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MSc in Speech and Language Therapy

Final Year Project:

"Clinical utility and safety of a new tool for tongue pressure measurement: the OroPress

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Abstract

Purpose: To date, various studies have been carried out to develop new tools for measuring tongue pressures during normal swallowing but in very few of these studies have researchers focused on the clinical utility and safety of those tools. The aim of this study was to investigate the clinical utility and safety of a newly designed tool for tongue pressure measurement: the OroPress.

Methods: Thirty five healthy adults; 17 males from 18 to 63 years and 18 females from 19 to 70 years were purposefully recruited from the UL campus. Some participants were also recruited through verbal request to personal friends and classmates. Each participant undertook a trial with the OroPress sensor adhered to their hard palate as controlled swallowing and isometric tasks were undertaken. All participants and student researchers then completed a safety and utility questionnaire that was designed to explore their perceptions of the OroPress in terms of clinical utility and safety. The questionnaire data were analysed using the principles of Grounded Theory.

Results: Seventy four percent of participants (n=26) reported that the sensor felt comfortable in his/her mouth and 88% (n=31) reported that it felt secure. Sixty eight percent (n=24) 'strongly disagreed' that the sensor made them gag when swallowing while 2% (n=1) 'strongly agreed.' In 48% (n=16) of trials, the researches agreed that the sensor was easily applied but in 42% (n=14) they disagreed.

Conclusion: Overall, the trials were a success and the results obtained were encouraging for the safety and clinical utility of the OroPress tool. Clinical practice must be effective, efficient and, more importantly, safe. Such information about safety is essential before a tool of this nature is used in clinical settings. More studies of this kind would support clinicians to make sound, well-informed clinical decisions about the tools they use in their practice.

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1. Introduction

1.1 Prevalence of Dysphagia

The prevalence of swallowing disorders in the elderly population is increasing rapidly (Yamaya et al, 2001). It is estimated that 15%–40% of people over 60 years of age have dysphagia (Robbins and Barczi, 2003). As many as 50% of nursing home residents have swallowing problems. (Trupe et al, 1984). Swallowing disorders are frequently associated with degenerative conditions such as Parkinson's Disease or stroke but studies have now proved that dysphagia becomes increasingly more prevalent with normal aging, even in the absence of these conditions (Hewitt et al, 2008).

1.2 The Tongue

The tongue has an important role in both the oral and the pharyngeal phases of swallowing. It assists in mastication, bolus formation and particularly in bolus propulsion during swallowing (Kahrilas et al, 1993.) The tongue is a muscular organ, consisting of connective and adipose tissues and it is covered in squamous cell epithelium (White et al, 2009). It has three sections; the anterior, medial, and posterior tongue. When a swallow is triggered, the anterior and medial sections of the tongue elevate in a sequential manner to create lingua-palatal contact creating pressure waves that sweep posteriorly, propelling the bolus into the pharynx (Chi-Fishman et al, 1998). A significant amount of tongue strength (tongue pressure) is needed in to safely propel the bolus into to the pharynx (Robbins et al, 1995).

Research has now suggested that dysphagia occurs due to the reduced ability of the tongue to propel the bolus into the pharynx (Utanohara et al, 2008). A decrease in tongue function can occur as a result of degenerative diseases and in normal aging as tongue muscles atrophy with age (Crow and Ship, 1996). If the tongue cannot effectively propel food into the pharynx, food or liquid can enter the airway which then causes severe health problems such as choking, pneumonia, dehydration and malnutrition (Hewitt et al, 2008). Dysphagia resulting from abnormal tongue function may be treated with tongue exercises to help build

tongue strength and maintain its function (Lazarus et al, 2003). Thus measurement of tongue pressure may form an important aspect of swallowing function assessments.

1.3 Instruments

Several devices, including the Iowa Oral Performance Instrument (IOPI), the Kay Elemetrics Swallowing Workstation and various pressure sensors have been developed to measure tongue pressures. There is very little research to support the safety and clinical utility of these tools thus highlighting the importance of the study at hand. The limitations and advantages of the tools mentioned above will be discussed in terms of safety and clinical utility, but first, a definition of the terms 'clinical utility' and 'safety' will be provided.

1.4 Clinical Utility

Smart (2006) defines clinical utility as a multi-dimensional judgement about the usefulness, benefits and drawbacks of an intervention. Law et al (1990) also wrote "if a measure has clinical utility, then it should be easy to use, possible to administer within a reasonable amount of time, its format must be acceptable to the client and the therapist and the information derived from the client must provide useful clinical information" (Law et al, 1990, p.243). Clinical utility is an important factor to consider when making health care decisions. It is also crucial to the success of a tool. Without empirically defined clinical utility, the tool could be discarded by many clinicians (Toomey, 1995).

1.5 Safety

Safety is also an important aspect in the use of medical devices. The World Health Organisation (2012) defines patient safety as "the prevention of errors and adverse effects to patients associated with health care". The safety of any medical device must be ensured before used on a patient due to the fact that medical device use errors are a common source of patient injury and death (Zhang et al, 2003). Thus determining the safety of tools such as the OroPress is empirical.

1.6 Iowa Oral Performance Instrument (IOPI)

Yoshikawa et al (2011) described the IOPI tool as handy and easy to use by everyone. That study found that the tool's position cannot be adjusted because the air filled bulb slides too easily on the surface of the tongue. Patients in a similar study reported that the

IOPI is difficult to use because the bulbs slide around the oral cavity too much (Hewitt et al, 2008). According to Utanohara et al (2008) the usefulness of the IOPI device is limited by the size of the bulbs, lack of precise fit and protruding recording wires that do not allow the jaws to close, thus proving to be an uncomfortable fit for the patient. Some subjects in a study undertaken by Gingrich et al (2012) reported a gag reflex in response to the insertion of the IOPI and the study also determined that the tool was prone to measurement error as it is difficult for a person to hold the device in a consistent way during swallowing. It is evident from the literature that the main disadvantage of the IOPI is its unsuitability for evaluating natural mastication and swallowing, as it must be used without complete closure of the teeth (Ono et al, 2004).

1.7 The Kay Swallowing Workstation

The Kay Swallowing Workstation (KSW) is one of the most commonly used instruments to record tongue pressure measurements. It has a silicon strip with three air-filled sensors situated the same distance apart. There are two versions of the KSW; one is a hand-held device, which is held on the tongue by the participants while they swallow and the other is a hands-free version, a silicon strip which is adhered to the hard palate for measuring tongue to palate pressure. Yoshikawa et al (2011) found that the KSW is not easy to handle and insertion can be tricky as an operator is needed to put the sensor sheets in the patient's mouth. In a study carried out by Pelletier and Dhanaraj (2006), only data from 10 of 18 healthy participants could be collected as some participants could not tolerate the device in the oral cavity. The device elicited gagging and there were also issues with adhesion to the hard palate due to excessive saliva production. This proves that not only are the attributes of the device itself, important for their success in clinical use, but the individual's tolerance and comfort levels with the device are paramount also.

1.8 Pressure Sensors

A study by Hori et al (2009) demonstrated that when a sensor was used for tongue pressure measurement, the participants could chew and swallow solid foods with minimum discomfort due to its thinness. It was easy to remove and the remaining adhesive was easily removed also. The thinness of the sensor sheet was effective in reducing discomfort in the oral cavity. Comfort and minimal obtrusiveness of a device is important as the presence of

any foreign object in the mouth may change the normal swallowing physiology and may also affect measurement accuracy (Pelletier and Djanaraj, 2006; Hind et al, 2005). With the OroPress in situ, subjects can close their mouth thus allowing a natural mastication and swallow. The tool does not slide around the mouth and it is a wireless tool which means subjects are not required to hold it in place.

The purpose of this study was to investigate the clinical utility and safety of a new wireless tool, the OroPress, which has been developed to record tongue pressures in individuals while swallowing boluses of different consistencies and volumes. This tool examined the range and variance of normal tongue swallowing pressures with the aim of obtaining normative date to improve the management and treatment of patients with dysphagia later down the line. The aim of this paper is to provide evidence, both positive and negative, regarding the safety and utility of the OroPress. What were the participants' opinions of the tool? Did the student researchers find it clinically useful? What do clinicians expect from such a tool?

2. Method

2.1 Participants

Thirty five healthy adults; 17 males of 18 to 63 years and 18 females from 19 to 70 years, were recruited purposefully across the UL campus and approximately one third of participants were recruited through verbal request to personal friends and classmates. Participants were approached by the student researchers on the UL Campus and were given a brief description of the study, both verbally and as a written flyer. If interested, their name and contact numbers were noted and the participants chose a time and a date that suited them from a proffered timetable. Participants were included if they provided written consent to participate in the study and appeared able to complete the tasks required. Participants were excluded if they reported a history of swallowing difficulties, a medical condition or use of medications that affected their swallowing, any reported structural or functional oral abnormality, an overly sensitive gag reflex or had an inability to follow verbal commands.

2.2 Materials

Prior to participation, all subjects completed a study information sheet (see appendix A), a consent form (see appendix B) and a medical screening form (see appendix C). The order of the bolus, the order of the trials (i.e. swallowing vs isometric) and the order in which the screen would be shown to participants during the isometric trials were pre-randomised using www.randomization.com. The pertinent researcher wore latex gloves throughout each trial for hygiene purposes. An oro-motor examination form (see appendix D), a pen torch and a tongue depressor were used for an oro-motor examination. A yellow circle was placed on the wall at the participant's eye level. This was done to stabilise head movements during the trials to allow for greater accuracy of measurement. The OroPress tool was used to capture tongue pressure measurements. The tool consists of a small pressure sensor implanted into a flexible silicon casing. The sensor was connected, via a headset, to a battery operated electronic system for data capture to a laptop. The sensor was attached to each participant's hard palate using denture fixative strips and, in cases where adhesion was an issue, (e.g., due to a very narrow hard palate) some denture fixative paste was additionally applied over the strip to secure adhesion. Ten and 5ml syringes were

used for both bolus measurement and for placing the food/fluid into each participant's mouth. Mineral water was the thin consistency and custard was the semi-solid consistency. A stopwatch was used to time the isometric strength tasks. A digital camera was employed to photograph and document each participant's oral cavity post-swallow to rate the level of residue on a three point rating scale (see appendix E). Immediately after each trial, both the student researcher and the participant completed a safety and utility questionnaire (see appendix F). A Tristel Trio sterilisation kit was used to sterilise each sensor after each trial and mini plastic bags were used to separate the sterilised sensors from the used ones.

2.3 Ethical committee approval

Written approval was obtained from the Faculty of Education and Health Sciences' Research Ethics Committee at UL prior to the commencement of the study.

2.4 Method

Three student researchers were each assigned the following roles; (i) the technician, who was responsible for data capture; (ii) the assistant, who loaded the syringes, prepared the materials between each subject, assisted the researcher or the technician when required, kept clinical notes during each trial and sterilised the sensors; and (iii) the researcher, who welcomed each participant, assisted them in completing the relevant forms and carried out the trials. In the clinic waiting room, each participant signed an informed consent form (appendix B) having first read the participant information sheet (Appendix A). Each participant also completed a medical screening questionnaire. A participant was then brought into a clinic room where an explanation of the trial was provided by the student researcher. An oro-motor examination was carried out by the student researcher, when the participant's gag reflex was tested. The headset device was placed on the participant's head and the sensor was attached to it. The technician asked the researcher to gently press the sensor to ensure data was being accurately fed to the laptop. The technician saved each data file with the subject identification, sensor number and date. A denture fixative strip was dipped in water for one second and placed on the sensor, which was then attached to the mid-point of participant's alveolar ridge. Water moistened the strip making it much stickier which assisted adhesion.

To become familiar with the sensor in situ, each participant was asked to undertake a dry swallow and was then given a sip of water, but no recordings were taken. Before data capture commenced, the researcher ensured that the yellow disc was at the participant's eye level and that the chair was at a distance of 180cm away from that disc. During each trial, the participant was instructed to keep their feet flat on the ground and to look ahead at the disc to stabilise their head movements. Participants were asked if they felt comfortable to proceed and then the data capture began. Each swallowing trial consisted of the researcher placing the measured boluses, singly, via a syringe into a participant's mouth. Participants were instructed to, "hold the bolus in your mouth, look straight ahead at the yellow disc and swallow in one go when I say swallow now." A digital photo was taken of each participant's oral cavity to assess any residue post-trial.

There were two tasks conditions in the isometric trials; strength and endurance. Each condition consisted of three trials, with the first being a practice (non-recorded). In the strength task, a participant was instructed to, "push the tip of your tongue against the sensor as hard as you can for 3 seconds." The assistant timed the task and told a participant when to stop. In the endurance task, the participants were instructed to, "push the tip of your tongue against the sensor as hard as you can for as long as you can." The technician watched the pressure wave on the screen and, when a noticeable dip in pressure occurred, she told the participant to 'stop.' A bio-feedback element was included in the strength and endurance conditions. For each trial, a participant was asked to look at the screen when undertaking one of the tasks.

When all trials were complete, the student researcher removed the sensor and headset. The participant was offered water. Each participant was then given a safety and clinical utility questionnaire to complete which the student researcher also completed (Appendix F). The assistant sterilised the sensor and placed it in the 'clean area,' ready for use with the next participant.

The technician ensured that all data had been successfully recorded before a participant left the room. The data were then saved onto a USB and copied to an Excel spreadsheet to be converted into graph form for post-hoc analysis. The assistant thanked the participant for

their time and asked whether they wished to receive general feedback about the study via e-mail and documented those who expressed an interest.

2.5 Data Analysis

Grounded theory is a qualitative methodology that is based on the idea of generating theory from research, i.e., theory is 'grounded' in the data. Morse (1992) suggests that grounded theory is useful when little is known about a particular subject or problem area. Stern (1980) advocates its use to gain a fresh perspective in a familiar situation, especially in areas of change. Given that this was the first time that the safety and clinical utility of the OroPress were being investigated and it was a newly developed tool, a fresh perspective was of benefit. Grounded theory therefore was an appropriate method of inquiry. The questionnaire data were formatted as tables, to create a textual database and to allow reading and re-reading of the data. The student researcher reviewed the tables several times to become immersed in the data and to distinguish significant codes within them. Data analysis was conducted using the constant comparison technique, open coding, axial coding and selective coding as outlined by Strauss and Corbin (1998), an example of this is in Table 1. Open coding relates to the breaking down, analysis, comparison and categorisation of data (Glaser, 1978; Strauss and Corbin, 1990). Axial coding distinguishes relationships between categories and subcategories (Strauss and Corbin, 1990), while selective coding involves relating categories to the core category which ultimately form the basis for the grounded theory (Glaser 1978, Strauss and Corbin, 1990; Urquhart, C. 2013).

Table 1

Coding Process

P/R	Comment	Open	Axial	Selective
P.3	Well-explained and plenty of time to get used to it.	Feelings re participation	Comfort	Safety
P.18	It was very interesting to be part of the trial. Quick, simple, effective. Easy to follow instructions and custard!	Feelings re participation	Comfort	Safety & Utility

P.20	It was good to be participating in a research study. The researchers made me feel at ease and appreciated my participation.	Feelings re participation	Comfort	Safety
P.21	It was quite interesting to see how the sensor fits in the mouth and how it feels to swallow with a sensor in situ.	Feelings re participation	Comfort	Safety
R. 1	Needed to use paste on top of the strips	Paste	Adhesion	Utility
R. 3	Participant disliked residue from the strips also helped to push p's head forward to secure sticking	Residue	Comfort	Safety
R. 2	Headset was too big for participant's head and kept slipping off (female)	Headset	Comfort	Safety

Note: P= Participant, R=Researcher

Another table was created to summarise the participants' and researchers' levels of agreement with the statements from the questionnaires. Percentages were then created, based on the figures. This is outlined in Table 2.

Table 2

Percentages

Statement	**Strongly disagree**	**Disagree**	**Neither agree/ disagree**	**Agree**	**Strongly agree**
Sensor was easily applied	5 (15%)	9 (27%)	3 (9%)	14(42 %)	2 (6%)
Difficult to locate alveolar ridge	3 (9%)	26 (74%)	0 (0%)	3 (9%)	1 (3%)

As a separate exercise, three questionnaires to ascertain which factors the OroPress 'must have' in terms of clinical utility were sent to three expert clinicians; a head and neck/ENT

surgeon and two speech and language therapists. The results will be discussed under ‘Results’.

3. Results

Thirty five participants took part in this study and data were obtained through questionnaires. Data was also obtained from the three student researchers who conducted the trials through sections that were aimed at the researches as part of the safety and clinical utility questionnaires. The only missing data were from two researchers' sections in the safety and utility questionnaires; only 33 out of the 35 of the researcher sections in the safety and utility questionnaires were completed as the student researcher forgot to complete this section for two trials on a particular day.

Data were also obtained from questionnaires returned from three expert clinicians; one head and neck surgeon and a speech and language therapist (SLT) in London and one SLT from Dublin. The questionnaires were designed to elicit opinions about a new tool in relation to safety and clinical utility. Codes and themes were derived from the written text. The researchers' and the participants' level of agreement with various statements pertaining to the safety and clinical utility of the OroPress were calculated and these are illustrated in Table 3 and in Table 4.

Table 3

Levels of agreement from Participants

Statement	**Strongly disagree**	**Disagree**	**Neither agree/ disagree**	**Agree**	**Strongly Agree**
I did not like the sensor being put in my mouth	42% (n=15)	35% (n=12)	20% (n=7)	2% (n=1)	0%
Sensor felt comfortable in my mouth	0%	5% (n=2)	20% (n=7)	54% (n=19)	20% (n=7)
Sensor felt secure in my mouth	0%	2% (n=1)	8% (n=3)	57% (n=20)	31% (n=11)

Headset was comfortable on my head	5% (n=2)	8% (n=3)	2% (n=1)	37% (n=13)	45% (n=16)
Sensor did not change the way I normally swallow	0%	8% (n=3)	20% (n=7)	45% (n=16)	35% (n=12)
Sensor made me gag when swallowing	68% (n=24)	25% (n=9)	2% (n=1)	0%	2% (n=1)
I felt safe with the sensor in my mouth	0%	0%	0%	35% (n=12)	65% (n=23)
I felt uncomfortable during the tongue pushing task	57% (n=20)	22% (n=8)	11% (n=4)	5% (n=2)	2% (n=1)
It was helpful to see the screen during the tongue pushing task	2% (n=1)	0%	11% (n=4)	40% (n=14)	45% (n=16)

Note: n = no. of participants

The significant results in the table above were as follows: a total of 88% (n=31) of participants felt secure with the sensor in their mouth; a total of 80% of participants (n=33) either 'agreed' (45%) or 'strongly agreed' (35%) that the sensor did not change the way they naturally swallow; sixty eight percent (n=24) 'strongly disagreed' and 25% (n=9) 'disagreed' that the sensor made them gag when swallowing; a total of 93% (n=33). A total of 85% (n=30) of participants thought it was helpful to see the screen during the tongue pushing task; 40% (n=14) 'agreed' and 45% (n=16) 'strongly agreed.' Only 2% of participants (n=1) disliked the sensor being put in their mouth and 22% (n=8) felt uncomfortable with the sensor in their mouth. In response to the statement '*the sensor changed the way I normally*

swallow', the highest number of participants chose 'neither agree/disagree': with 22% (n=8) of participants choosing that statement.

Table 4

Level of agreement from researchers

Statement	**Strongly disagree**	**Disagree**	**Neither agree/ disagree**	**Agree**	**Strongly agree**
Sensor was easily applied	15% (n=5)	27% (n=9)	9% (n=3)	42% (n=14)	6% (n=2)
Alveolar ridge was easily located	0%	9% (n=3)	0%	75% (n=25)	15% (n=5)
Sensor easily adhered to alveolar ridge	15% (n=5)	27% (n=9)	12% (n=4)	37% (n=13)	6% (n=2)
Sensor was easily sterilised	0%	3% (n=1)	0%	48% (n=16)	48% (n=16)
Headset was easily placed on the participant	6% (n=2)	30% (n=10)	9% (n=3)	39% (n=13)	15% (n=5)
Computer software was difficult to use	42% (n=14)	54% (n=18)	0%	3% (n=1)	0%

Note: n = no. of trials

The significant findings in Table 4 are that, in 32 out of 33 trials, the student researchers felt that the sensor was easily sterilised; the researchers 'agreed' with this for 16 trials and 'strongly agreed' for another 16 trials. The researcher 'disagreed' for only one trial. From a total of 32 trials, the researchers 'disagreed' that the computer software was difficult to use;

they ‘strongly disagreed’ for 14 and ‘disagreed’ for 18 trials. There was only one trial in which a researcher ‘agreed’ with this statement.

There were mixed results regarding the application and adhesion of the sensor. In relation to the statement ‘*the sensor easily adhered to the alveolar ridge*’, researchers ‘disagreed’ in 14 trials; ‘strongly disagreed’ in 5 trials and ‘disagreed’ in 9 trials. They all, however, agreed that the sensor easily adhered to the alveolar ridge in 15 trials out of 33; ‘agreed’ in 13 and ‘strongly agreed’ in 2, indicating a very near 50/50 result regarding adhesion. In relation to application, results were similar. In a total of 14 out of 33 trials, the researchers reported that the sensor was easily applied - but disagreed with this in 16 trials out of 33. The highest number of trials in which ‘neither agree/disagree’ applied was in relation to the statement; ‘*the sensor easily adhered to the alveolar ridge’*.

The number of attempts it took to apply the sensor during the trials is illustrated in table 5.

Table 5

No. of attempts to apply sensor

1	**2**	**3-4**	**5-10**	**10+**
42% (n=14)	21% (n=7)	36% (n=12)	0%	0%

Note: n= no. of trials

One attempt was the most frequent, occurring in 14 trials out of 33, with 3-4 attempts being the second most frequent, for 12 trials.

3.1 Themes

There were a total of 24 codes that were identified and aggregated, according to semantic relationships, into two main themes. The 24 codes were; feelings about participation, comfort, paste, adhesion, palate, braces, residue, water, head positioning, pressure, headset, software, portable, ease of use, size, replicable placement, multiple uses, fast, cost, non-interference with swallow, data retrieval, wireless, sterilisation, and dislodgement.

Two main themes were developed from these codes: safety and utility. Figure 1 and Figure 2 illustrate how the codes were aggregated in relation to their semantic relationships and how they specifically related to each theme.

Figure 1: *Safety Category Map depicting corresponding codes*

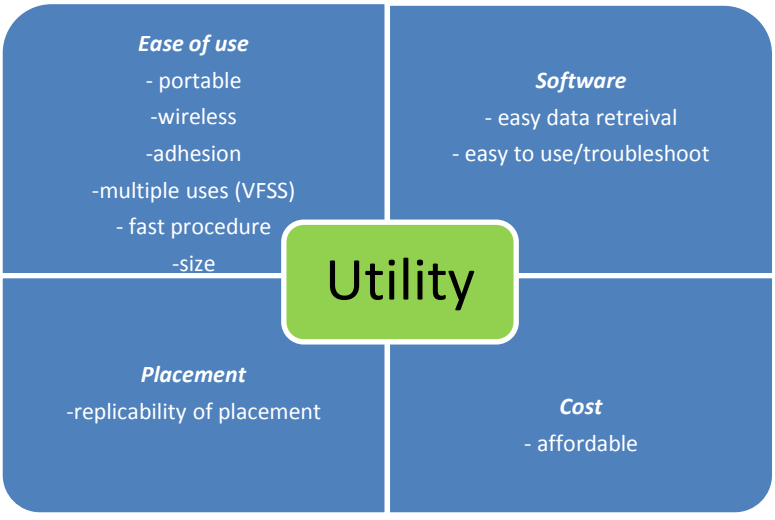

Figure 2: *Utility Category Map depicting corresponding codes*

An example of the coding process is in Table 1. Table 6 gives a summary of the most frequent codes from the analysis, along with their corresponding verbatim quotations.

Table 6

Most frequent codes revealed in the analysis

Open codes	**Verbatim quotations**
Feelings re participation	*"well explained and plenty of time to get used to it", "it was fun taking part", quick, simple, effective", "the researchers made me feel at ease and appreciated my participation", "easy to follow instructions", "researchers were very confident and reassuring, also fast procedure", "it wasn't invasive and staff were very gentle", "very easy and painless", "I was comfortable and I felt like I was making a contribution".*
Adhesion	*"participant had a very narrow and high palate", "alveolar ridge had a number of indents", "firm pressure needed to stick the sensor", "participant had a high-arched palate", "asking participant to take a sip of water and push head down against pressure helped adhesion".*
Comfort	*"Participant disliked residue from denture strips", "headset too big for participant", "headset was a little small for this participant", "participant said she felt like she was wearing a brace".*

The data obtained from the three expert clinicians were combined into a table which clearly highlighted the properties that were agreed upon by all three clinicians. This is represented in Table 7.

Table 7

Properties the OroPress must have, according to Expert Clinicians

"Must Have"	**Clinician 1**	**Clinician 2**	**Clinician 3**
Easily portable tool	x		x
Small profile/size of sensor	x	x	x
Ability to achieve replicable sensor position	x	x	x
Ability to use tool during a VFSS	x	x	
Ability to have data storage on the laptop			x
Fast and easy to setup and use	x	x	x
Fast and easy data retrieval		x	x
Sterlisable (re-use) sensor			x
Single use sensor			
100% wireless tool			x
Sensor can be left in situ for data capture (e.g. through a meal) and removed later, so data download is post-hoc	x		

There were three properties that were agreed on by all three clinicians, which were; 'small profile sensor', 'ability to achieve replicable sensor position' and 'fast and easy to set up and use.' All three clinicians also commented that it was important that a new tool be 'affordable' or be available at a 'reasonable cost'. Two clinicians agreed that 'fast and easy data retrieval' were a 'must have' alongside it being an 'easily portable tool' and having the

‘ability to use the tool during a VFSS.’ No clinician thought that a ‘single use sensor’ was a ‘must have’ and only one clinician opted for the following items as ‘must haves:’ ‘Sensor can be left in situ for data capture’ (e.g., through a meal); ‘100% wireless tool’; ‘sterilisable (reusable) sensor’; and ‘ability to have data storage on the laptop.’ These results will be further examined under ‘discussion.’

4. Discussion

The significant findings obtained in this study will be further discussed in this section. Indications for further research and the strengths and weaknesses pertaining to the study will also be considered. This section will focus on too on the importance of this study and what the OroPress tool has to offer in comparison to other tools that are already being utilised in clinical settings. The final paragraph in this section will address where this study sits in terms of the literature that is already out there. The following paragraphs will firstly discuss the significant findings drawn upon in this study.

There were a number of significant factors that emerged from the student researchers' perceptions of the various attributes of the OroPress, they were: sterilisation; computer software; insertion; adhesion; and the headset. The results show that the student researchers found the sterilisation of the sensor and the usage of the computer software very straightforward and easy to use, supporting good clinical utility in terms of ease of use and safety in terms of sterilisation and infection control.

Feedback was mixed in relation to the application of the sensor, the adhesion of the sensor and the placement of the headset on the participants. Researchers had some difficulty with the adhesion and the application of the sensor to the hard palate for nearly 50% of the trials. This was particularly difficult when participants had high-arched and/or narrow palates or if they had dental bars inserted behind their top teeth.

It took 3-4 attempts to secure the OroPress tool to the hard palate in 12 trials (or one third of the trials). However on the final day of the trials, it was discovered that asking the participant to push their head slightly down against the pressure being applied by the researcher when applying the sensor significantly improved adhesion and, on this particular day, attempts at applying the sensor reduced to one attempt per participant for 8 of the 9 participants who attended that day. This indicated a learning effect for the student researchers.

The headset also raised some concerns in a number of trials. It could not be adjusted sufficiently to the exact size of each person's head, so it frequently slipped off during

testing. The student researcher had to hold the headset in place in these instances. In future, this issue could be easily addressed by using an adjustable headset.

The study results were extremely positive for safety of the OroPress. The majority of participants felt safe with the sensor in their mouth, reporting that it did not change the way they normally swallow and they also reported that the sensor did not make them gag when swallowing. In this study, there was no apparent risk of choking as the sensor did not dislodge, it did not interfere with any participant's normal swallow and the sensor did not elicit gagging. As a safety feature, the intra-oral sensor has a very thin whisker that protrudes from the mouth, thus making it very hard to dislodge and swallow the sensor accidentally.

The results were also favourable in terms of comfort. Of 35 participants, 26 reported that the sensor 'felt comfortable in their mouth,' 29 reported that the headset 'felt comfortable on their head' and 27 participants were 'comfortable with the insertion of the sensor into their mouth.' The most frequent item that emerged from the analysis of the participant's comments was, 'comfort.' Many participants commented that the trials were 'fun', 'painless', 'interesting' and 'comfortable.'

The level of participant compliance during the trials was 100% and the student researchers believed that this was due to the comfort levels experienced by the participants with the OroPress in situ. These are very encouraging results for use of the OroPress as the high comfort levels associated with the tool, will in turn, contribute to the safety and the clinical utility of the tool. The participants were comfortable, thus compliance was high which made the study an enjoyable and painless process for all involved. A very promising outlook for the OroPress and the tool also did well in comparison to the requirements outlined by the three expert clinicians, as the next paragraph details.

4.1 OroPress 'must haves'

From a questionnaire survey, three expert clinicians (a head and neck surgeon and two experienced speech and language therapists) agreed unanimously on the following factors as 'must have' properties that the OroPress should possess: 'small profile'; 'ability to achieve replicable sensor position'; and 'fast and easy to set up and use.'

The OroPress demonstrates all of the 'must have' properties agreed upon by all three clinicians. The sensor has a small profile and the high comfort levels reported by the participants with the tool in their mouth supports this. The student researchers each used the alveolar ridge as a reference point when inserting the tool and, in a total of 90% (n=30) of the trials, the researchers agreed that the alveolar ridge was easily located. Although each mouth may be of a different shape and size, using the alveolar ridge as a reference point for fitting the sensor proved to be very successful.

The results also revealed that the OroPress tool was very straightforward and fast to set up and use. The student researches agreed that the software was easy to set up and use in 96% (n=32) of trials. The trials ran very smoothly and some participants even commented on the prompt nature of the process. Among the written comments from the feedback questionnaire were, "quick, simple, effective"; "fast procedure"; and "very easy." It is evident from the results obtained in this study that the OroPress meets all the 'must have' requirements desired by experts.

This pilot study, although robust in many facets, had some strengths and weaknesses which are now discussed as follows:

4.2 Study Strengths and Weaknesses

All three researchers were pleasantly surprised at the reaction of the participants who were approached on the university campus. An overwhelming majority of them agreed to participate immediately. A total of 35 participants were recruited and 34 participants attended the trials, with only 1 participant who failed to attend. Alternative arrangements were made through convenience sampling to replace that person. The student researchers were extremely pleased with this accrual. All 35 participants also expressed they would like to receive feedback regarding the outcome of the study and overall, showed a keen interest in the study results.

All 35 participants were extremely compliant throughout the trials which made the process both enjoyable and trouble-free. As the study was a pilot, it was important to source a representative sample from both genders and across a wide age range of ages; between 18 and 70 years. The researchers achieved their planned sample size, with a good

representation for a pilot study of this kind. For future studies, the sample could be larger with a wider age representation from both sexes.

4.3 Literature

Little research has been done to examine the clinical utility, and in particular the safety, of tongue pressure measurement tools. Given that the tongue's role in swallowing is extensive and that disordered tongue strength and coordination can be detrimental to safe and efficient swallowing, objective evaluation of tongue functioning is imperative to clinical swallowing evaluation (Youmans, 2006; Gingrich et al, 2012). Objective instruments to measure tongue function have not yet been widely implemented at a clinical level. This may be due, in part, to insufficient research on tongue function measures that then inhibit the clinical usefulness of instrumental devices (Youmans, 2003; Youmans et al, 2006). The research undertaken to date focuses on the measurement accuracy of these tools rather than their clinical usefulness and safety. If such devices are not deemed safe, they simply cannot be used on patients (Zhang et al, 2003). Although accuracy of measurement is imperative, this study emphasises that the safety and clinical utility of such tools must not be overlooked.

5. Conclusion

Overall, the results obtained in this study were encouraging for the safety and clinical utility of the OroPress tool. The OroPress was shown to be both safe and clinically useful, as a fast and easy tool to use for recording tongue pressure measurements. Some small alterations to the headset design may improve clinical utility in future studies. Asking the participant to push their head down slightly when the researcher inserts the sensor should be incorporated to the protocol for more secure sensor adhesion.

Clinical practice must be effective, efficient and, most importantly, safe. Safety information is essential before a tool of this nature can be used in clinical settings. This study provides a positive outlook for the OroPress in terms of its safety and clinical utility with patient populations. As accountable clinicians, we must be cautious when using tools where clinical utility and safety is unknown, while we endeavour to provide high-quality care based on strong evidence. More studies of this kind would support clinicians to make sound, well-informed decisions about the tools they use in practice.

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Appendix A: Study Information Sheet

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

What Is The Purpose Of This Study?

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

What Does The Study Involve?

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

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

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

We will then ask you to push the tip of your tongue against the sensor as hard as you can for three seconds. This will be repeated three times with small intervals in between. Finally we will ask you to push the tip of your tongue against the sensor for as long as you can. This will also be repeated three times with small intervals in between. We will then remove the sensor and ask you to complete a short questionnaire about the comfort of the OroPress

and your views about it. The whole study will take place at the University of Limerick. All in all, the study time will last approximately one hour.

What will I need to do next?

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

What Are The Benefits Of Participating In The Study?

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

Is There Any Risks If I Participate In The Study?

There are no risks associated with participating in this study.

Do I Have to Participate In The Study?

Your participation in the study is purely voluntary.

Will I Receive Any Compensation?

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

What Will The Information I Give Be Used For?

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

What About My Confidentiality?

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

What If I Want To Leave The Study?

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

Is There Ethical Approval For This Study?

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

Is There A Complaints Procedure?

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

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

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

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

Address: Dept. of Clinical Therapies, Faculty of Education and Health Sciences, University of Limerick.

Phone: 0857809500

Email: 11010223@studentmail.ul.ie

Appendix B: Consent Form

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

Consent Form

Please read the statements below and tick the appropriate box.

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

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

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

Signed: _____ Date: _____

(Print Name): _____

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

Signed: _____ Date: _____

(Print Name): _____Phone Number: _____

Email Address: _____

Appendix C: Medical Screening Form

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

Participant Details

ID Number _____

Sex: Male ☐ Female ☐

DOB: _____ Age: _____

Address: _____

Ph No: _____ (house) _____ (mob)

Medical History

Please tick the appropriate boxes:

1. How is your general health today? ☐ Good ☐ Not Good
   If not good, please describe:

   _____

   _____

2. Do you have any swallowing problems? ☐ Yes ☐ No
   If yes, please describe:

   _____

   _____

3. Have you had any swallowing problems in the past? ☐ Yes ☐ No
   If no, go to Q 5. If yes, please describe below and then continue to Q4.

_____

_____

4. Are you currently receiving any help with swallowing? ☐ Yes ☐ No

   If yes, please describe:

   _____

   _____

5. Do you have any major medical problems? ☐ Yes ☐ No

   If yes, please describe below. If no, go to Q8.

   _____

   _____

6. Does your medical condition affect your breathing? ☐ Yes ☐ No

   If yes, please describe:

   _____

   _____

7. Does your medical condition affect your swallowing? ☐ Yes ☐ No

   If yes, please describe:

   _____

   _____

8. Are you taking regular medication? ☐ Yes ☐ No

   If yes, please list:

   _____

   _____

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

   _____

   _____

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

    _____

    _____

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

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

Appendix D: Oro-Motor Form

ORO MOTOR EXAMINATION

Participant No: _____

Date: _____

Student: _____

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

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

			perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
	Elevation	Try to touch your nose with your tongue like this (demo)	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
	Depression	Put your tongue down to your chin like this (demo).	1) 0 abnormalities noted 2) Mild abnormality noted	

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

		to hold your tongue down with a wooden spatula to look at the back of your throat, with a torch.	noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task:	
	Elevation of Uvula on 'ah'	Now say 'ah' and hold it for a few seconds	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Voluntary Cough	Strength	Cough/clear you throat for me please	1) 0 abnormalities noted 2) Mild abnormality	

			noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	
Gag reflex	Sensitivity	Open your mouth wide please, I'm going to test your gag reflex.	1) 0 abnormalities noted 2) Mild abnormality noted 3) Abnormality obvious but can perform task reasonably well 4) Some production of task but poor in quality, unable to sustain, inaccurate/extremely laboured 5) Unable to undertake task	

Appendix E: Residue Rating Scale

Residue Rating

Please circle accurate rating

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

Appendix F: Safety and Utility Questionnaire

Safety and Utility Questionnaire

Participant Number: _____

Date of Assessment: _____

Place of Assessment: _____

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

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

**Please check ✓only one:*

Statement	**Strongly disagree**	**Disagree**	**Neither agree/ disagree**	**Agree**	**Strongly Agree**
I did not like the sensor being put in my mouth	□	□	□	□	□
Sensor felt comfortable in my mouth	□	□	□	□	□
Sensor felt secure in my mouth	□	□	□	□	□
Headset was comfortable on my head	□	□	□	□	□
Sensor did not change	□	□	□	□	□

the way I normally swallow					
Sensor made me gag when swallowing	□	□	□	□	□
I felt safe with the sensor in my mouth	□	□	□	□	□
I felt uncomfortable during the tongue pushing task	□	□	□	□	□
It was helpful to see the screen during the tongue pushing task	□	□	□	□	□

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

Please explain:

_____

_____

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

**Please check ✓only one:*

Statement:	**Strongly disagree**	**Disagree**	**Neither agree/ disagree**	**Agree**	**Strongly agree**
Sensor was easily applied	☐	☐	☐	☐	☐
Difficult to locate alveolar ridge	☐	☐	☐	☐	☐
Sensor easily adhered to alveolar ridge	☐	☐	☐	☐	☐
Sensor was difficult to sterilise	☐	☐	☐	☐	☐
Headset was easily placed on the participant	☐	☐	☐	☐	☐
Computer software was difficult to use	☐	☐	☐	☐	☐
Alveolar ridge was easily located	☐	☐	☐	☐	☐
Sensor was difficult to apply	☐	☐	☐	☐	☐
Sensor was easily sterilised	☐	☐	☐	☐	☐
Sensor did not adhere easily to alveolar ridge	☐	☐	☐	☐	☐
The computer software was easy to use	☐	☐	☐	☐	☐
Headset was difficult to place on the participant	☐	☐	☐	☐	☐

How many attempts did it take to apply sensor?

1	2	3-4	5-10	10+
14 (42%)	7 (21%)	12 (36%)	0 (0%)	0 (0%)

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

_____

_____

_____