

Intraoral Swallow Pressure Profiles-General Features and Aids to Categorization

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Intraoral Swallow Pressure Profiles - General Features and Aids to Categorization

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Abstract • Purpose The primary goal of this study was to establish a normative data set representing intraoral time series swallow pressure profiles for healthy adults using a novel wearable intraoral pressure sensing system, OroPress, developed to help with dysphagia (swallow disorder) clinical screening. • **Methods.** Swallow intraoral pressure-time profiles for 35 healthy adults (17 male, 18 female) swallowing water ($3 \times 5\text{cm}^3$; $3 \times 10\text{cm}^3$) and custard ($3 \times 5\text{cm}^3$) boluses ($N = 9 \times 35 = 315$) were recorded using OroPress. • **Results** General swallow profile traits are identified to characterise an effective, efficient swallow. A profile-specific swallow envelope function is devised which in combination with profile metrics, provides a simple means of categorizing swallows as effective or impaired. • **Conclusion** The swallow profile data trace with superimposed and colour coded peaks, envelope function and related swallow metrics provides a simple human readable graphic to aid the real-time instrumented identification of subjects warranting more in-depth clinical assessment. It may also prove useful in the selection of training set profiles for machine learning and other analysis tools which could improve the discriminatory capabilities of intraoral pressure measurement in dysphagia diagnostics.

Keywords Tongue Pressure · Swallowing · Intraoral · Preprocessing · Dysphagia Screening · Threshold Screening · Swallow Envelope Function · Swallow Envelope Excess · Swallow Effort

Clinical data collection was undertaken by Carmel Ni Chualain, Catraoine Hickey, Joanne McCormack as part of their Honours MSc Degree in Speech and Language Therapy.

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1 Introduction

Dysphagia has been extensively investigated using a variety of techniques including radiography, ultrasound, electromyography (EMG)¹, videofluoroscopy [1] and endoscopy together with direct observations of individuals with dysphagia [2]. Intraoral swallow pressure-time profiles offer a relatively non-invasive means of interrogating the swallow process and so have been used in many studies designed to improve our general understanding of normal and impaired swallowing [3–5]. Researchers tend to use pressure peak amplitude [6–8] and pressure rise/fall times [9] as dependent variables. While these variables have an immediate intuitive appeal, their discriminatory capabilities are limited given the large dynamic ranges encountered across different studies but also within a given study and even within individual swallows. The variety and complexity of swallow pressure profiles reflects, to some extent, the complexity of the swallow process [10] but pressure measurement artifacts and lack of control of independent variables is also likely to add to the variety of profiles captured [11]. Nevertheless, it has been possible to identify general features in profiles for healthy volunteers [12, 13] which provides some encouragement in the search for a universal profile which could be used as a reference to identify subjects with impaired swallow function.

Statistical techniques such as principal component analysis (PCA), linear discriminant analysis (LDA) and machine learning may provide more robust metrics with improved discrimination [14]. However, a ‘normal’ swallow profile set, the so-called training set, obtained from individuals with unimpaired tongue function or swallow function is required [15]. Selecting a ‘normal’ population sample is difficult since participants may not be aware of, or manifest with clear symptoms of dysphagia. In addition, tongue function impairment is understood to increase with age [16], affecting, according to some studies, more than 40 % of adults over 50 [17]. Therefore, a sample drawn from a healthy adult population is unlikely to guarantee a robust training set unless rigorous invasive clinical screening is used to identify healthy participants.

There is a need therefore, both from a clinical and an analysis perspective, for a simple objective tool or instrument which could be used to classify human oral swallow pressure profiles into normal or impaired swallow categories in real time. The OroPress system [18] was developed in an attempt to meet this need.

2 Background

Tongue pressure generation and articulation within the oral cavity is a critical element of normal speech and swallow function [12] and involves the volitional and reflexive activities of more than 30 nerves and muscles [10]. Two distinct kinds of pressure may arise within the oral cavity during liquid bolus swallowing. The bolus hydrostatic pressure HP may be changed by applying a force which tends to change the volume of the bolus compartment created by the tongue.

¹ Abbreviations: Electromyography, EMG; Principle Component Analysis, PCA; Linear Discriminant Analysis, LDA; Hydrostatic Pressure, HP; Interfacial Pressure, IP; Biomedical Interface Pressure Transducer, BIPT; Maximum Pressure Excursion, PEMAX; Maximum Pressure, Pmax; Minimum Pressure, Pmin; Positive Excess Pressure, PEXS; Negative Excess Pressure, NEXS; Pulse Width at Half Maximum, PWHM; Pressure time product, Pt.

According to Pascal's principle [19], and assuming a low viscosity liquid bolus, the pressure generated within the bolus will be uniform or constant throughout the liquid contained within the compartment and may be positive or negative relative to ambient pressure [13, 20]. In forming a container for the bolus the tongue also forms a seal around the bolus through tongue contact with other tissue structures. Provided shear forces are decoupled leaving only normal forces, the seal pressure may be measured as a biomedical interface pressure *IP* [21]. The effectiveness of swallow function is expected to depend on the mechanical integrity and effectiveness of compartment and seal formation [22], and swallow efficiency similarly might be expected to depend on the bolus transport efficiency of the tongue [23]. In this context, an effective, unimpaired swallow can be defined as one which forms and dispatches the bolus to the stomach with minimum mechanical effort (force/work/energy) and in minimum time. Consequently, direct intra-oral tongue pressure measurement during swallowing can provide an objective means of monitoring the mechanical effectiveness of a swallow, not only during the oral phase of swallowing but for subsequent phases also since this effort continues until the swallow is complete [24]. Hence the large number of studies focusing on pressure measurement during swallowing in the dysphagia literature.

A range of commercial instruments and approaches exist [6] for swallow and tongue function measurement such as the Kay Swallowing Workstation [25], the Iowa Oral Performance Instrument [26] and the Madison Oral Strengthening Therapeutic [27]. In general these systems rely on deformation by the tongue of an elastic element such as a gas filled elastomer bulb which is linked via a tube to a remote pressure sensor which in turn measures the changes in pressure in the gas due to deformation of the bulb. The bulb deformation and consequent gas pressure change is used as an indicator of the strength and movement of the tongue during swallowing. However, while pressure sensors may be used in these devices, the probes used do not measure intraoral pressures. To measure such pressures, the pressure sensors need to be located within the oral cavity or coupled directly to it using an open ended tube.

It is now possible to modify microelectromechanical sensors (MEMS) pressure sensor modules to measure intraoral pressures directly using probes [28] which are relatively non-intrusive and which provide absolute measures of pressure, i.e. can measure both positive and negative *HP* values relative to ambient atmospheric pressure but which will also respond to biomedical *IP* values [11, 29]. The sensitivity of these sensors to both *HP* and *IP* is likely to further add to the complexity of the swallow pressure profile. However, such complexity is probably a realistic reflection of the complexity of the actual processes involved in swallowing. Such profiles may therefore contain detail sensitive to bolus related properties such as temperature, consistency/viscosity [30], voluntary or on-command swallowing [9] as well as subject attributes such as gender [31], age and habituation. The major challenge is to identify the general or, if possible, universal features of such profiles to allow the extraction of clinically meaningful metrics indicative of the effectiveness and efficiency of a swallow.

Some very general intraoral swallow pressure profile features may be identified from the dysphagia literature. First, a swallow pressure profile is continuous and may comprise multiple peaks but generally has one dominant peak most simply characterised by its maximum pressure value. Second, the duration of such profiles depends on bolus consistency and volume but is typically less than half a second

for saliva [6, 32] and somewhat longer but less than one second for water and custard. Third, the area between the pressure profile and the time axis serves as an index of the overall ‘effort’ or energy expended in swallowing [12, 33] the bolus. Clearly there is an interdependence between these features. However, they provide a basis for a simple definition of an effective swallow, in the context of intraoral pressure-time profiles, as one in which the bolus is transported from the mouth to the stomach in the minimum of time and with the minimum of effort. Furthermore, while the discriminatory value of the maximum pressure may be limited, its uniqueness within each profile identifies it as an ideal alignment feature in order to compare swallow profiles. These general profile features and the uniqueness of the profile maximum value are used to guide the analysis of swallow profile data here.

3 Experimental Details

The OroPress system [18] was used to directly monitor and record intraoral pressure and temperature during liquid swallowing and isometric strength and endurance tasks. This system uses a modified MEMS pressure sensor (biomedical interface pressure transducer (BIPT) [29]) capable of responding to both bolus HP and tissue IP , connected to a wearable wireless module. The wireless module transmits real time data to a remote notebook computer which displays and records the data as well as participant and clinician details. The pressure data is absolute, i.e. referenced to vacuum. A baseline may be established by ensuring that the participant’s mouth is open at commencement of the testing sequence, i.e. zeroed while exposed to ambient atmospheric pressure.

The measurement protocol, participant recruitment and screening details and results for isometric strength and endurance tests carried out as part of this study have been reported previously [18]. A preliminary attempt to use PCA on the swallow data has also been reported [34]. A total of $N = 35$ normal healthy adults were purposefully recruited (17 males and 18 females) ranging in age from 18 to 70 years (average age 36) and screened as admissible to the study. Each participant was seated facing a wall 2.4 meters distant on which was placed a viewing disc target at subject eye-level. The BIPT probe was adhered to the participant’s alveolar ridge using a Poligrip ComfiSeal Strip®. Each participant first practised oro-lingual isometric tongue ‘pushing’ pressure tasks to become habituated to the probe. Once they indicated that they were comfortable, recorded tests commenced. Participants were instructed to gaze at the disc during data collection to ensure that their head was stabilized in a neutral position, i.e. neither tilted up nor down. Isometric (strength and endurance) and swallow tasks were performed in counterbalanced order.

Swallow data was obtained for randomized sequential sets of three boluses for each participant: $3 \times 5 \text{ cm}^3$ water; $3 \times 10 \text{ cm}^3$ water and $3 \times 5 \text{ cm}^3$ custard. The bolus was drawn from fridge stored stock and delivered to the oral cavity using a syringe. The participant was instructed to hold the bolus in their mouth briefly before swallowing on command. Once completed, the participant test data was saved to individual participant Microsoft (MS) Excel® spreadsheets. The swallow segment of the participant data set thereby comprised a total of 9 swallows. A total of $9 \times 35 = 315$ swallow pressure profiles were recorded in this clinical study.

Individual swallow data sets for a single participant were extracted into sequential columns of an MS Excel spreadsheet. Once all nine swallows were extracted for a particular participant, the entire procedure was repeated for each other participant data file. Swallow durations varied so column lengths in the spreadsheet varied accordingly. Once all participant swallows were extracted (swallow vectors), the spreadsheet containing the swallow column vectors (see data files) was imported to MATLAB(Mathworks, Natick, Massachusetts, USA) as a matrix of swallow vectors. The matrix row size (number of rows), corresponded to the longest swallow vector imported which was 700 and so the 2D swallow matrix dimension was 315×700 . Custom MATLAB scripts, described below, were developed to extract swallow parameters, e.g. maximum positive and negative excursion pressures, as well as to carry out general numerical processing of the matrix of swallow vectors.

4 Results and Analysis

An example of a participant extracted swallow set profile recorded in this study is shown in Fig. 1 where the zero baseline corresponds to ambient atmospheric pressure. The data rate is 100 readings (pressure and temperature) per second, i.e. pressure and temperature are recorded every 0.01 s. The temperature data is used to compensate the pressure data for temperature induced changes. However, it is also useful as an indicator of bolus presence around the BIPT probe provided there is a temperature contrast between bolus and body temperatures. For instance, the temperature trace shown displays localised drops in temperature once a bolus is introduced (fridge stock bolus is at a temperature lower than body temperature). A saliva swallow, on the other hand, does not, in general, display an accompanying temperature drop. However, a bolus clearance swallow of residual bolus will have an associated temperature drop, so will be distinguishable from a saliva swallow thereby aiding swallow selection and isolation. Swallows extracted in this way were validated by reference to swallow times/locations noted by the clinicians.

The inset to Fig. 1 shows an expanded time-base view of a single swallow pressure profile. The pressure fluctuates above and below the baseline, i.e. comprises positive and negative pressure excursions relative to atmospheric pressure. It has a clear start defined by the departure of the pressure from baseline and a clear completion point defined by a return to baseline. There is evidence of a short clearance swallow just before 72 s since the temperature continues to drop across the entire swallow profile sequence. For this particular swallow the maximum pressure excursion P_{max} , from baseline, is positive and close to 90 mmHg, [$1kPa \simeq 7.50 \text{ mmHg}$]. MATLAB ‘max’ and ‘min’ functions were applied to the swallow matrix to extract the maximum positive, P_{max} , and maximum negative/minimum, P_{min} , pressure excursion values from baseline for each swallow. Out of 315 swallows recorded, the maximum pressure excursion, P_{max} , was positive for 287(91%) swallows, i.e. $P_{max} > |P_{min}|$, and negative for 28(9%) swallows of which 14 were attributable to just 3 participants. The P_{max} mean and median values were 154 mmHg and 118 mmHg respectively while the corresponding values for P_{min} were -41 mmHg and -19 mmHg respectively. In all, 95% of P_{max} values are less than or equal to 380 mmHg while the corresponding value for P_{min} values is -135 mmHg. Therefore, while the pressure range of peaks encountered for all swallows spans just over 1,300 mmHg (maximum of 630 mmHg to min-

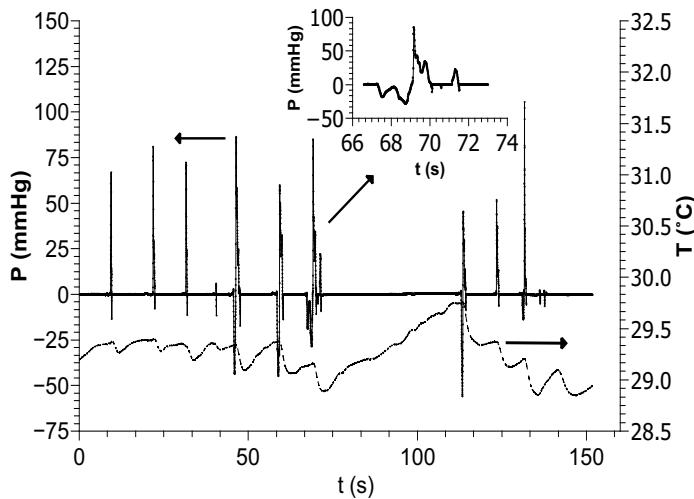


Fig. 1 Pressure and temperature profile for 3 sets of 3 swallows in the order: $3 \times 5 \text{ cm}^3$ water; $3 \times 5 \text{ cm}^3$ custard; $3 \times 10 \text{ cm}^3$ water. Insert shows a time-axis expanded single swallow.

imum of -690 mmHg), 95% fall within an approximately 500 mmHg dynamic range.

The maximum pressure excursion value P_{max} , as noted above, provides a unique marker within each swallow profile. A MATLAB script was used to align all profile vectors (see data file) on their P_{max} value (P_{max} or P_{min} depending upon which had the greater absolute value). Swallow vectors were truncated $\pm 1.5 \text{ s}$ either side of the maximum pressure excursion as a 3 s sample window was judged to be sufficient to cater for both normal and ‘impaired’ swallow profiles. Where a profile was less than 3 s duration, it was padded with zero values in the aligned swallow vector matrix. Such time shifting and temporal truncation/padding of pressure profiles greatly facilitates profile comparison, (see data file density plot).

Terminology used in amplitude envelope analysis of sound events [35] is useful in describing these pressure profiles. The swallow effort starts to build on the leading edge or ‘attack’ side of maximum and builds up slowly about 1 s before maximum for a large number of swallows, increasing more rapidly within 0.5 s of maximum. On the ‘release’ or falling edge side of maximum the effort drops rapidly for the first 0.5 s after maximum returning slowly to baseline thereafter. Averaging swallow pressures for all aligned profiles at each time point provides a generalised profile shape for these liquid swallows, Fig. 2, irrespective of bolus type. Regression analysis of the data 0.75 s either side of maximum gave a reasonable fit ($R^2 > 0.97$) to exponential attack and decay functions with amplitude 140 mmHg and time constant $\tau = 0.26 \text{ s}$, i.e. $P = 140\exp \pm ((t - 1.50)/\tau)$, Fig. 3. Based on this, a swallow envelope function was created in MATLAB composed of a set of exponential functions, parameterised using two amplitudes (the P_{max} and P_{min} values for each profile) and a single time constant $\tau = 0.26 \text{ s}$, and formed into a composite swallow envelope function with, where appropriate, positive and negative attack and release components, see insert to Fig. 2. Thus the profile en-

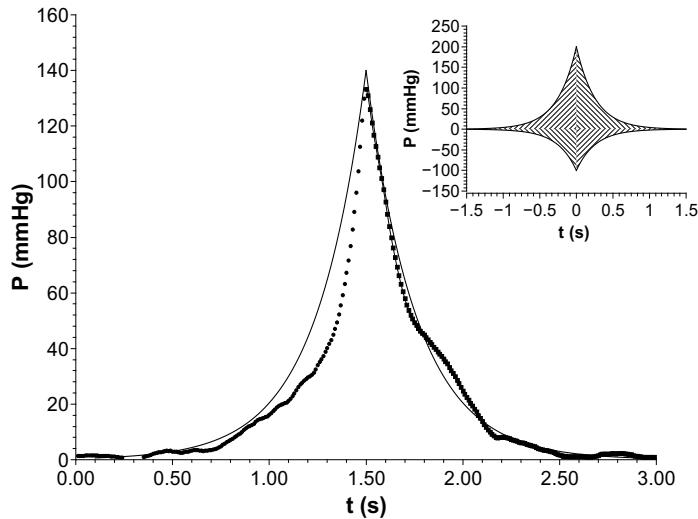


Fig. 2 Averaged pressure data for all aligned swallow profiles at corresponding times within the 3 s profile interval. The solid curves correspond to exponential ‘best-fit’ functions with amplitude 140 mmHg and time constant 0.26 s. The insert shows composite envelope function plots centered on P_{max} with different positive (200 mmHg) and negative (-100 mmHg) amplitudes and fixed time constant $\tau = 0.26$ s.

velope functions were normalised to individual profile maximum/minimum values but a single time constant, $\tau = 0.26$ s was used for all profiles.

Using the customized envelope functions for each profile, as described above, it is possible to devise metrics to indicate the degree to which a given profile conforms to, or deviates from, the envelope profile. Actual swallow profile pressure values were compared with envelope values for all time-series data points within the 3 s profile window, i.e. ± 1.5 s of P_{max} . Pressure values P_i greater than the positive envelope values PE_i or less than the negative envelope values NE_i were individually summed in order to provide numerical estimates of the Pt area which was outside the positive envelope bounds, $PEXS$, and negative envelope bounds, $NEXS$, for each swallow profile, i.e. $PEXS$ or $NEXS = \sum_{i=1}^{300} (|P_i| - |PE_i|) \times \Delta t$.

Analysis of the excess values showed that small excess values dominate with 91% of all $PEXS$ values being less than or equal to 50 mmHg s. The corresponding value for $NEXS$ is approximately 14 mmHg s. These values were used as threshold levels to categorize swallow profiles according to whether they were within thresholds or, if outside, whether they exceeded positive, negative or both thresholds. Sample profiles from each of these categories are shown in Fig. 3 along with their corresponding envelope functions. In all 24 (7.6%) swallow profiles were found to exceed the positive excess threshold only, Tab. 1. A further 21 (6.7%) exceeded the negative excess threshold only and 5 (1.6%) profiles exceeded both the positive and negative excess thresholds giving a total of 50 (15.8%) profiles which exceeded one or both thresholds. Tab. 1 lists the participant numbers with their total of peaks in excess of these thresholds. While 17 of the 35 participants had one or more swallows which exceeded the thresholds, one participant (*PN13*) had all 9 swallows, *PN07* had 7, while participants *PN06*, *PN16* and *PN35* each

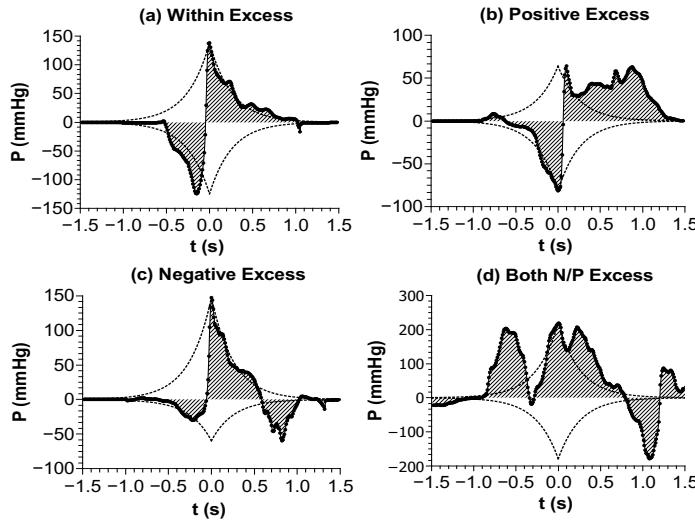


Fig. 3 Examples of swallow profiles: (a) within the envelope excess thresholds; (b) exceeded the positive envelope excess threshold only; (c) exceeded the negative envelope excess threshold only; (d) exceeded both positive and negative envelope excess thresholds.

had 4 swallows in excess of threshold thereby accounting for more than half those identified as having profiles with significant portions outside the swallow envelope, Tab. 1.

Table 1 Participant number and number of swallows (in brackets) which exceed both excess thresholds, positive threshold only and negative threshold only.

Both	Positive Only	Negative Only	Total	Gender	Age
		1(1)	1	M	34
		4(3)	3	M	45
	6(4)		4	F	27
7(1)	7(6)	7(1)	8	F	26
	9(2)	9(1)	3	F	70
		11(1)	1	M	28
13(3)	13(3)	13(3)	9	F	42
	14(1)	14(2)	3	M	21
		16(4)	4	M	19
	19(1)		1	F	27
	20(1)		1	F	34
		24(1)	1	M	19
25(1)	25(2)		3	F	57
		26(1)	1	F	31
		31(2)	2	M	43
		34(1)	1	M	41
	35(4)		4	M	62
5	24	21	50		

While the envelope function provides a simple graphical aid to profile interpretation and yields metrics relating to the degree of profile conformation to the

envelope function, metrics commonly used in standard signals analysis can also prove useful in the placement of a particular swallow on a swallow effectiveness scale ranging from effective to impaired. The predominance of a single maximum pressure excursion peak leads naturally to a consideration of the pulse width at half maximum $PWHM$ as a measure of swallow duration. The $PWHM$ values for all swallows were computed in MATLAB by finding the index for $Pmax$ and then finding the indices either side of $Pmax$ where the pressure first drops to half $Pmax$, i.e. $Pmax/2$. The $PWHM$ and pulse rise and fall times (time for pressure to increase from half maximum to maximum on the attack side or decrease from maximum to half maximum on the release side respectively) were calculated directly from these indices. A histogram of $PWHM$ values is shown in Fig. 4 with an inset showing a box-plot for $PWHM$ and the rise and fall times. A lognormal distribution function gives a reasonable fit to the $PWHM$ data which ranged from 0.02 to 1.20 s. The boxplots show that 90% of $PWHM$ values fall in the range 0.20—0.70 s and that the rise and fall times are similar to each other and close to 0.4 s reflecting a high degree of symmetry in the dominant pressure pulse(s) centered on $Pmax$.

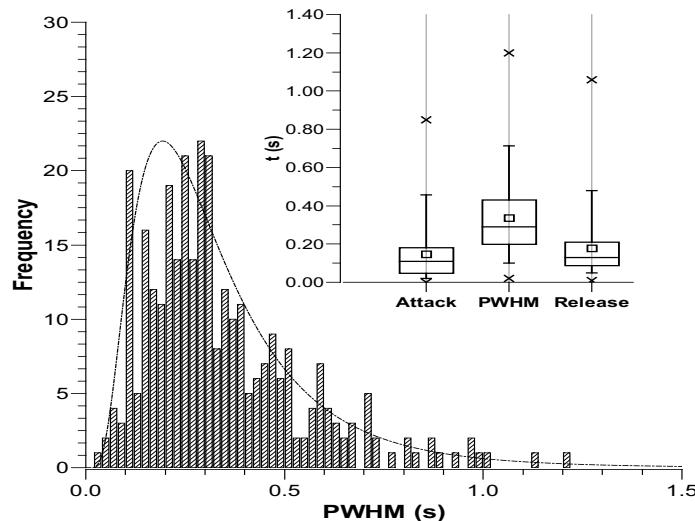


Fig. 4 Box plots of Pulse Width at Half Maximum ($PWHM$) for the maximum magnitude peak within each swallow profile. The ‘Attack’ plot refers to the time taken to rise from half maximum to maximum on the commencement portion of the profile whereas the ‘Release’ plot refers to completion portion of the profile, i.e. time take to fall from maximum to the first instance of half maximum. (Whiskers correspond to the 5 and 95% limits, the large rectangle gives the interquartile range, the line across the large rectangle is the median value and the small square is the mean value.)

As is clear from Fig. 1 multiple subsidiary peaks in addition to the maximum pressure excursion peak may arise in these intraoral pressure profiles. A very useful peak finder function [36] developed for MATLAB® may be used to count peaks in time-series data. Using this function, positive and negative peaks were counted based on their magnitude relative to $Pmax$ (because of the dominance of positive

pressure peaks) for a given swallow profile. Positive peaks were counted provided their maximum value was above a threshold of $P_{max}/5$ and that they were at least $P_{max}/10$ greater than surrounding data. Similarly, negative peaks were counted provided the peak's absolute value was greater than $P_{max}/5$ and that it was at least $P_{max}/10$ greater than surrounding data, i.e. more negative. Positive and negative peaks were counted separately and added to provide a total peak count for the time interval ± 1.5 s of P_{max} , i.e. a 3 s interval. A histogram of total peak count is shown in Fig. 5 along with an inset which shows box plots for individual peak counts and total peak count. Swallow profiles had a dominant (single peak) for 58 swallows (18%) whereas 116 swallows were double peaked (37%). The maximum peak counts per swallow were 4 for profiles with negative peaks, 6 for profiles with positive peaks and the maximum total peak count per swallow was 8, i.e. comprising both positive and negative peaks. For total peak count, 95% of swallow profiles had 5 or less peaks, with 75% having 3 or less peaks. The median total peak count was 2. A log-normal distribution function provides a reasonable fit ($P = 0.17$ at the 0.05 level, Shapiro-Wilk for transformed data).

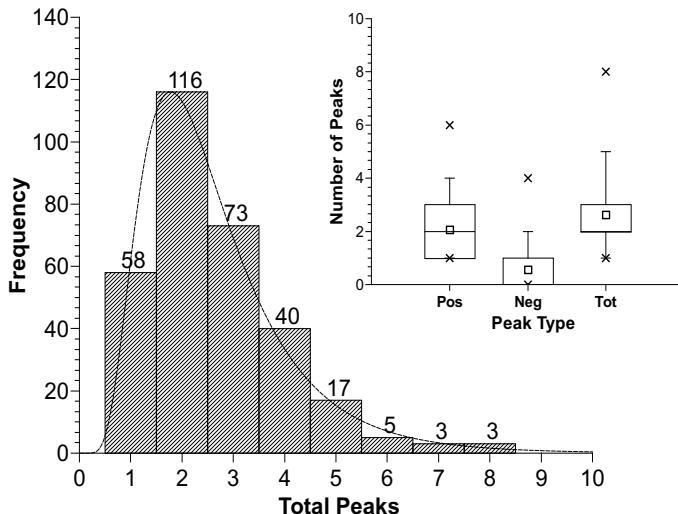


Fig. 5 Histogram of total peak count per swallow. The inset shows box plots for positive, negative and total peak counts. (Markers as for Fig 4.)

The pressure-time product was summed in order to estimate the profile area, i.e. Pt product, as an “effort index”, for both the positive and negative pressure profile elements for each profile 1.5 s either side of P_{max} for each swallow, i.e. $(\sum_{i=1}^{300} |P| \times \Delta t)$, where $\Delta t = 0.01$ s is the sampling interval. Total effort, gauged via the Pt product, is typically less than 230 mmHg s (within 95 percentile). More than 75% of swallows had a total pressure-time effort value below 100 mmHg s with 5% of swallows having values less than 20 mmHg s. All swallows were clinically assessed as being effective, yet the effort involved (without differentiating between bolus volume or type since these are similar on an order of magnitude basis), spans two orders of magnitude. The wide range of effort involved in swal-

lowing and the dominance of positive pressure-time products is possibly due to the tongue pressing on the sensor to provide a sealing function rather than a propulsive effort (probe location close to or at the alveolar ridge).

5 Categorization Aid

In order to demonstrate how an OroPress intraoral pressure profile might be used as a real time screening tool to assess the effectiveness of human swallowing, a script was written in Python which takes a swallow profile, truncates it ± 1.5 s of P_{max} , generates the corresponding envelope functions and “effectiveness” parameters. It then plots and displays the profile and envelope functions, annotated with parameters, peak markers and highlighted envelope excess areas, as an easily interpreted single page graphic, Fig. 6. If implemented on the OroPress data acquisition device (Laptop/Hand-held device), this graphic provides a simple real time output which may prove useful in initial clinical screening for dysphagia. Clearly, the tool needs to be tested and validated through use on subjects with swallow disorder. Application to OroPress data recorded on head and neck cancer patients who have undergone radiotherapy treatment will be presented in a subsequent paper.

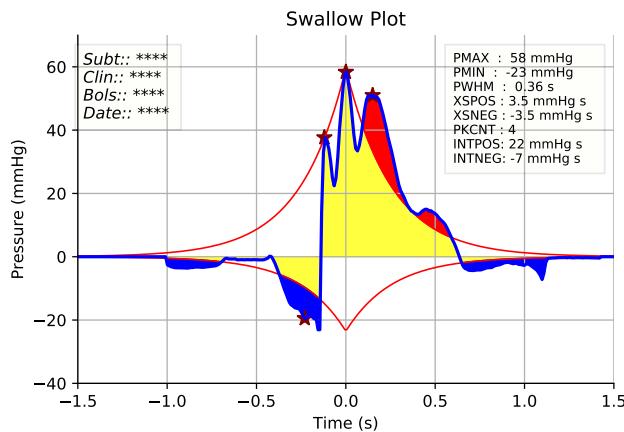


Fig. 6 Python generated plot of swallow profile, envelope functions and parameters with marked positive and negative peaks and highlighted envelope excess areas.

6 Discussion

Tongue movement is varied and active throughout the entire swallowing process [24] involving volitional and reflexive activities of more than 30 nerves and muscles [10]. A pressure sensing device placed directly in the oral cavity will provide swallow profile data for the entire swallow, not just the oral phase, particularly

if the device is sensitive to both *HP* and *IP*. The partly reflexive, partly voluntary nature of the tongue motor activity during swallowing is likely to contribute to the large variety of pressure profiles observed and makes it difficult to define a normal or universal profile in contrast to the situation which pertains to ECG heart monitoring. Nevertheless, as has been demonstrated, there are distinct patterns to the pressure signals and consistent patterns are present in multiple sensor signals from the same subject and across subjects [12].

Two easily extracted but interdependent features of intraoral swallow pressure profiles were identified: profile duration characterised by the pulse width half maximum, *PWHM* and the swallow effort characterised by the profile pressure-time product, *Pt*. These could be used as a basis for a simple classification scheme for liquid bolus swallow effectiveness. One such scheme could define an effective swallow as one which would transport the bolus from the mouth to the stomach in the minimum of time, i.e. *PWHM* < 0.3 s, and with the minimum of effort, *Pt* < 150 mmHg s.

The value of *Pmax* is less useful as a characterization parameter since it can relate to a combination of *HP* and *IP*. However, since the maximum pressure excursion is single valued and therefore unique within each profile, it is useful as an alignment feature for all profiles in order to allow easy profile comparison. A profile window of ± 1.5 s either side of *Pmax* may be sufficient to capture both effective and ineffective swallows.

A superposition of all *Pmax* aligned swallow profiles revealed relatively high data density within a set of envelop functions characterised by two amplitudes (one positive, the other zero or negative) and a single time constant centered on *Pmax*. Swallows could then be classified into groups based on the degree to which they exceeded or strayed outside the envelope functions. Such envelope functions may prove useful as aids to the identification of participants/patients requiring further clinical assessment.

It is easy to combine graphically rendered swallow profiles with numeric metrics such as *PWHM*, peak count, *Pmax* and *Pmin*. Numerical processing also facilitates assessment of swallow effort from pressure profiles through the pressure-time *Pt* product and through *PEXS* and *NEXS*. A display of the profile with its envelope function augmented with parameters such as those mentioned above, if available in real time, i.e. contemporaneous with swallow testing, could add significantly to our understanding of swallow pressure profiles and if combined with rigorous clinical evaluation/assessment, could also provide an evidence base supporting the use of the tool and this approach in clinical pre-assessment for dysphagia, e.g. Fig. 6

Because the analysis of profiles reported here was done subsequent to swallow testing, it was not possible to do follow up clinical assessments of participants with multiple swallows having envelope excesses outside the thresholds. This represents a major limitation in the study since it was not possible to identify whether such anomalous profiles and associated parameters are attributable to actual swallow difficulties, i.e. dysphagia, probe invasiveness or other causes. Related to this limitation is the general difficulty with selecting a sample participant population which has unimpaired swallow function. Currently, there is no reliable way of doing this without resort to videofluoroscopic or other relatively invasive screening.

In an attempt to overcome these limitations a further study has been approved and completed where the participants are head and neck cancer patients who have

had radiotherapy treatment. OroPress has been used in parallel with videofluoroscopy on a small group of such patients. Analysis is on-going and results will be reported separately.

7 Declarations

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Conflicts of interest/Competing interests The authors have no relevant financial or non-financial interests to disclose.

Availability of data and material (data transparency) Available on Open Science Framework, OSF:

- <https://osf.io/7c2va/> MS Excel Spreadsheet of all swallow pressure-time swallow vectors.
- <https://osf.io/n9gw8/> MS Excel Spreadsheet of all swallow vectors aligned on Pmax.
- <https://osf.io/bf8sw/> Supplementary Figures
- <https://osf.io/68a5c/> Python Code for swallow data graphical analysis and rendering.

Authors' contributions Vincent Casey and Richard Conway designed and developed the OroPress tool in consultation with Alison Perry. Alison Perry supervised the clinical use of OroPress on healthy volunteers by MSc speech and language therapy students. Vincent Casey developed the code to support the research, and carried out the post processing of raw pressure-time series swallow data and the analysis and presentation of results.

Ethics approval Ethics approval for this study, which conformed to the Helsinki Declaration, was obtained from the University of Limerick, Faculty of Education and Health Sciences research ethics committee. Approval to use a novel medical device, OroPress, in this clinical investigation was approved by the designated authority for Ireland, the Health Products Regulatory Authority (HPRA) with reference numbers CI0053#0 – CRN 2148129 EUDAMED Reference Number: CIV-IE-14-06-012200, 15 Dec 2015.

Consent to participate Participants were recruited by use of advertising posters and verbal requests. A total of 35 normal healthy adults were purposefully recruited (17 males and 18 females). Participants were screened by use of a short questionnaire about their past and present swallowing function. Exclusion criteria included having a history of a swallowing and/or speech disorder; having a medical condition, or use of medications, that may affect swallowing. An oromotor examination excluded people with any oral abnormality and those with an overly sensitive gag reflex (i.e., gag reflex triggered in the middle portion of the anterior tongue). Persons unable to give informed consent or to follow oral instructions were also excluded. Informed consent was obtained from all individual participants included in the study.

Consent for publication Informed consent was obtained from all individual participants included in this clinical investigation.

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