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O L L S C O I L L U I M N I G H

**The Effect of Age, of Gender and of Swallow
pattern on Isometric Tongue Pressures in
Healthy Adults.**

By

Róisín Cunningham

12011797

Supervisor: Professor Alison Perry

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The Effect of Age, of Gender and of Swallow Pattern on Isometric Tongue Pressures in a sample of Healthy Adults

Background

Lingual pressure generation is integral to achieving an efficient oropharyngeal swallow (Hirota *et al* 2010; Konaka *et al* 2010; Van den Engel-Hoek *et al* 2013) and is thus typically evaluated as part of a comprehensive oro-motor assessment. Subjective assessment methods are commonly used by speech and language therapists to determine if an individual is presenting with reduced isometric ('against') tongue pressures (ITPs), recognised risk factors for dysphagia (Nicosia *et al* 2000; Robbins *et al* 1995). Despite the widespread use of such methods, they do not provide an optimal means of assessing ITPs (Adams *et al* 2013).

Oral manometry tools provide a solution. One such tool – OroPress - was designed to provide clinicians with an objective means of assessing ITPs. However, before this tool can be used to differentially diagnose reduced versus normal ITPs a large norm data set of ITPs must be established.

Objectives

To examine the effect of age, of gender and of swallow pattern on isometric tongue pressures in two discrete tasks – isometric tongue strength (ITS) and isometric tongue endurance (ITE) - using OroPress. **Rationale:** to determine whether these variables (age, gender and swallow pattern) merit consideration in the development of ITP norms.

Methods

Fifty three healthy adults (26 males, 27 females), were purposefully recruited from two age groups; 18-49 years (N=31; m=16, f=14) and ≥ 50 years (N=22; m=10, f=12) and then further classified in terms of swallow pattern (tippers, N=40; dippers, N=12). The sensor of OroPress was adhered to each participants' hard palate to capture pressure values produced during strength and endurance tasks. This data was later subjected to statistical analyses to examine the effect of age, of gender and of swallow pattern on ITPs.

Results

Younger adults produced significantly higher ITS ($p \leq 0.05$) than older adults, irrespective of gender or swallow pattern and males produced significantly higher ITS ($p \leq 0.05$) than females irrespective of age or swallow pattern. No other statistically significant differences were observed.

Conclusions

Although the sample size in this study was not large enough to establish a normal range of ITPs using OroPress, the findings from this study are of clinical value. Results of this study indicate that discrete ITS norm sets are warranted for males and females across two age groups (18-49 years; ≥ 50 years). Conversely, such factors do not merit consideration in the development of ITE norms.

Despite limitations, this study provides a critical first step in the development of a large norm ITP data set - a development that is essential to ensure the successful application of OroPress to dysphagia assessment in the future.

Introduction

The Structure and Function of the Human Tongue

The significance of this study relies on understanding the anatomical and physiological characteristics of the human tongue. The tongue, a muscular organ composed of skeletal muscle tissue, is involved in respiration, speech production and swallowing. Lingual movements required for these tasks are accomplished through the selective recruitment of motor units (MUs). These units are typically categorised on the basis of the contractile and endurance characteristics of their constituent fibres; Type I MUs contain slow twitch muscle fibres that are slow to contract and resistant to fatigue; Type II MUs contain fast-twitch muscle fibres that are fast to contract and fatigue rapidly (Burke *et al* 1971). These motor units collectively enable the range of lingual movements required to perform the physiological functions of the tongue.

Assessing Isometric Tongue Pressures

Researchers have already demonstrated the crucial role of lingual pressure generation in achieving an efficient oropharyngeal swallow (Hirota *et al* 2010; Konaka *et al* 2010; Van den Engel-Hoek *et al* 2013) and thus such pressure, generated by the tongue contacting the hard palate (Shaker *et al* 1988) is typically evaluated as part of a comprehensive oro-motor assessment.

Traditionally, speech and language therapists (SLTs) use subjective methods to examine lingual pressure (Youmans and Stierwalt 2006). Such methods of assessment involve an SLT making a subjective judgement regarding the lingual force a patient generates against resistance, typically a tongue depressor or the clinician's fingers resting against a patient's cheek (Adams *et al* 2013). However researchers have raised concerns about the reliability and validity of these measurements, arguing that instrumental tools provide clinicians with a more sensitive and reliable means of measuring isometric ('against resistance') tongue pressures (ITPs) (Reddy *et al* 1990; Adams *et al* 2013).

A variety of tools including the *Iowa Oral Pressure Instrument* (IOPI), the oro-lingual pressure array of the *Kay Swallowing Workstation* (KSW) and the *Utanohara disposable bulb device*, have been designed to objectively measure ITPs. All such tools incorporate intra-oral pressure probes as a means of capturing pressure measure data but they differ in terms of the size, number, composition and placement of these probes (See Appendix A).

Although these tools have been implemented in research and clinical practice, there is a paucity of evidence to confirm their reliability and validity (Adams *et al* 2013; Youmans *et al* 2009; Ball *et al* 2006; White *et al* 2008) - two psychometric properties of fundamental importance in research tools (Portney and Watkins 2007). Additional shortcomings of these tools include their intrusiveness, the high cost of the single use probes, costs of hardware, and the poor consistency of intra-oral probe positions (Hewitt *et al* 2008; Kennedy *et al* 2010; Hori *et al* 2005; Utanohara *et al* 2008; Furlan *et al* 2011).

Commercially available tools therefore do not provide an optimal solution for assessing ITPs (Ball *et al* 2006; Furlan *et al* 2011). OroPress, a new wireless oral manometry tool, was designed to overcome the identified shortcomings of these existing tools with the intent of providing clinicians with a psychometrically sound tool for measuring ITPs - isometric tongue strength and isometric tongue endurance.

The Relationship between Isometric Tongue Pressures and Swallowing Function

Instrumental measures of isometric tongue strength (ITS) are typically captured by asking individuals to press their tongue against their hard palate with maximal intensity for a predetermined length of time. Intra-oral probes are applied to record ITS and captured values are expressed in terms of either millimetres of mercury (mmHg) or kiloPascals (KPa) – comparable pressure units. Given that swallowing requires sub-maximal lingual pressure (Steele *et al* 2010; Robbins *et al* 1995; Hayashi *et al* 2002), the relevance of this measure to the examination of swallowing function is not exceedingly clear.

The clinical significance of ITS becomes more apparent however when considered in the context of lingual pressure reserve. This index reflects the difference in lingual pressures produced in an ITS task and a regular effortful saliva swallow (Steele 2013) - the greater the difference between these values, the higher the level of reserve. Limited lingual pressure reserve, secondary to reduced ITS, has been reported as a risk factor for dysphagia (Nicosia *et al* 2000; Robbins *et al* 1995). The clinical value of ITS is clear when considered within the context of such findings – it serves as a surrogate indicator of swallowing function.

By contrast, an understanding of the relationship between isometric tongue endurance (ITE) and swallowing function has received little attention. Measures of ITE are typically obtained by asking individuals to press their tongue against their hard palate with sub-maximal intensity (50-70% of maximal intensity) for as long as possible. Intra-oral probes are used to record ITE and captured values are expressed in units of time, typically in seconds. Given that reduced muscle endurance can indicate fatigue (Kays *et al* 2010) which is a risk

factor associated with aspiration (White *et al* 2008), it seems plausible that this measure may serve as an indicator of swallowing function. However there is no evidence to support such a relationship, so further research into the usefulness of ITE as a measure of swallowing function is warranted.

The Effect of Age on Isometric Tongue Pressures

The effect of age on ITS has been widely examined in healthy adults using the *IOPI*, the *KSW* and the *Utanohara disposable bulb device*. Despite procedural differences across studies (e.g. ITS task instructions and measurement tools) researchers have consistently reported that age has a significant effect on ITS in this population (Nicosia *et al* 2000; Todd *et al* 2013; Robbins *et al* 1995; Youmans and Stierwalt 2006, Youmans *et al* 2009; Hayashi *et al* 2002; Utanohara *et al* 2008; Crow and Ship 1996; Stierwalt and Youmans 2007).

In determining the existence and significance of this effect, researchers have compared ITS across a range of age groups. Age group classifications employed in these studies are broadly as follows: young adults (18-39 years), middle aged adults (40-59 years) and older adults (60+ years). Results from these studies consistently indicated that young adults produced significantly higher ITS than older adults. Differences were also reported between middle aged and older adults, with the former group producing significantly higher ITS than the latter (Nicosia *et al* 2000; Todd *et al* 2013; Youmans *et al* 2009; Utanohara *et al* 2008; Crow and Ship 1996), however this pattern was not observed in all studies that examined differences between these groups (Youmans and Stierwalt 2006; Stierwalt and Youmans 2007). A marginal difference in ITS between young and middle aged adults was also noted, however, this difference was significant in only one report (Todd *et al* 2013).

These results indicate a gradual decline in ITS across the lifespan with the most significant decline occurring around the age of 60 years. This pattern of decline is likely related to sarcopenia, an overall age-related decline in skeletal muscle mass and strength (Carmeli and Reznick 1994; Roos *et al* 1997) which results from a decrease in the size and number of muscle fibres (Campbell *et al* 1973; Macaluso and DeVito 2004) and an increase in non-contractile tissue (Overend *et al* 1992; Rice *et al* 1989).

The reported effect of age on ITS appears to be a robust finding. Thus, results from a recent pilot study using OroPress (McCormack 2013) which failed to support existing findings are likely explained by differences in age group categorisation – unlike previous

studies, McCormack (2013) classified younger adults as those aged between 18-38 years and older adults as those aged between 39-68 years. Further research examining the effect of age, classified as per previous studies, on ITS in healthy adults using the OroPress is thus warranted.

Conversely, the effect of age on ITE in healthy adults has received little attention - to date in only 3 studies have researchers employed instrumental measures to examine this association (Crow and Ship, 1996; McCormack 2013; Stierwalt and Youmans 2007) and these studies differ in terms of age group classifications and ITE tasks. Two of these studies (Crow and Ship 1996; Stierwalt and Youmans 2007) used the following classification: young adults (18-39 years), middle aged adults (40-59 years) and older adults (60-96 years), while the remaining study (McCormack 2013) classified younger adults as those aged between 18 and 38 years and older adults as those aged between 39 and 68 years. Despite differences in age group classification and ITE tasks (the percent of maximal pressure participants were asked to sustain ranged between 50-100%) the results of these studies have consistently indicated that age does not have a significant effect on ITE.

Given that the same lingual muscles are recruited in ITS and ITE tasks, it seems plausible that sarcopenia would influence both ITS and ITE; however results of published studies indicate that this is not the case. Macaluso and De Vito (2004) suggest that the differential effects of sarcopenia on ITS and on ITE may be explained by the fact that sarcopenia represents a selective atrophy of fast-twitch muscle fibres, thereby resulting in skeletal muscles that are still resistant to isometric fatigue, but lack strength. Although the absence of an age effect therefore seems logical, additional research is merited as there are only a small number of studies in this area.

The Effect of Gender on Isometric Tongue Pressures

The effect of gender on ITS has been widely examined in healthy adults using the *IOPI*, the *KSW* and the *Utanochara disposable bulb device*, with conflicting evidence reflected in the published literature. A number of researchers have reported that males produce significantly higher ITS than females (Youmans and Stierwalt 2006, Youmans *et al* 2009; Utanochara *et al* 2008; Crow and Ship 1996; Stierwalt and Youmans 2007; McCormack 2013; Gingrich *et al* 2012), a difference that has been attributed to the fact that males have an overall larger muscle mass than females (Todd *et al* 2013). Conversely, some researchers (Hayashi *et al* 2002; Nicosia *et al* 2000) have reported that gender has no effect on ITS.

Gingrich and colleagues (2012) suggested that mediating variables, such as physical characteristics (height and weight), oral structure and body mass index, may explain findings of equivocal gender differences in the literature. Further research with large sample sizes is merited, to determine with more certainty the effect of gender on ITS.

In contrast to the wide range of studies conducted to examine the effect of gender on ITS, only 3 published studies have been carried out to examine gender differences in ITE (Crow and Ship, 1996; McCormack, 2013; Stierwalt and Youmans 2007). Despite variations in ITE tasks (the percent of maximal lingual pressure participants were required to produce ranged between 50 and 100% across studies), the results of all three studies indicated that gender had no significant effect on ITE.

These results are not surprising given that lingual pressure levels for ITE tasks were determined relative to each participant's abilities (e.g. 50% of the maximal lingual pressure they could produce), so participants were sustaining ITE at a comfortable level. Although the absence of a gender difference in ITE seems logical for this reason, additional research is warranted given the small number of studies in this area.

The Effect of Swallow Pattern on Isometric Tongue Pressures

Dodds and colleagues (1989) devised the tipper/dipper classification to describe normal variation in swallow patterns. In the tipper-type swallow, 'the tongue simply elevates and rolls posteriorly to transport the bolus from the mouth into the oropharynx' (Dodds *et al* 1989, p. 1198) whereas in the dipper-type swallow, 'the tip of the tongue must first dip beneath the bolus to move it from a sublingual to a supralingual position, the oral phase then proceeds as a tipper swallow' (Dodds *et al* 1989).

Although the effect of swallow pattern on ITPs has never been examined, a predominance of dipper type swallow patterns have been reported in adults aged 60 years and over (Dodds *et al* 1989). In light of documented effects of sarcopenia in this age group, it is possible that a dipper type swallow pattern serves as a clinical indicator of sarcopenia and we would therefore expect that adults presenting with a dipper type swallow pattern might produce lower ITPs than those presenting with tipper type swallow patterns. However this association is entirely speculative, so research is indicated to determine the presence and probable effect of such a swallow pattern.

Aims and Hypotheses

In order to use the newly developed tool – OroPress - to facilitate differential diagnosis of reduced versus normal ITPs, a normal range of ITPs generated by healthy individuals must be established. To ensure said norms are representative, the effect of recognised and potentially cofounding variables on ITPs must first be investigated.

The primary purpose of this investigation, therefore, was to determine the range and variability of ITS and ITE as a function of age, gender and swallow pattern in healthy adults using the OroPress tool thereby building on findings reported from the OroPress pilot study (McCormack 2013).

Based on previous investigations, the hypotheses of this study were as follows:

1. Older adults will demonstrate significantly lower ITS when compared to younger adults
2. Females will demonstrate significantly lower ITS than males
3. There will be no significant differences in ITE generated by younger and older adults
4. There will be no significant differences in ITE generated by males and females

In addition, the following research question was also examined: Is there a relationship between swallow pattern and isometric tongue pressures (ITS and ITE)?

Method

This study forms part of a larger body of research, the overarching aim of which is to examine the psychometric properties - specifically stability (aka reliability) and validity - of a newly developed wireless oral manometry tool OroPress when used to measure oro-lingual pressures – isometric tongue pressures and linguo-palatal swallowing pressure.

Participants

A total of fifty three healthy adults participated in this study. An equal number of males and females (N=53; m= 26, f= 27) were purposefully recruited from two age groups - 18-49 years (N=31; m=16, f= 14) and ≥ 50 years (N=22; m=10, f=12). Participants were recruited through verbal requests to friends, family, members of the public and leaders of local volunteer groups.

Interested participants were screened by use of a short medical questionnaire (Appendix B) and an oro-motor examination (Appendix C). The following exclusion criteria were applied: a history of swallowing and/or speech problems; a structural or functional oral abnormality; an overly sensitive gag reflex (i.e. a gag reflex triggered in the middle portion of the anterior tongue); a tongue piercing in situ; and/or an inability to give informed consent and/or to follow oral instructions in English.

Research Design

This was a pilot cohort study with three Independent Variables (see Table 1) and two Dependent Variables (see Table 2).

Table 1

Independent Variables and their levels

Independent Variables (IVs)	Levels
Age	Younger (18-49 years) vs. Older (>49 years)
Gender	Male vs. Female
Swallow Pattern	Tipper vs. Dipper

Table 2

Dependent Variables and their scale of measurement

Dependent Variables (DVs)	Scale of Measurement
PMaxS Maximum isometric tongue pressure recorded during isometric tongue strength (ITS) trials	Millimeters of mercury (mmHg)
t100 Maximum time that tongue pressure is maintained above 100mmHg in ITE trials.	Seconds

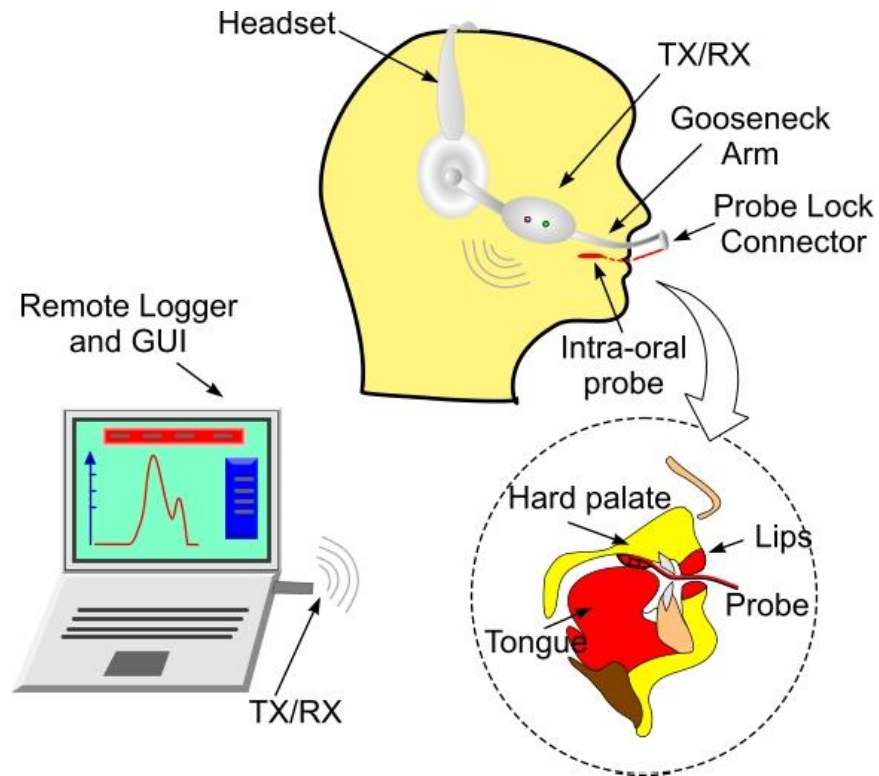
Materials**Screening process**

Consent forms were used to obtain written permission from participants. A brief questionnaire, which incorporated demographic questions and questions pertaining to medical history, was used to screen volunteers' eligibility to participate in this study. Disposable tongue depressors, a pen torch, latex gloves and oro-motor assessment forms were used to conduct the oro-motor examination.

Data capture

OroPress, an oral manometry tool comprising of a pressure sensor embedded in a silicone body connected, via a battery operated wireless system, to a laptop computer was used to capture all pressure data (See Figure 1).

The pressure sensor was adhered to the hard palate of each participant using Poligrip ComfiSeal Strips and a camera (Nikon D3100) was used to photograph the position of the sensor in situ. The TristelTrio50 wipes system was used to sterilise the sensor between trials.



Source: Casey 2014

Figure 1. *Components of OroPress*

Data management and analysis

The IBM® Statistical Package for Social Sciences (SPSS®) Version 20 software package (2011) and a Microsoft excel spreadsheet were used for data entry and analysis.

Procedure

Full ethical approval for this study was granted by the University of Limerick's Faculty of Education and Health Sciences research ethical committee.

Data capture

During recruitment the researchers provided each participant with a verbal description of the study and a detailed information sheet incorporating consent from (Appendix D). If immediate written consent was obtained, trials were scheduled, an appointment card was given and the participant's contact details were noted. If consent was not immediately obtained, interested participants were encouraged to contact the student researchers via email or telephone (contact information was detailed on the information sheet) to schedule an

appointment. A reminder text was sent to each participant 24 hours prior to their scheduled appointment.

Trials took place in a large room of the Speech and Language Therapy clinic at the University of Limerick and were conducted by two student researchers. In order to determine eligibility, an oro-motor examination was conducted by the student researcher and the participant was asked to complete a brief medical questionnaire, incorporating demographic questions and a question to determine swallow pattern. Once a participant met the inclusion criteria, he/she was assigned an I.D. number and invited to sit in a chair, positioned a measured distance from a wall of the room while the student researcher placed a coloured circle on that wall, at the participant's eye level. Participants were instructed to gaze at this disc during data collection to reduce unnecessary head movements.

The sensor was sterilised and then calibrated using 0 to 100mmHg datum points. The sensor was then connected via the battery-operated wireless system, to the laptop computer for data display and recording. 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, the file name was set on the laptop and a photo of the sensor in situ was taken to record its' position (See Figure 2).

The participant's file on the laptop incorporated the participant's I.D. number, the sensor's I.D. code and the date of the trials.



Figure 2. *OroPress sensor in situ*

Each participant undertook two ITP tasks; strength and endurance, the order of which was counterbalanced to control for any learning and/or fatigue effect (s) on pressure generation. Each task was repeated four times, the first trial served as a practice, so it was not recorded. The instructions given by the student researcher for the strength and endurance tasks are detailed below:

Isometric tongue strength (ITS) task

Each participant was instructed as follows; “*When I say ‘go’ push the tip of your tongue as hard as you can against the sensor for three seconds I will tell you when to stop*”. Each trial was timed and the participant was instructed to “stop” at three seconds. These instructions were repeated before each trial.

Isometric tongue endurance (ITE) task

Each participant was instructed as follows; “*When I say ‘go’ push the tip of your tongue as hard as you can against the sensor for as long as you can - I will tell you when to stop*”. The student researcher said ‘stop’ once a significant drop in oro-lingual pressure (i.e. below 100 mmHg) was noted in the data displayed on the laptop screen. Instructions were repeated before each trial and a fifteen second rest break was given between trials.

The drop below 100 mmHg protocol was applied in the ITE task to ensure that recorded pressure readings were intentional and not attributable to extraneous variables – e.g. the participant experimenting with the sensor using their tongue.

Upon completion of trials the researcher removed the sensor and placed it in the wash area for sterilisation.

Data management

Forms that contained identifying information were stored in a locked filing cabinet in the principal investigator’s office. Raw data captured using OroPress, together with de-identified participant information (identification number, age and gender), were transferred to a Microsoft Excel spreadsheet, stored on a password-secured computer and backed up on Dropbox.

Data extraction

Data collected from each participant were represented as a graph in Microsoft Excel (see Figure 3 for an example). Each graph was analysed by one researcher - PMaxS and t100 values for each recorded trial were determined using a manual extraction method (see Figure 5).

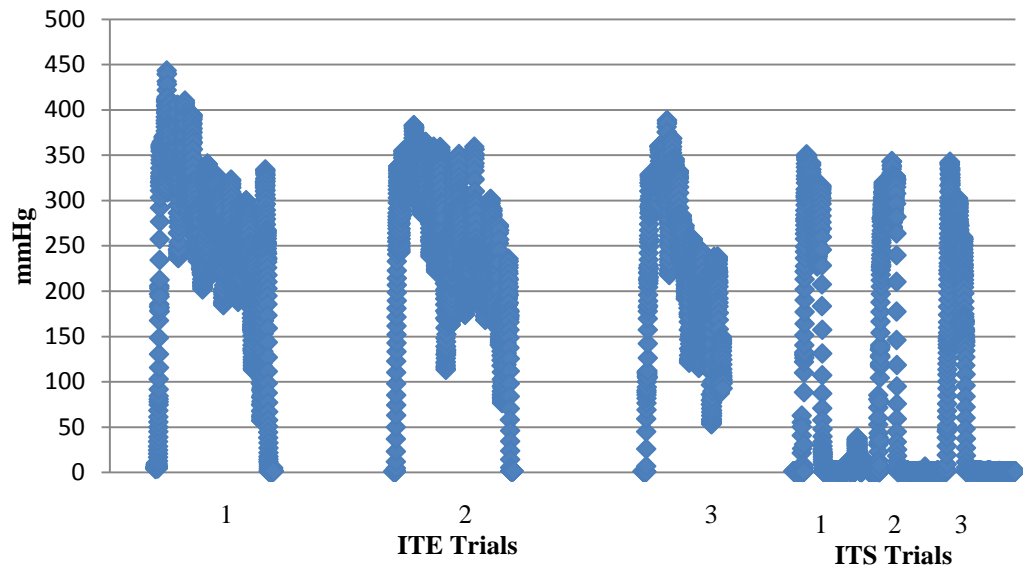


Figure 3: Captured data – Participant 1

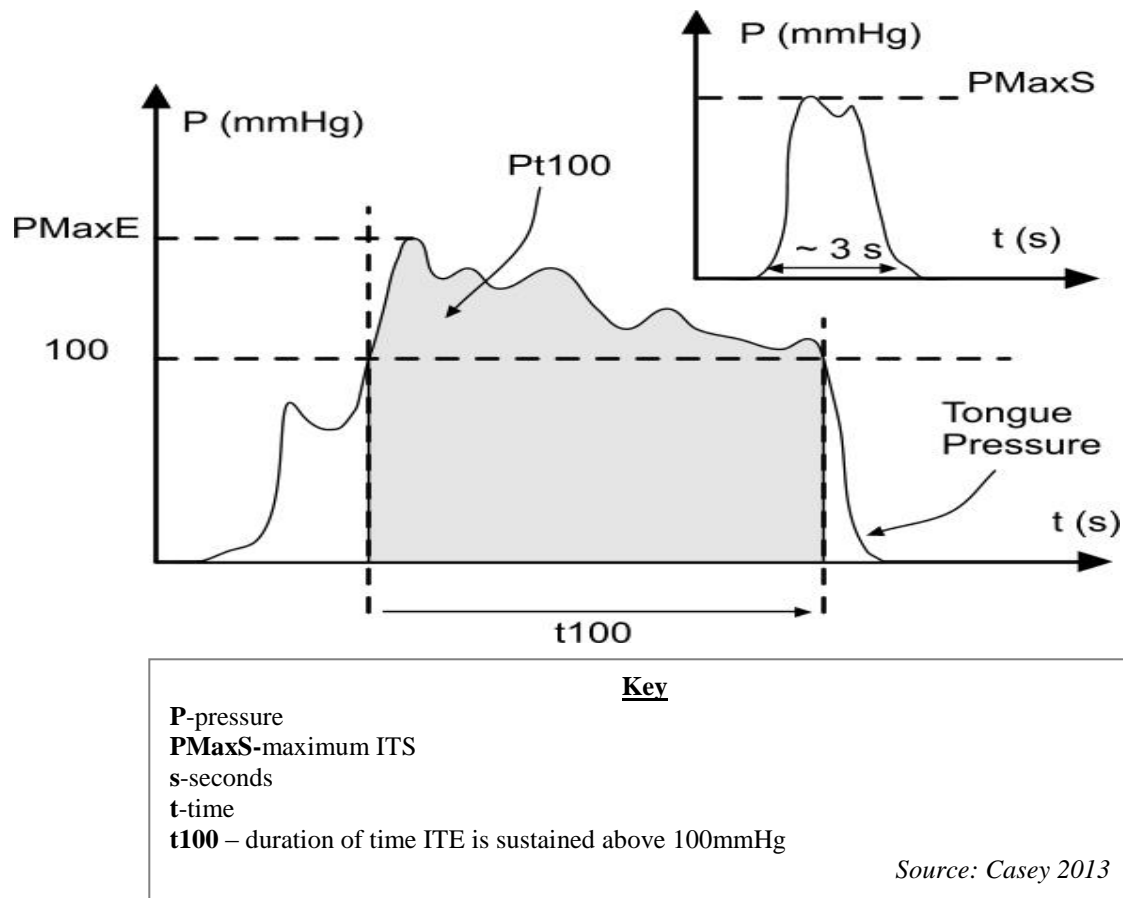


Figure 4. A graphical representation of the parameters used to measure PMaxS and t100.

Data analysis

Statistical analyses were conducted using IBM® SPSS® Version 20 software package (SPSS 2011).

Data screening

This process was incorporated to determine if the captured data conformed to assumptions of normality. Screening involved examining mean, median and standard deviation values, analysing box plots and histograms, calculating skewedness and kurtosis and examining results of the Shapiro-Wilk test (Tabacknick and Fidell 2007). Analysis revealed that ITS data conformed to the assumptions of normality, so parametric testing was applied in subsequent analyses of these data. Conversely, the ITE data (t100) was not normally distributed so non-parametric testing was applied to these data.

Descriptive statistics

Descriptive statistics were used to characterise the sample (Portney and Watkins 2009). Values of interest included measures of central tendency, mean and median, and measures of variability, range and standard deviation (SD) (Portney and Watkins 2009).

Alpha level

For hypothesis testing in this study the alpha level (α) was set at 0.05. This alpha level was applied as it is generally considered unacceptable to designate values of alpha higher than 0.05 (Portney and Watkins 2009) and there was no compelling justification for applying a more rigorous significance level in this study.

Reliability statistics

Inter-rater reliability

Percent agreement and Intraclass Correlation Coefficients, both of which are appropriate indices for measuring reliability between two or more ratings recorded by two raters (Portney and Watkins 2009; Shrout and Fleiss 1979), were selected to determine how reliably the researchers implemented the data extraction protocol, outlined in Figure 4.

To determine percent agreement, 10% of the data analysed by each respective researcher was subjected to cross evaluation and reported values were manually compared. A satisfactory level for perfect agreement (100%) was set at +/- 1 unit (mmHg or seconds) for all values.

Despite the utility of this index, percent agreement calculations fail to discount the proportion of agreement that is potentially attributable to chance alone (Watkins and Pacheco 2000). To overcome this shortcoming, this analysis was supported by an Intraclass Correlation Coefficient (ICC), a chance corrected measure (Streiner and Norman 1989). A two-way mixed model (ICC Model 3, 1) was conducted. The confidence interval was set at 95% and ICC (3.1) values of above 0.75 were considered to reflect 'good' reliability (Portney and Watkins 2009).

Test-retest reliability

Intraclass Correlation Coefficient (ICC) analyses - (Model 3-1) - were performed to examine the degree of correlation and agreement between PMaxS and t100 values

respectively across trials. This analysis was selected as it permits the assessment of reliability between two or more ratings recorded by the same rater (Portney and Watkins 2009). The confidence interval (CI) was set at 95% and ICC (3.1) values of above 0.75 were indicative of ‘good’ reliability (Portney and Watkins 2009).

Statistical analyses to compare groups

The effects of age, of gender and of swallow pattern on PMaxS values were examined using Independent Samples T-tests. For these analyses P values ≤ 0.05 were considered significant (Pallant 2007). This parametric test was selected as it is suitable for examining differences between two independent groups on a continuous variable when data are normally distributed (Pallant 2007) as was the case here.

The effects of age, of gender and of swallow pattern on t100 values were examined using Mann-Whitney U tests. For these analyses, P values ≤ 0.05 were considered significant (Pallant 2007). This test, the non-parametric equivalent of the independent samples t-test (Pallant 2007), was selected on the basis of data screening which indicated that the data were not normally distributed.

Post hoc analyses

A number of two-way between-groups analyses of variance (ANOVAs) were conducted to determine if various combinations of the independent variables (age, gender and swallow pattern) had differential effects on PMaxS and t100 values. In these analyses, p values of ≤ 0.05 were considered significant (Pallant 2007).

Results

Excluded Data

Data from one young female participant were excluded as they incorporated abnormal pressure waveforms. The probable cause of these irregularities was an unstable sensor as the participant reported that the sensor “felt slippery”. Results are thus reported on data captured from the remaining 52 participants (see Table 3 and 4).

Table 3

Demographic Information

		Males (m)	Females (f)	Total
Age	Younger Adults (18-49 years)	16	14	30
	Older Adults (≥ 50 years)	10	12	22
Total		26	26	52

Table 4

Self-reported Swallow Patterns

		Younger Adults	Older Adults	Total
Swallow Pattern	Tipper	26 (m=13, f=13)	14 (m=6, f=8)	40
	Dipper	4 (m=3, f=1)	8 (m=4, f=4)	12

Descriptive Statistics

Descriptive statistics for examining PMaxS and t100 values captured across trials are presented in Table 5.

Table 5

Measures of centrality tendency and variability of group data

Trial Number	ITS (PMaxS)			ITE (t100)		
	1	2	3	1	2	3
Mean	527.9	525.4	519.5	22.0	21.5	19.4
SD	162.9	153.9	155.8	14.3	13.1	11.9
Median	521	515	523	20	21.1	18.2
(min-max)	125-943	128-933	116-815	1.5-61	0.5-51	1.3-50

The wide range of reported PMaxS and t100 values reflects the considerable variation in isometric tongue pressures across participants.

Reliability Statistics

Inter-rater reliability

Percent agreement calculations and ICCs were conducted to examine inter-rater reliability. These analyses were conducted on 5 data sets, selected at random. Reported values (PMaxS and t100) and subsequent percent agreement calculations were displayed in tabular form (see Table 6 and Appendix E).

Table 6

Reported Values and Percent Agreement - Participant 8

Value	Trial Number	Rater 1	Rater 2	Percent Agreement
PMaxS	1	591	591	100%
	2	432	432	100%
	3	437	437	100%
t100	1	2	2	100%
	2	5	5	100%
	3	15	14	100%

Reported figures reflect perfect agreement across all five datasets (Portney and Watkins 2009). These findings were supported by ICC (3, 1) analyses (see Table 7) which revealed excellent inter-rater reliability ($p \leq 0.05$) (Portney and Watkins 2009; Cicchetti 1994).

Table 7

Results of ICC (3,1) analyses conducted to determine inter-rater reliability

Value	Trial Number	ICC Value	95% Confidence Intervals		P-value
			Lower Bound	Upper bound	
PMaxS	1	1.0	1.0	1.0	0.000
	2	1.0	1.0	1.0	0.000
	3	1.0	1.0	1.0	0.000
t100	1	0.999	0.994	1.0	0.000
	2	1.0	0.997	1.0	0.000
	3	0.999	0.991	1.0	0.000

Test-retest reliability

Intra-class correlation coefficients (ICC 3, 1) were conducted to examine the level of agreement between oro-lingual pressures (PMaxS and t100 respectively) recorded by a single researcher across three trials. Results are detailed in Table 8.

Table 8

Results of ICC Analyses conducted to determine test-rest reliability across trials 1-3

Value	Trials	ICC Value	95% Confidence Intervals		p-value
			Lower Bound	Upper bound	
PMaxS	1 & 2 & 3	.877	.814	.925	0.000
t100	1 & 2 & 3	.497	.334	.648	0.000

These results indicate that PMaxS measures are stable across trials; reported ICC value is above .75 suggesting excellent reliability (Portney and Watkins; Shrout and Fleiss 1979). Conversely, the reported ICC value for t100 measures indicates poor to moderate reliability (Portney and Watkins; Cicchetti 1994). Additional ICC (3,1) analyses were thus conducted on t100 measures to examine reliability between trials 1 & 2, trials 1 & 3 and trials 2 & 3 respectively. Results are detailed in Table 9.

Table 9

Results of ICC Analyses conducted to determine test-retest reliability in ITE task

Value	Trials	ICC Value	95% Confidence Intervals		p-value
			Lower Bound	Upper bound	
t100	1 & 2	.641	.447	.777	0.000
	1 & 3	.392	.140	.598	0.002
	2 & 3	.442	.197	.636	0.000

Comparing trials 1 & 2 the ICC value indicates good reliability at .641 (Shrout and Fleiss 1979) but ICC values for trials 1 & 2 and trials 2 & 3 were both below 0.75, indicating 'poor' to 'moderate' reliability (Portney and Watkins; Cicchetti 1994). When the ICC values were examined collectively it was clear that the source of variation across t100 data was trial 3.

A mean of the three PMaxS values for each participant was used in later statistical analyses of the data as ICC values reflected a high level of agreement between these figures and because measures of centrality are considered the best indicators of the true value when an element of variability exists between values (Portney and Watkins 2009), as was the case in this study.

For t100, mean values were calculated on the basis of only trials 1 & 2, as ICC (3, 1) values indicated good agreement between these figures, but trial 3 was identified as the source of variation.

Statistical analyses to compare groups

Age, gender and swallow pattern differences in PMaxS values were investigated using Independent Samples T-tests. These analyses indicated that younger adults produced significantly higher PMaxS values than older adults ($p < 0.05$), males produced significantly higher PMaxS values when compared to females ($p < 0.05$) and tippers produced marginally higher PMaxS values than dippers, however this difference was not significant ($p > 0.05$). See Figure 5.

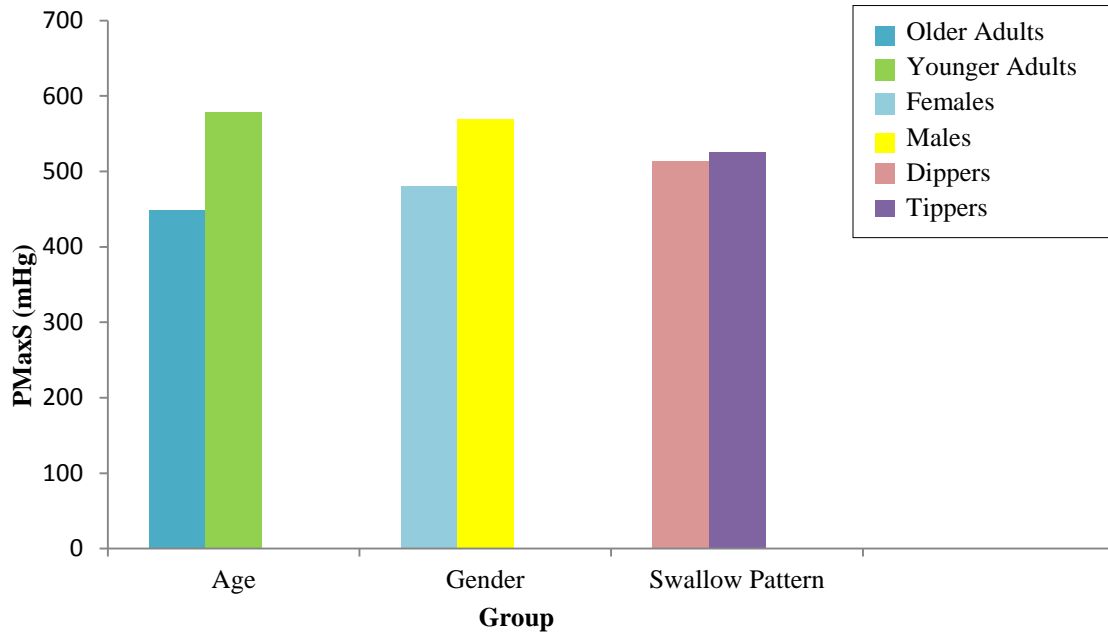


Figure 5: Age, gender and swallow pattern differences in ITS

Mann-Whitney U-Tests were used to examine the effect of age, gender and swallow pattern on t100 values. These analyses indicated that there were no significant differences ($p > 0.05$) between male and female participants; younger and older participants; and participants with a tipper or a dipper swallow pattern on t100 values. However, some marginal differences were noted, see Figure 6.

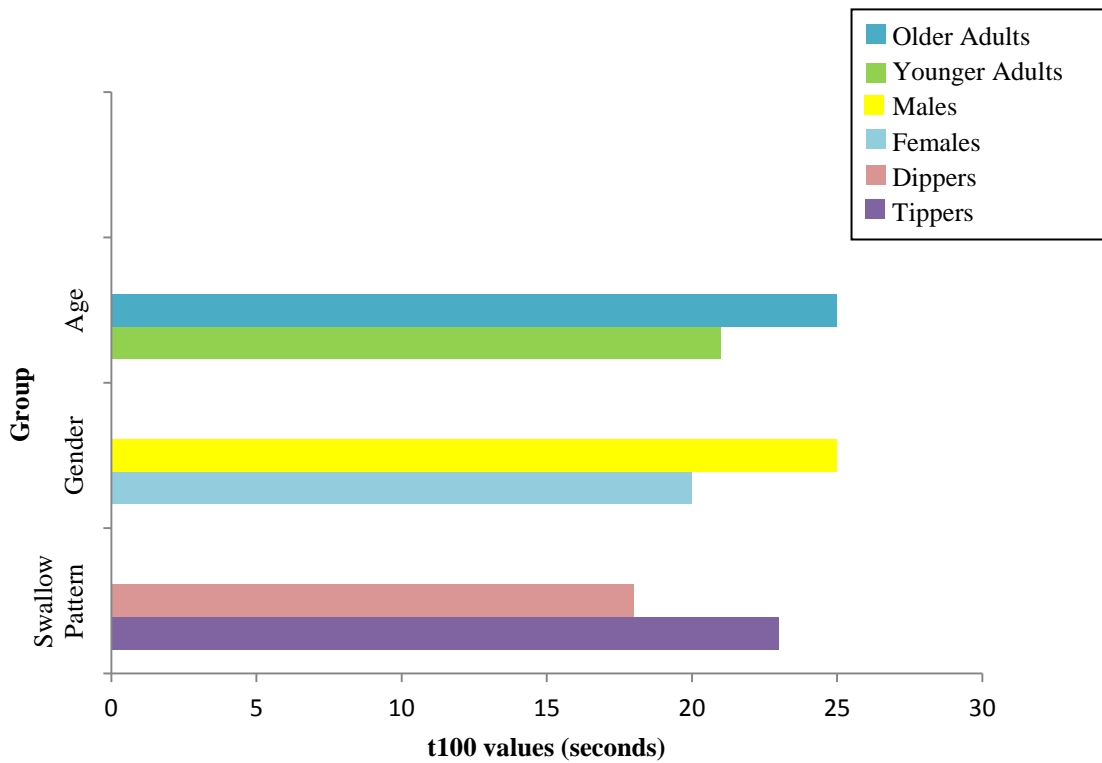


Figure 6: Differences in t100 values across groups

Post-hoc analyses

Two-way ANOVAs were conducted to determine the effect of age, gender and swallow patterns on PMaxS and t100 values and to detect the existence of interaction effects between these variables. These analyses indicated that age and gender both had a significant effect on PMaxS (Age: $p=0.31$; Gender: $p= .002$) accounting for some of the observed variance in this measure, 18.3% and 9.3% respectively (Age; partial eta squared= 0.183; Gender; partial eta squared=.093). No other significant effects were evident ($p>0.05$).

Interaction effects were examined to determine whether each significant result was confounded by other variables (see Table 10).

	PMaxS
<i>Age*SwallowPattern</i>	.042
<i>Age*Gender</i>	.491
<i>Gender*SwallowPattern</i>	.938

Table 10

Interaction effects expressed in terms of p-values

These figures revealed an interaction effect ($p \leq 0.05$) between age and swallow pattern. Analysis of the line graph generated in SPSS (Appendix F) to express this interaction revealed that the effect of swallow pattern on PMaxS values was compounded by age but that the effect of age on PMaxS was not influenced by swallow pattern.

These findings indicate that:

- Gender had a significant effect on PMaxS, irrespective of age or swallow pattern.
- Age had a significant effect on PMaxS, irrespective of gender or swallow pattern.

Discussion

The purpose of this study was to investigate the effect of age, of gender and of swallow pattern on isometric tongue pressures (isometric tongue strength and isometric tongue endurance) generated by healthy adults using a newly developed instrumental tool called OroPress.

The Effect of Age on Isometric Tongue Pressures

As hypothesised, younger adults produced significantly higher ITS than did older adults. This is in agreement with published findings (Nicosia *et al* 2000; Todd *et al* 2013; Robbins *et al* 1995; Youmans and Stierwalt 2006, Youmans *et al* 2009; Hayashi *et al* 2002; Utanohara *et al* 2008; Crow and Ship 1996; Stierwalt and Youmans 2007) and is likely a result of sarcopenia, an age-related decline in musculoskeletal strength in healthy adults (Roos *et al* 1997).

Younger and older adults produced statistically equivalent durations (measured in seconds) in the ITE task. Although no statistically significant difference was detected, older adults nevertheless demonstrated greater ITE than younger adults. These findings are comparable to previous reports using OroPress (McCormack 2013) and other tools (Stierwalt and Youmans 2007; Crow and Ship 1996). Morphological changes in the skeletal muscles of the aging human tongue may account for the unexpected age difference observed in this study (i.e. older adults producing greater ITE than younger adults).

Researchers have reported an age-related increase in the number of slow-twitch muscle fibres (i.e. those that are slow to contract and resistant to fatigue) in the skeletal muscles of the leg (Larsson *et al* 1978; Pierobon-Bormioli *et al* 1981) - the consequence of which is a muscle that demonstrates heightened resistance to fatigue with advancing age. Although this explanation may account for the finding observed in this study, the effect of aging on skeletal muscle is variable across muscle groups (Hoop 1993; Guccione 1993; Roger and Evans 1993) and thus research examining morphological changes in the skeletal muscles of the human tongue is warranted.

The Effect of Gender on Isometric Tongue Pressures

As hypothesised, gender had a statistically significant effect on ITS – with males generating significantly higher ITS than females. This result is in agreement with findings

reported from a prior study using OroPress (McCormack 2013) and the published literature using other measurement tools (Youmans and Stierwalt 2006, Youmans *et al* 2009; Utanohara *et al* 2008; Crow and Ship 1996; Stierwalt and Youmans 2007; McCormack 2013; Gingrich *et al* 2012).

This finding is likely attributable to the fact that males have a greater muscle mass than females (Velleso 2008; Roth *et al* 2000). In light of the documented positive correlation between muscle mass and muscle strength (Newman *et al* 2006) it is plausible that this gender difference in muscle mass may account for differences in ITS generation reported in this study. However, the mediating effect of muscle mass on ITS has not yet been determined, further research is warranted.

Conversely, in this study gender had no impact on measures of ITE, statistically equivalent durations (in seconds) were recorded for both males and females, a finding which supports results of previous studies using OroPress (McCormack 2013) and other recording devices (Crow and Ship 1996; Stierwalt and Youmans 2007). Although not statistically significant, males nevertheless demonstrated greater ITE than females. No physiological explanation exists to account for the observed gender difference in this task (Hunter 2009) thus alternative explanations must be considered. Gender differences in competitiveness and/or intrinsic motivation may account for this marginal discrepancy in ITE between males and females.

The Effect of Swallow Pattern on Isometric Tongue Pressures

Tipplers and dippers generated statistically equivalent ITS and ITE in this sample of healthy adults. Although no statistically significant difference was detected, tipplers nevertheless generated marginally higher ITS and ITE than dippers. The effect of swallow pattern on ITS and ITE respectively does not appear in published literature, so these results provide novel information about ITPs. Furthermore, although the dipper-type swallow was, as expected, observed more commonly in older adults, it was not exclusively observed in this age group so this swallow pattern is not a reliable clinical indicator of sarcopenia as previously suggested.

The tipper/dipper classification reflects variations in swallowing pattern and thus it is plausible that this variable may have a more profound effect on lingual pressure generation in swallowing tasks, research is warranted to investigate the existence of such an effect.

Study Strengths and Limitations

This study has many strengths, the purposeful recruitment of an equal number of male and female participants across planned age ranges facilitated a robust analysis of the effect of these variables on ITPs. Furthermore, the order of ITS and ITE tasks were counterbalanced to control for any learning and/or fatigue effect (s) on pressure generation thereby ensuring captured data was representative. Despite these strengths some limitations remain. This study is limited by a small sample size (N=52) and the use of convenience sampling, two factors which collectively increase the chance that reported findings may not truly represent all population characteristics (Portney and Watkins 2009; Fraenkel and Wallen 2003).

A further limitation of this study is related to the placement of the OroPress sensor. Although the intention was to adhere the sensor to the hard palate at the alveolar ridge this was not always possible as the placement of the sensor was dependent on each person's intra-oral anatomy. A very narrow or arched hard palate provided a non-flat surface area on which to adhere the sensor so it was placed more posteriorly where such parameters could be achieved. This variability in sensor placement has some implications for reproducibility of findings.

Clinical Implications

Although the sample size in this study was not large enough to establish a taxonomy of healthy 'normal' ITPs using OroPress, the findings from this study are clinically important. Results of this study suggest that age and gender influence ITS, thereby indicating that discrete norm sets are warranted for males and females and younger and older adults. It is suggested that ITS norms are developed in 4 discrete categories which correspond to the following groups: older males, younger males, older females and younger females. The absence of an age or gender effect on ITE suggests that these variables do not merit consideration in the development of ITE norms i.e. one set of norms will apply for both males and females across all age groups. Similarly as findings indicated that swallow pattern did not have an effect on either ITS or ITE, this variable does not need to be considered in the development of ITP norms.

Furthermore, although it had been envisaged, that data captured in this study would be merged with ITP values reported in the OroPress pilot study (McCormack 2013) differences in data capture methods prevented this amalgamation. Thus data captured in this study provides the first step towards the development of a large norm data set. Such a development

is integral to the successful application of this tool to dysphagia assessment as in order to use OroPress to facilitate differential diagnosis of reduced versus normal ITPs, a normal range of ITPs generated by healthy individuals must first be established.

Future Research

A number of directions for future research have been identified. Firstly, additional testing to establish norms for healthy adults aged 75 years and above is warranted. This study did not capture ITP data from individuals in this age bracket but generation of such norms is essential to ensure OroPress can be utilised to accurately identify reduced ITPs in adults of all ages. In addition to examining ITPs in this age group it is recommended that this current study is replicated with a larger sample of healthy adults of all ages. Collectively these investigations will further contribute to our understanding of the effect of age and gender on ITPs, thereby advancing the development of OroPress ITP norms.

Finally some minor adaptations need to be made to the OroPress sensor. Increasing the flexibility of the sensor and/or decreasing its surface area may prove successful in overcoming challenges associated with intra-oral placement in participants presenting with narrow/arched hard palates. These adaptations will be incorporated into the next design prototype.

Conclusion

This study serves as an exciting and critical first step in the development of a taxonomy of healthy 'normal' ITPs using OroPress - a development that is integral for the successful application of this tool to dysphagia assessment in the future.

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Appendix A

Tool	Number of sensors/ bulbs	Dimensions and shape of sensor(s)	Placement sites	Pressure Value
IOPI	1 fluid-filled bulb	37 mm long, 17 mm wide, 4 mm high Rounded rectangle	Hand- held in anterior or posterior tongue	kPa
Oro-lingual pressure array of the KSW – 2 variants hand-held and fixed	3 air-filled bulbs	13 mm diameter, 5 mm high Hemisphere	Adhered along midline of hard palate (anterior, mid and post palatal bulbs) <u>or</u> sensors are placed along the midline of the tongue	mmHg
Utanohara disposable bulb device	1 air-filled bulb	8.5 mm long, 4.7mm diameter Sphere	Hand-Held in anterior oral position	kPa
Hori/Ono sensor sheet	5 pressure sensors	0.1 mm thick Circle	The sensors (3 along the midline of the palate and 2 posterior-lateral) are attached to a T-shaped resin film sensor sheet which is adhered to the palate.	kPa
OroPress	1 sensor	2mm thick Circle	Adhered to hard palate/alveolar ridge	mmHg

(Steele 2012; Mc Cormack 2013)



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O L L S C O I L L U I M N I G H

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

Participant Details

ID Number _____

Sex: Male

Female

DOB: _____

Age: _____

Address: _____

Ph No: _____ (house) _____ (mob)

Medical History

Please tick the appropriate boxes:

1. How is your general health today? Good Not Good

If not good, please describe:

2. Do you have any swallowing problems? Yes No

If yes, please describe:

3. Have you had any swallowing problems in the past? Yes No

If no, go to Q 5. If yes, please describe below and then continue to Q4.



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

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

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

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

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

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



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

-
-
-
11. I now want you to dry swallow.

When you started that swallow, was your tongue tip raised up, behind your top set of teeth, or pushed down, behind your lower set of teeth?

(If unsure, try again and/or ask for a drink of water. Take a sip and note below where you think you placed your tongue for the start of that swallow.)

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

Appendix C



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ORO- MOTOR EXAMINATION

Participant No: _____

Date: _____

Student: _____

<u>Organ:</u>	<u>Assessment of:</u>	<u>Method:</u>	<u>Outcome: (Circle as applicable)</u>	<u>Comments</u>
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)	Hold your lips firmly closed while puffing up your cheeks like this (demo). Hold the air in your cheeks for	Time in secs: _____ 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production	

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

Voluntary Cough	Strength	Cough/clear your throat for me please	<ol style="list-style-type: none"> 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task 	
Gag reflex	Sensitivity	Open your mouth wide please, I'm going to test your gag reflex.	<ol style="list-style-type: none"> 1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task 	

Residue Rating

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

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

Appendix D



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OLLSCOIL LUIMNIGH

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.

Phone: Roisin 0877533765

Email: Roisin 12011797@studentmail.ul.ie

Triona 0879457687

Triona 12011991@studentmail.ul.ie



UNIVERSITY of LIMERICK
O L L S C O I L L U I M N I G H

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 E

Participant 1	Value	Trail Number	Rater 1	Rater 2	Percent Agreement
	PMaxS	1	351	351	100%
		2	343	343	100%
		3	343	343	100%
	PMaxE	1	384	384	100%
		2	412	412	100%
		3	418	417	100%
	t100	1	14	13	100%
		2	14	14	100%
		3	13	13	100%

Participant 15	Value	Trail Number	Rater 1	Rater 2	Percent Agreement
	PMaxS	1	617	616	100%
		2	469	469	100%
		3	486	486	100%
	PMaxE	1	349	349	100%
		2	234	234	100%
		3	258	258	100%
	t100	1	2	2	100%
		2	1	1	100%
		3	1	1	100%

Participant 25	Value	Trail Number	Rater 1	Rater 2	Percent Agreement
	PMaxS	1	938	938	100%
		2	872	872	100%
		3	795	795	100%
	PMaxE	1	630	630	100%
		2	704	704	100%
		3	687	686	100%
	t100	1	32	33	100%
		2	29	30	100%
		3	32	31	100%

Participant 31	Value	Trail Number	Rater 1	Rater 2	Percent Agreement
	PMaxS	1	456	456	100%
		2	502	502	100%
		3	468	468	100%
	PMaxE	1	387	387	100%
		2	453	453	100%
		3	477	477	100%
	t100	1	5	5	100%
		2	23	23	100%
		3	24	23	100%

Appendix F

