.
2. To examine the usefulness of the OroPress when it is used as a biofeedback tool.

What does this study involve?

There are three things to know;

1 If you are taking part in this study you will formally sign your consent and you will be given an appointment card with a date and time convenient for you to attend a one hour session at the Speech and Language Therapy Clinic, University of Limerick.

2 During this one hour session your age and gender will be noted and you will complete a short questionnaire on your medical history.

Your lips, tongue and jaw will be examined. The researcher will look inside your mouth, test your gag reflex and discuss your swallowing pattern. This will take approx. 10 minutes.

3 A small sensor will be ‘glued’ to the roof of your mouth, behind your upper teeth and you will be given time to get used to it in position.

You will then be asked to carry out a practice test where you must push the tip of your tongue against the sensor as hard as you can for three seconds. When we are sure the device is recording accurately we will begin the trial and you will be asked to push the tip of your tongue against the sensor as hard as you can for three seconds (as above). You will do this six times. On three of those times you will view your tongue pressure on a small computer screen (which will be using ‘biofeedback’).

During the second part of the session you will be asked to push the tip of your tongue against the sensor as hard as you can for as long as you can. As above, this will be done six times and on three of these occasions you will have biofeedback.

At this point all required data has been collected and the sensor will be removed.
Why is this study important?

This study will help the researchers to understand more about normal tongue pressures and will allow them to determine the ‘typical’ range of tongue pressures produced by healthy adults. It will also provide information about the relationship between tongue pressures and age, gender and existing swallowing patterns. The study will provide information about the use of OroPress as a biofeedback tool. Such information is important for research into swallowing problems, as reduced tongue pressure may be linked to swallowing difficulties.

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 which will form the basis of the final year projects of two speech and language therapy students at the University of Limerick. The results of this study may also be presented at a national conference and printed in a scientific journal, but your identity at all times will remain totally confidential.

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 and the data will be stored on a password-protected computer, with hard copy locked in the office of the Principal-Investigator and student supervisor, Prof Alison Perry.

Are there any risks associated with participating in this study?

No

Do I have to participate in this study?

Your participation in the study is completely voluntary.

Will I receive any compensation?

No compensation will be offered to any study participants.
**What if I want to leave the study?**

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

**Has Ethical Approval been granted for this study?**

The study has full Ethical approval from the UL/EHS Research Ethics Committee.

**What is the complaints procedure?**

Complaints or queries about the study can be directed to the Principal-Investigator (Prof Alison Perry on 061 234987; 086 0210360 or e-mail Alison.Perry@ul.ie) or to the UL/EHS Ethics Committee Chairperson, Aidan Hickey (061 202700).

**Whom do I contact if I want further information about the study?**

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

Speech and Language Therapy (SLT) student researchers: Roisin Cunningham and Triona O’Brien

**Address:** Dept. of Clinical Therapies, Faculty of Education and Health Sciences, University of Limerick.
The OroPress in normal healthy adults: a pilot study of clinical utility and the properties of the tool.

Consent Form

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

If you agree with all the above statements please tick the below box to confirm your participation in the study.

I consent to participate □

Signed: _________________________________ Date: __________________

(Print Name): __________________________

Researcher Signature: __________________________
### Appendix 2

#### 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>
<tbody>
<tr>
<td><strong>Face</strong></td>
<td>Symmetry</td>
<td>Observe participant’s face and note any abnormalities of symmetry/tone</td>
<td>1) 0 abnormalities noted</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2) Mild abnormality noted</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3) Abnormality obvious but can perform task reasonably well</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5) Unable to undertake task</td>
<td></td>
</tr>
<tr>
<td><strong>Lips</strong></td>
<td>Lip seal (norm=15 secs)</td>
<td>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.</td>
<td>Time in secs: ________</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1) 0 abnormalities noted</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured</td>
<td></td>
</tr>
</tbody>
</table>
| Range and speed of movement (norm = 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) | 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). | 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 | 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 |
<table>
<thead>
<tr>
<th></th>
<th>Depression</th>
<th>Lateral movements (norm=4secs)</th>
<th>Soft Palate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Move your tongue down to your chin like this (demo).</td>
<td>Move your tongue to the outside corner of your mouth, first to the right and then left, like this (demo).</td>
<td>Open your mouth as wide as you can while I hold your tongue down with a wooden spatula to look at the back of your throat, using a</td>
</tr>
</tbody>
</table>
### Elevation of Uvula on ‘ah’

Now say ‘ah’ and hold it for a few seconds.

- **trend**: of task but poor in quality, unable to sustain, inaccurate/extremely laboured
- **score**: 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>
<thead>
<tr>
<th><strong>Voluntary Cough</strong></th>
<th><strong>Strength</strong></th>
<th><strong>Cough/clear you throat for me please</strong></th>
<th><strong>score</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>0 abnormalities noted</td>
<td>Cough/clear you throat for me please</td>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Gag reflex</strong></th>
<th><strong>Sensitivity</strong></th>
<th><strong>Open your mouth wide please, I’m going to test your gag reflex.</strong></th>
<th><strong>score</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>0 abnormalities noted</td>
<td>Open your mouth wide please, I’m going to test your gag reflex.</td>
<td>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</td>
</tr>
</tbody>
</table>
Unable to undertake task

5) Unable to undertake task

### Residue Rating

Please circle your rating from observing the oral cavity post-swallow:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No residue in oral cavity post-swallow</td>
</tr>
<tr>
<td>1</td>
<td>Minimal residue or coating post-swallow</td>
</tr>
<tr>
<td>2</td>
<td>Marked pooling in oral cavity post-swallow</td>
</tr>
</tbody>
</table>