

# ULRR

## Examining the perspectives of patients, clinicians and product designers on the design of a tool for measurement and rehabilitation of swallowing

Item Type	Thesis
Authors	Wallace, Nicole
Download date	2026-05-08 15:43:30
Item License	<a href="https://creativecommons.org/licenses/by-nc-sa/1.0/">https://creativecommons.org/licenses/by-nc-sa/1.0/</a>
Link to Item	<a href="https://hdl.handle.net/10344/4963">https://hdl.handle.net/10344/4963</a>



**UNIVERSITY of LIMERICK**  
OLLSCOIL LUIMNIGH

---

*Examining the perspectives of patients, clinicians and  
product designers on the design of a tool for measurement  
and rehabilitation of swallowing.*

---

SL6036

Student: Nicole Wallace

Student No: 13012134

Principal Supervisor: Professor Alison Perry, Dean of Education & Health Science

Co-Supervisor: Dr. Adam de Eyto, Lecturer in Dept. of Design & Manufacturing  
Technology

*A final year project in part fulfilment of the requirements for the Masters of Science in*

*Speech and Language Therapy*

**For the consideration of the Journal of Assistive Technology**

Word count: 7873  
May 12th, 2015



*Acknowledgments*

I would like to thank my supervisors Professor Alison Perry and Dr. Adam de Eyto for their continued support and advice.

Thanks to my final year project partner Tara Hussey for all of her hard work and teamwork.

I'd like to also thank Elayne Taylor for her help in recruiting participants from South Infirmary Victoria University Hospital (SIVUH), Cork.

A special thanks to all of the participants for sharing their knowledge and insights, without which the study and ongoing development of OroPress could not happen.

Finally, thanks to my friends and family for their support all the way.

## Table of Contents

1.0 Abstract .....	p5
2.0 Convention & Glossary.....	p6
3.0 Introduction .....	p7
3.1 Aims.....	p10
4.0 Methods .....	p11
4.1 Participants .....	p11
4.2 Data Collection .....	p14
4.3 Data Analysis .....	p16
5.0 Results .....	p17
5.1 Patient Group.....	p17
5.2 Cross comparison across all groups .....	p21
6.0 Discussion & Conclusion.....	p28
7.0 References.....	p32
8.0 Appendices.....	p35
8.1 Appendix A.....	p36
8.2 Appendix B.....	p43
8.3 Appendix C.....	p45

## 1.0 Abstract

### **Examining the perspectives of patients, clinicians and product designers in the design of a swallowing rehabilitation tool.**

**Background:** Tools available for dysphagia rehabilitation are limited in number and type. OroPress is a clinic-ready prototype tongue pressure measurement tool which may be used by clinicians for assessment and by patients as a rehabilitation tool. To ensure future tool development, it was important to gain the views of key stakeholders.

**Objectives:** To: (i) explore whether patients would use a swallowing rehabilitation tool, (ii) establish how they might use such a tool; (iii) ascertain possible product format and (iv) elicit responses to OroPress as a prototype rehabilitation tool.

**Methods:** A qualitative methodology was applied. Purposeful sampling was used to recruit a sample of participants (N=13) for three Focus Groups (FGs). These were: medical product designers (PD) (N=5), speech and language therapists (SLT) experienced in dysphagia management (N=4) and post-surgical head and neck (HN) cancer patients (N=4). A topic guide, photographs and models facilitated discussions. Data were audio recorded and transcribed post hoc. Thematic analysis was then used to develop open codes, selective codes and themes.

**Results:** Across groups, four converging themes emerged from the data as important considerations in the design of a swallowing rehabilitation tool. These included; ease of use (Primary user usability), how the user might interact with the tool (User interface), how the device operates (product format) and OroPress specific responses (OroPress).

**Conclusions:** Participants in all groups agreed that patients would find a tool useful but views differed across groups on tool use and the desired product format. OroPress may be further developed by incorporating the FGs' convergent views and closely examining divergent views.

**Keywords:** Focus groups, dysphagia, head and neck cancer, rehabilitation, medical device design

## 2.0 Convention

This paper has been formatted for the submission of the Journal of Assistive Technology. Accordingly, it is submitted using the convention of the American Psychological Association (APA). Terms used in this paper are operationalised below.

### Glossary

Activity	The execution of a task or action by an individual (WHO 2001)
Biofeedback	The use of equipment to measure and display signals of body functions (usually visual or auditory signals) to allow clients to develop control over such functions (Steele 2004 p2)
Distress & wellbeing	Level of concern experienced by an individual (Enderby 1998)
Format	The particular way the device operates.*
Impairment	Problems in body function and structure (WHO 2001)
Isometric tongue pressures	Maximal pressure exerted by the tongue on the hard palate (McCormack 2013)
OroPress (C)	A clinic ready prototype swallowing pressure measurement tool (Current model)
OroPress (R)	Proposed rehabilitation model of OroPress
Out of Box experience	Features associated with using the tool for the first time when taken out of its box*
Participation	Involvement in a life situation (WHO 2001)
Primary User or PU	Patient or user*
PU usability	How easy or difficult a primary user finds a product to use*
Secondary User or SU	Clinician, carer, product designer *
User	How the user interacts with the device*

---

\* Definitions provided by Co-supervisor Dr. Adam de Eyto

### 3.0 Introduction

It is estimated that 15-40% of individuals over 60 years of age have dysphagia (swallowing impairment) (Hewitt et al., 2008). This can result in serious medical complications, such as malnutrition, dehydration, aspiration-pneumonia and / or airway obstruction. Dysphagia may also negatively affect a person's quality of life by limiting their participation in social activities which revolve around food (Nund et al., 2014). Dysphagia can manifest differently, depending on whether the structures of the oral cavity (oral dysphagia) pharynx (pharyngeal dysphagia) or both (oropharyngeal dysphagia) are affected. Dysphagia rehabilitation (the reduction of disability by restoring safe - i.e. without aspiration - intake of food, fluids, by mouth following an injury or disease - Linden, 1989 pp 189) is focused on a specific impairment. Typically this is achieved using specific exercises to generate a permanent change in swallowing muscle physiology (Logemann, 1998).

Despite widespread use of such rehabilitation exercises, clinicians lack clarity about how best to guide their patients' rehabilitation and how to assess treatment fidelity. For example, Archer et al. (2013) reported that 93% of clinicians working in dysphagia in the UK and Ireland do not use any protocol for progressing patients' exercises and only 37% used standardised outcome measures. Consequently, patients have reported inadequate clinical support following hospitalisation, as cited by head and neck (HN) cancer patients in an Australian study by Nund et al. (2014). While no similar published study has been undertaken on patients in Ireland, inconsistent follow-up care has been identified for Irish patients who have dysphagia (Kennelly & O'Neil, 2012). Such reports reinforce the need for a reliable instrumental tool to measure and document progress in swallowing rehabilitation.

Numerous swallowing rehabilitation tools are described in the literature, such as the lingual sensors of the *Kay Swallowing Workstation* (KSW) and the *Iowa Oral Pressure Instrument* (IOPI). Such devices work by measuring oro-lingual pressure generation (see Isometric tongue pressures in glossary); a widely documented surrogate used for measuring swallowing efficiency and for predicting a person's risk of dysphagia (Hewitt et al., 2008; Nicosia et al., 2000; Youmans & Stierwalt, 2006; Yoshida et al., 2006). However, these tools have limitations, which includes obstructive sensors, a lack of portability and high

costs (Hewitt et al., 2008). A cross comparison of these tools' design features is provided in Table 1.

An alternative to these devices is OroPress(C); a clinic-ready prototype tool designed for tongue pressure measurement. It consists of a single small sensor that adheres to the hard palate to measure pressures (mmHg) (McCormack et al., 2013). Its fixed position enables reliable and stable measurement of oro-lingual pressures over time. Previous studies have reported participants increasing their isometric tongue pressures in response to biofeedback provided by OroPress (C) (McCormick et al., 2013; O'Brien et al., 2014). OroPress relies on a wireless technology which contributes to its low cost and portability for home use. Further, OroPress(C) was deemed to have a non-intrusive sensor according to a study in which 68% -88% of participants rated it highly for 'comfort', 'secure attachment' and 'sensor tolerability' (Ní Chualáin et al., 2013). These positive attributes (summarised in Table 1) provide support for OroPress(C) to be developed for rehabilitation (OroPress R). At this early stage in design, it is unknown what features patients with dysphagia consider to be useful /essential in a device such as OroPress(R).

Table 1:

*Comparison of tool features of three available oro-lingual pressure measurement devices.*

<u>Tool Domain</u>	<u>OroPress</u>	<u>IOPI</u>	<u>KSW</u>
Bulb/sensors	1 sensor	1 air filled bulb	3 air filled bulbs
Pressure value	mmHg	kPa	mmHg
Level of sensor intrusion	Single flat sensor	Large bulb prevents mouth closure	Multi-sensor intrusive apparatus
Hand Held or Fixed position	Fixed position	Hand held	Both
Portable	Yes (wireless headpiece contains sensor and transducer)	NO - wired	NO-wired to computer
Biofeedback	Yes-graphic or audio	Yes- LED light display	YES – pressure screen
Cost	Low	High	High

*Note.* Adapted from McCormack 2013; O'Brien 2014; Hewitt et al 2008.

Successful medical device development is dependent on understanding the specific needs and behaviour patterns of users. User input has been associated with health related benefits such as improved patient safety, compliance, outcomes and user satisfaction. This may also reduce device development time because usability (ease of use) issues are addressed prior to launch avoiding design changes and (possibly costly) product recalls. (Money et al., 2011). The commercial success of a device such as OroPress (R) therefore requires a user-centred approach to design, to validate and refine the concept behind its use, identify any likely barriers to use and collect user opinions about design preferences (Martin et al., 2012).

Many variables need to be evaluated in tool design. With this particular tool, mode of delivery and tolerance for intra-oral sensors are important factors to explore, as well as the importance that users may place on features such as biofeedback. Biofeedback (see glossary) is a key concept in swallowing rehabilitation tools as it can assist patients to complete their therapy programmes (Steele, 2004).

It is unknown what design features are important to encourage tool use, from both a clinician's perspective and from dysphagic patients' perspectives. Consulting potential users- Speech & language therapists (SLTs), patients and product designers (PD) is required in order to correctly anticipate OroPress(R) users' needs.

Evidence for the importance of user-centred design in anticipating users' needs comes from an NHS study where clinicians' perspectives on an imaging device were investigated, which revealed a fundamentally different clinical need for the device than developers had originally anticipated (Martin et al., 2012). A further example of the importance of documenting user perspectives comes from Nund et al. (2014) who collected HN cancer patients' views for the improvement of follow-up dysphagia care services.

HN cancer is the most frequent cause of structural dysphagia. Therefore HN cancer patients with dysphagia are key stakeholders in using swallowing rehabilitation devices (Corbin-Lewis & Liss, 2015). A further benefit of using participants with HN cancer was that these patients are cognitively intact and usually have no major expressive or receptive language difficulties. They were therefore able to express clear views, unlike many other populations

with dysphagia. For these reasons, this population was chosen to provide design views in the current study.

To develop valid design criteria from these participants' views, a qualitative methodology was chosen. This enabled us to both document patient views and obtain an accurate recording of their described experiences and attitudes (Mays & Pope, 1996). Focus groups (FGs) were useful at this early stage of study to explore and identify the significant issues pertaining to tool use. FGs encourage participants to explore issues of importance to them in their own vocabulary, generate their own questions and pursue their own priorities (Mays & Pope, 1996). Using this approach, we established a design brief grounded in the data.

### 3.1 Aims

There were 4 aims to this study:

**(i): To explore whether patients would use a swallowing rehabilitation tool.**

*Rationale:* It was necessary to validate the target population and clinical need for a tool (Martin et al., 2012). This was important as OroPress has only been used diagnostically to date and the concept of it as a dysphagia rehabilitation tool had not yet been investigated.

**(ii): To establish how stakeholders might use such a tool.**

*Rationale:* Truly anticipating users' needs increases the likelihood of such a device being used and leads to higher user satisfaction (Money et al., 2011). It was therefore necessary to observe the practicalities of using a rehabilitation tool such as OroPress (R) and ensure that patients' behaviours and experiences were fully considered in development.

**(iii): To ascertain a possible product format of OroPress-R.**

*Rationale:* The current model OroPress (C) is a headset format with intra-oral sensor. This was designed as a clinical prototype rather than for rehabilitation. It is conceivable that format preference may differ between such contexts. No published research pertaining to patient perspectives of swallowing rehabilitation tools were found. OroPress (R) may therefore provide the first opportunity for patients and clinicians to provide input for a well-designed rehabilitation tool.

**(iv): To elicit specific views about OroPress as a prototype rehabilitation tool.**

*Rationale:* As all stakeholders were unfamiliar with OroPress(C) it was important to gain their views, their likes and dislikes about the current prototype which may influence the design of a future OroPress (R).

## 4.0 Materials and Methods

This study was approved by the University of Limerick's Education Health Science Ethics Committee (to access PDs and SLTs) and the Clinical Research Ethics Committee Cork (to access SIVUH patients).

### 4.1 Participants

A total of 13 participants were purposefully recruited for this study. Medical product designers (n=5) from the *Department of Design & Manufacturing Technology, University of Limerick* were recruited through email invitation by the student researchers and Dr. de Eyto. Their experience in medical device design ranged from <1-10 years. The PD group consisted of three females, (one aged >45 years and two aged 26-45 years) and two males (aged 26-45 years and 18-25 years).

SLTs (n=4) experienced in dysphagia management were recruited by the student researchers through an oral presentation at a Dysphagia Special Interest Group event. Experience in dysphagia management ranged from <1-10 years. The SLT group consisted of four females in the age range 26-45 years.

Post-surgical HN cancer patients (n=4) were recruited through a local SLT at SIVUH. Time since surgery ranged from 1-9 years. All patient participants had previous or current experience with oropharyngeal dysphagia. The patient group consisted of two males (aged 45-64 years; >65 years) and two females (aged 45-64 years; >65 years). Participant data are summarised in Tables 2-4.

Inclusion criteria included having relevant experience, being fluent in English (to express views accurately at the FG) and being able to give informed consent. Exclusion criteria included having a cognitive impairment or not being able to give consent.

*Table 2*

*Product Designer participant Details*

Participant	Gender	Age (years)	Years in product design	Years in medical design	Education (degree level)
D1	Female	>45	10 +	10 +	Undergraduate
D2	Male	26-45	4-10	<1-3	Postgraduate
D3	Male	18-25	<1-3	<1-3	Undergraduate
D4	Female	26-45	4-10	<1-3	Postgraduate
D5	Female	26-45	4-10	4-10	Postgraduate

Key: D= Product Designers

*Table 3*

*Clinician participant Details*

Participant	Gender	Age (years)	Population	Clinical Setting	Dysphagia experience (years)	Education (degree level)
C1	Female	26-45	Adult rehab	Hospital	10 +	Undergraduate
C2	Female	26-45	Adult acute/ rehab	Hospital	4-10	Postgraduate
C3	Female	26-45	Adult rehab	Hospital	<1-3	Undergraduate
C4	Female	26-45	Adult acute	Hospital	<1-3	Postgraduate

Key: C= SLT Clinicians

Table 4  
*Patient participant Details*

Participant	Gender	Age	Site of cancer	Forms of treatment	Description of difficulties	Effect of dysphagia on everyday life
P1	Female	>65	Thyroid	Surgery (1 yr.), Radiotherapy	Narrow oesophagus where food lodges. Soft diet, can't tolerate spicy food or alcohol.	Slow eater, dislikes spices, curries and alcohol.
P2	Male	>65	Right sinus	Surgery (3 yrs.), Radiotherapy	Plastic palate inserted. Nasal regurgitation and double vision (surgical complication).	Slow eater, avoid eating out in public
P3	Female	46-65	Mouth & Neck	Surgery (9yrs), Radiotherapy	Food left in throat and mouth, difficulty initiating swallow. Ongoing swallowing difficulties. Poor tongue manipulation. Soft/liquid diet. Still aspirates on occasion.	Eating and speech
P4	Male	46-65	Neck and palate	Surgery (3yrs), Radiotherapy	Food gets stuck at side of throat	Socialising and eating out

Key: P= Patients

Note: \*Time since surgery

## 4.2 Data Collection

Participants took part in three separate FGs to explore issues of importance to them. The sessions were organised to suit participants' commitments and were conducted at these locations: University of Limerick (PDs), National Rehabilitation Hospital, Dublin (SLTs) and SIVUH, (HN cancer patients).

Study information sheets were distributed and written consent was obtained prior to the FGs (See Appendix A for consent forms).

All FGs were each run similarly. Participants were welcomed and the purpose of the session was explained by the moderator (student researcher). Participants were informed that the session was being audio-recorded. The moderator had no prior involvement with the participants.

Participants were invited to speak frankly about anything relevant and to feel comfortable about voicing different opinions. They were encouraged to provide negative comments in addition to positive feedback. Confidentiality on the part of the researchers and group members was stressed. A research assistant (another student researcher) was also present, making field notes to capture additional aspects of communication, such as gestures and facial expressions. The student researchers alternated roles of moderator and assistant at each FG.

Discussions were facilitated by a topic guide (See Figure 1 and Appendix A), photographs and models (see Figure 2). The topic guide included open questions about general swallowing tools and then specifics in response to the OroPress (C) device. Discussions were not however confined to these topics. The physical prototype OroPress (C) was only presented to the PD group. Due to logistical issues, OroPress (C) was presented to the other FGs in photographic form. The photograph depicted OroPress (C) being worn by one of the student researchers in an effort to provide scalar information to the participants. At various points in the discussions the moderator summarised points that had been discussed, sought verification and expansion and asked for additional comments. In a few instances, direct questions were asked for clarification purposes. Each session lasted approximately one hour and concluded when all present indicated they had no further contributions to make.

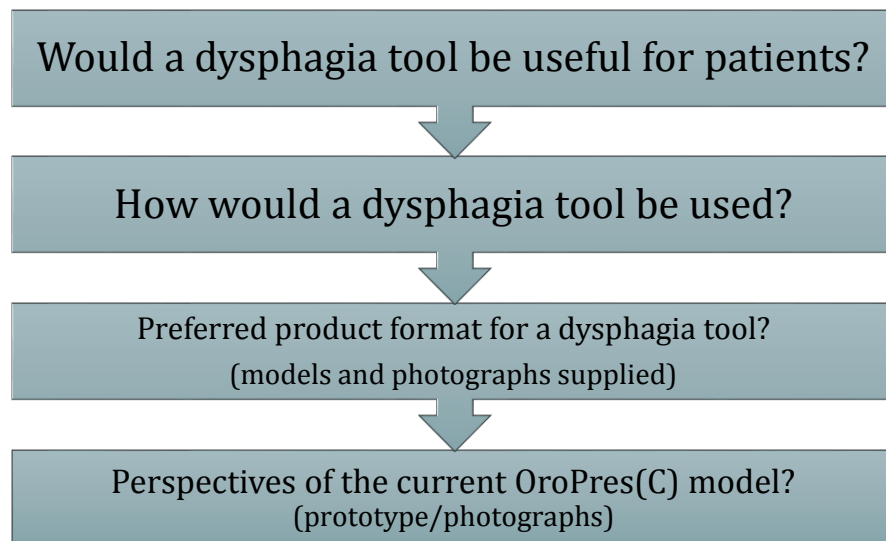


Figure 1. Topic guide questions from the beginning of the FGs to closing the discussion.



Figure 2. Materials used to facilitate FG discussions. (1) Photographs. A: Headset device. Adapted from O'Brien et al., 2014. B: Sensor adhered to neck. Adapted from CPD by DJO Education, (2015). Retrieved from <http://www.djoed.co.uk/cpd-vital-stim.html> C: Sensor adhered to roof of mouth. Adapted from IOPI Medical,. (2013). Retrieved from [http://www.iopimedical.com/Tongue\\_strength.html](http://www.iopimedical.com/Tongue_strength.html). D: Sensor held against neck. Adapted from Laryngectomy Association NSW,. (2011). Retrieved from <http://www.stilltalking.org/booklet.html>. (2) Foam models. A: Handheld tool B: Screen C: Headband D: neck type device E: Sensor. (3) OroPress. A: Current model B: Sensor in situ. Adapted from O'Brien et al. 2014.

### 4.3 Data Analysis

Data were audiotaped using a dictaphone (Olympus VN-755) and transcribed post-hoc by the two student researchers. Two listeners allowed more accurate transcription of the data when intelligibility was poor, e.g. with the patient group. To ensure rigour, a modified Delphi technique was used where reports characterising participants' views were compiled and later posted to participants, giving them the opportunity to make any necessary amendments (a technique previously used in a study by Perry et al., 2004). This ensured that the student researchers understood the meaning behind the verbatim data and assisted categorisation of the data during thematic analysis. Very few alterations were made and no participant changed information content. Of note, the SLT FG only had three participants because of a late cancellation. That FG was run with three clinicians present and subsequently another SLT was interviewed to ensure equal sample size numbers across groups. The transcripts were later together.

The datasets were managed using a Microsoft Excel spreadsheet and were coded using Glaserian coding principles (Urquhart 2013 -see examples in Tables 5-8 and Appendix B.) This involved grouping similar excerpts together and applying analytical (open) codes to meaningful units of data. These were then categorised into subthemes (selective codes).

Using thematic analysis, the subthemes were grouped into themes and were colour coded. First, the patient data were grouped according to three ICF health domains (Impairment, Activity, Participation WHO, 2001) and another UK-TOM domain, Distress & Wellbeing (Enderby, John & Petheram, 1998). Second, all FGs' data were further coded and themes identified independently by the two student researchers. This was performed using a constant comparative method. A deliberate attempt was made to approach analysis without any preconceptions. This process continued until the student researchers fully agreed that the data were correctly represented. Thematic maps were built, reflecting the themes and sub-themes derived from each FG (See Appendix C). Text was examined for convergent and divergent themes, both within and across the three FGs, to fully understand population-specific requirements and compare perspectives common to all stakeholders.

## 5.0 Results

This section presents the major findings of the study and discusses the implications for OroPress (R) development.

### 5.1 Patient Group:

The patient group consisted of four individuals who had experienced dysphagia. Three of the participants (P1, P2, P3) were chatty and willing to voice their opinions whilst one participant (P4) adopted a quieter stance. Identified concepts from the patients' data were linked to health domains from the ICF and UK-TOMs.

Four main themes were categorised from the dataset: (i) Activity, (ii) Impairment (iii) Participation (WHO 2001) and (iv) Distress & Wellbeing (Enderby 1998). A further 24 sub-themes were identified; device format, current functioning, progress, targets, concerns of tool use, compensation, rehabilitation, unsuitability of oral format, primary body structure, comorbidities, time of use, private use, social impact, discretion, distress, depression, discomfort, self-consciousness, fear, caution, wellbeing, coping, perseverance, motivation. These results are presented in the thematic map (Appendix C) and are discussed below, with verbatim quotes.

**Activity**

Activity (WHO, 2001) was strongly represented by the patients. This theme reflected patients' strong desire to return to a 'normal' diet indicating their willingness to use a rehabilitation tool.

*"I suppose there's an optimum number of swallows one can do in an hour or percentages.... something like that to get it normal"- Patient 1 (1 year post-surgery).*

Patients' desires to monitor their own progress and current functioning were also identified.

*"I would tend to be one of those people that if you told me to do it 7x7x7 I would do it 8x8x8 for the results"-Patient 3 (9 years post-surgery)*

Further examples pertaining to Activity can be found in Table 5.

Table 5:

*Activity theme subcategories and illustrative examples*

Subcategory	Example participant quotes
Current treatment	<i>P1: "I don't eat sort of very crusty stuff cause I find that hard. Soft and plenty to drink and no spicy stuff, I can't tolerate that or alcohol. It scalds it or anything sharp".</i>
Motivation	<i>P3: "I would tend to be one of those people that if you told me to do it 7x7x7 I would do it 8x8x8 for the results"</i>
Progress	<i>P1: "I suppose there's an optimum number of swallows one can do in an hour or it could be percentages.... something like that to get it normal".</i>
Design features	<i>P3: "You'd need something portable"</i>

Key: P=Patient

Note. Subcategory refers to selective code.

***Impairment***

Impairment (WHO, 2001) was also significantly discussed (See Table 6 for examples). The patients acknowledged that every patient will have different needs due to varying tumour sites. Nonetheless, as a group they decided an oral format was unsuitable due to their shared experiences of reduced mouth opening and tongue manipulation.

*“Something like that (intraoral) wouldn’t work for me on the palate because the tongue wouldn’t be able to move”. -Patient 3 (9 years post-surgery).*

They further considered comorbid conditions e.g. hearing loss which may require further accommodations in tool design.

Table 6:

*Impairment theme subcategories and illustrative examples*

Subcategories	Example participant quotes
Acceptance & Psychological considerations	<i>P2: “Well I’m resigned to the fact that with the nerve gone up there and seven teeth missing I’ll never be able to chew. I think I’m resigned to that. If I was 30/40 years younger maybe it would be a problem but at 73 it’s not a problem”.</i>
OroPress	<i>P2: “The only thing is this woman (pictured wearing sensor) can open her mouth like a whale I couldn’t get it in”.</i> <i>P3: “I am hypersensitive with nerve damage all down one side so that (weight of headset) will really hurt and irritate. If you’ve had a lot of head surgery, even a little weight on your head hurts”.</i>

Key: P=Patient

Note. Subcategory refers to selective codes.

### ***Participation***

Occasionally, patients referred to participation (WHO, 2001). Examples are found in Table 7 but a main subtheme found was the social impact of dysphagia.

*“Well eating out is something I tend to turn down now because...or if we’re in the restaurant I might face the wall, just in case it runs down my nose or whatever” -Patient 2 (3 years post-surgery).*

Social impact was linked with designing a tool which could be used discretely

*“If you want to use a device in a restaurant you wouldn’t want to be carrying a screen with you or a radio or whatever while other people are there” –Patient 3 (9 years post-surgery)*

Table 7:

*Participation theme subcategories and illustrative examples*

Subcategories	Example participant quotes
Place of use	<i>P3: “I think you’d feel a little too conscious in public, maybe in the house you’d use it but I certainly wouldn’t be wearing a head one like that outside (photograph of a headset)”.</i>
Mode of delivery	<i>P3: “Something against the throat I wouldn’t have a problem with. Something that could be discrete and you could just put a scarf around it or something”.</i>
OroPress	<i>P1: “Wouldn’t wear it in public unless I had to.”</i>

Key: P=patient

Note. Subcategory refers to selective codes.

### ***Distress & Wellbeing***

Elements of distress & wellbeing (Enderby, 1998) were discussed to a lesser extent however the patients did emphasise some influential factors of tool use (See Table 8).

These included positive influences, such as motivation and coping strategies.

*“I think there’s always room for improvement. I’m still trying to improve. I say to myself every morning I’m still trying. I’m still trying” (Patient 3, 9 years post-surgery)* as well as

more negative factors, such as insecurity and an ongoing fear of aspirating. *“I don’t know how many of you have aspirated but my god it is the scariest thing”*- Patient 3 (9 years post-surgery)

Table 8:

*Distress & Wellbeing theme subcategories and illustrative examples*

Categories	Example participant quotes
Clinician involvement	<i>P3: “Initially the amount of appointments, when you're going for chemo, radio, dental, the speech and language therapist, physio and you don't feel well, you're feeling horrible, you don't want people to necessarily see you after surgery, it seemed 2/3 appointments every week”.</i>
Psychological Impact	<i>P2: “There’s an element of depression having had to have this surgery over the years, sometimes you feel low”.</i>
Motivation	<i>P3: “I think there’s always room for improvement. I’m still trying to improve. I say to myself every morning I’m still trying. I’m still trying”.</i>

Key: P=Patient

Note. Subcategory refers to selective codes.

This level of analysis revealed elements of patient behaviour which a potential tool would need to address, such as time and place of use, as well as the physical impairments that a tool might have to accommodate. It further reflected the high awareness patients had of their abilities and difficulties highlighting the importance of user-centred design.

## 5.2 Cross Comparison across all groups

As with the patient group described previously, the SLT group consisted of three talkative participants (C1, C2, C4) and one less forthcoming individual (C3). The PD group on the other hand tended to be dominated by the three female participants (D1, D4, D5) while the male participants offered less input (D2, D3).

The users’ requirements were grouped into a total of five themes. These were: PU usability, User interface, Format, OroPress and Out of Box experience (OBE). Themes and related sub-themes are shown in thematic maps found in Appendix C Figures 3-6 with respect to patient, SLT and PD datasets. Illustrative quotations are included below.

***Would you use a tool?***

There was a number of significant findings which emerged from the data. First, all groups agreed that patients would find a tool useful. This objective was addressed by the prominence of PU usability across groups reflecting the importance of user-centred design. SLTs and patients were most interested in this theme, indicating that ease of using a tool is a primary design priority for both primary and secondary users. There was agreement across all groups that patients could confidently and independently use the tool at home.

*“Something that’s discrete and easy for patients to self-administer is what is needed. They shouldn’t be reliant on a carer especially if they’re trying to garner their independence back. Even if they’re in hospital, they should be able to do this themselves so there’s less of a stress on the carer or the nurses in hospital and then once at home they have a little bit of independence to monitor and manage themselves.”- Designer 4 (3 yrs. experience).*

Secondary User (SLT) involvement was noted across all groups as an important subtheme of PU usability. A consensus was established to transmit patient data to the SLT so that patients can perform rehabilitation exercises at home and only have to come into hospital when necessary. Designer 1 commented,

*“So for example if there’s feedback coming to the clinician, the clinician gets an email to say 'yeah X is doing well', then that clinician could email the patient and say I got your readings, everything is fine and we won’t need you to come in this week, work away. Or else, we’ve a concern, can you come in”.*

Expanding on this point, Clinician 4 stated,

*“The onus is on them, we would give advice and check in twice weekly, then monthly like we would still review people that have been on therabites for years down the line so you would have a connection with them, you’d be putting it on them this is something they do at home, work on and bring them back”.*

This link in service was welcomed by patients.

*“Initially the amount of appointments, when you're going for chemo, radio and the dental hospital, to the speech and language therapist, when you're going to physio and you see*

*that amount of appointments cause you don't feel well, you're feeling horrible, you don't want people to necessarily see you after surgery that initial to me it seemed 2/3 appointments every week”- Patient 3 (9 years post-surgery).*

Compliance was a further point raised by both the SLTs and PDs. The SLT group had particular insight into how a rehabilitation tool could improve treatment fidelity.

*“If you give them something that they can use themselves, something to work towards I think it would definitely give them a better outcome or at least I think it gives them something substantial to work on other than just a few pages wrapped up in their pocket”-*

Clinician 4 (3 years HNC experience)

Some concerns did occur regarding the acceptance of technology by older patients.

However, clinician 4; an SLT working with HN cancer patients, noted that her caseload was much younger and more accepting of technology than other populations. Typically HN cancer patients are also cognitively intact, which may differentiate them from other populations and may influence the complexity of tool design.

### ***How would you use a tool?***

The theme ‘user interface’ was also highly represented across groups. This was a particular priority of the designers. They identified the need for tool functions, such as displaying targets and ways of monitoring progress in a rehabilitation tool. Displays, such as functional scales, percentages, number of swallows and cautionary signals were all proposed but no consensus was reached on one particular method, either within or across groups. For example, within groups designer 4 questioned,

*“Would just eating be enough though, I mean you have eaten this much soup is that not a measure? It’s far more relatable to somebody than arbitrary numbers”* while designer 1 stated

*“Maybe something that’s linked to a screen; a wireless output telling somebody today you did 100 swallows, that’s 90% of what we want you to do”.*

Participants concurred that progress and fidelity to treatment would be encouraged by a form of feedback. Unanimously, feedback was thought to be an important factor across all groups.

*“You can’t compare (feedback). Having that target, whether you’re reaching it or not is crucial”*- Clinician 1 (10 yrs. experience).

However there was disagreement about what kind of feedback would be most suitable. Although the SLTs and PDs discuss many forms of feedback and noted the need for a range of feedback (dependant on the comorbidities of patients), their statements and interactions clearly conveyed a primary interest in visual feedback.

*“I think myself that visual feedback is good, it is really good. I mean I would try to incorporate that into as much dysphagia therapy as possible. I think something like that would work well, and again it’s all about getting the patient on board to take part in the therapy so if they can visually see or are able to track their own progress they see I’m not as good or I’m getting better”* - Clinician 4 (3 years HNC experience).

The patients on the other hand were only enthusiastic about tactile feedback. *“If there was some kind of sensor when you start to swallow correctly, to sort of just pulse that’s not right, try again”*- Patient 3 (9 years post-surgery).

Other tool functions explored by the group included the importance of conceptualisation and taking measurements. Again views differed on where and how measurements should be taken; for example the clinicians debated whether this could be done internally, at the posterior pharyngeal wall or externally, on laryngeal muscles.

### ***What is your preferred tool format?***

Format was critically important across groups. One major design consideration was the unsuitability of the headset format. On examining images of potential formats, Patient 3 remarked,

*“I think you’d feel a little too conscious in public, maybe in the house you’d use it yourself but I certainly wouldn’t think about wearing a head one like that outside (image of headset). It’s like making a fashion statement!”*

Clinician 4 further explained that,

*“Across the head maybe not so much, I think you’re trying to make this as normal as possible for the patients without making them look like they stand out.”*

Design was further complicated by patients stating that they did not wish to have sensors in their mouth due to multiple oral surgeries.

*“Well I have this already (rubber palate) and I’d prefer if I didn’t have it. I’d have enough in my mouth as it is. I wouldn’t fancy any of that stuff”* - Patient 2 (3 years post-surgery)

No consensus was reached over what sort of format should be chosen over another; however there was most agreement that a neck type device should be developed instead. The patient group in particular, all gestured to a neck type device and verbally agreed that such a neck device would offer them the best solution.

*“Something against the throat or something on the throat, I wouldn’t have a problem with. Something that could be discrete and you could just put a scarf around it or something you know, like I wear a scarf already to hide the scar”*. Patient 3 (9 years post-surgery).

Unfortunately, it was not determined how this could specifically be achieved whilst obtaining accurate swallowing measurements.

#### ***What are your thoughts on OroPress?***

Participants across all groups concurred that OroPress could be reduced in size and weight to ensure comfort and discretion. PDs described the OroPress as “too big”, “bulky” and “a little bit degrading” and recognised the need to reduce the technology to a minimum. Weight and size were also important factors to the patients. They suggested making the tool more lightweight as it looked heavy to them. Some patients indicated they had nerve damage following their surgery, so heavy devices would be uncomfortable to wear. The clinicians agreed that the current OroPress model was too bulky and not discrete. They proposed reducing it in size and not having a sensor directly attached as this was very visible and would add to the patients’ dislike of an oral sensor.

*“I suppose the piece coming around from the mouth is very obvious it’s there for everyone to see, they’re going to be very aware”* - Clinician 4 (3 years HNC experience)

Some SLTs had concerns that intra-oral devices may not appropriately target pharyngeal dysphagia seemingly unaware of the influence of isometric tongue pressures on swallowing. This was however, mainly the view of SLTs working with neurological populations rather than HN cancer but suggests a need for evidence based marketing of any new tool.

Patients themselves expressed concerns at not having the physical abilities to use a tool which required tongue-palatal control. When presented with photographs of various tools, all patients preferred an external neck device (adhered to the skin) and suggested such a device would be more suited to their needs and easier for them to use at home. They suggested that such a device could be worn underneath a scarf to ensure discretion.

Further preferences highlighted by the participants were for a tool which could be used sporadically, and be hands free, both of which can currently be facilitated by OroPress.

***Are there other considerations for developing the product?***

OBE was an additional theme commented on in both the PD and SLT FGs. Subthemes included education, cost, storage, and environment. The SLTs stated that a strong evidence base would need to accompany any tool that they would consider buying. Whilst professional input can provide important considerations, it is important to remember that OBE was not represented in the patient group, whom of course are the primary users. This likely indicates that patients are not concerned with education or cost. It was clear from the patients’ views that they would use anything if it could help them return to normality.

Overall, seven properties emerged from the data which were agreed by all groups; SU involvement, other/current treatments, unsuitability of a headset device, preference for a neck device, progress monitoring, feedback and weight/size. These agreed design considerations are compiled in Table 9. Each FG is compared so that convergent and divergent views on design features are identified.

Table 9

*Design considerations across groups*

Considerations	Product designers	Clinicians	Patients
<b>PU usability</b>			
Patient considerations	X	X	
Secondary User Involvement*	X	X	X
Compliance	X	X	
Other rehabilitation/therapy	X	X	X
Body structure			X
User population	X		
Psychosocial considerations (social impact, motivation), distress	X		X
Tool usage (time, place)			X
<b>User Interface</b>			
Visualisation & conceptualisation	X	X	
Measurement	X	X	
Progress*	X	X	X
Feedback*	X	X	X
Cautionary features			X
<b>Format</b>			
Anatomical target concerns		X	
Unsuitability of headset *	X	X	X
Unsuitability of oral device		X	X
Suitability of neck device*	X	X	X
Suitability of hand held device		X	
Suitability of other device	X		
Size/weight concerns*	X	X	X
<b>OroPress</b>			
Aesthetics		X	X
Placement	X		
Usability Concerns	X	X	
Technology	X		
Sensor Placement concerns		X	X
External preference			X
Oral device concerns			X
<b>OBE</b>			
Health & Safety	X	X	
Cost	X	X	
Education	X		
Environment	X		
Evidence base		X	

Key: X= Mentioned at group

\*Topic common to all groups

## 6.0 Discussion

This study described the views of key stakeholders on OroPress (R). “Qualitative and user-centred design methods provide researchers with insights into the subjectivity of patients’ experiences of disease and yield detailed empirical knowledge grounded in their personal and social contexts” (Nasr et al. 2015 p7).

### ***Would a tool be used?***

In this study, the participants provided rich information about how dysphagia affects patients’ daily lives. Patients reported negative changes to taste, drooling and ingestion (ICF Body Function WHO, 2001) as well as daily eating routines and recreational activities (ICF Activities and Participation, WHO, 2001). These results are in large agreement with that of a study by Tschiesner et al. (2009). The patients strongly indicated a desire to return to ‘normal’ confirming the need for a swallowing rehabilitation tool. By ‘normal’ the patients were referring to eating mixed diets, not having to hold their nose while eating and drinking and being able to eat at restaurants without having to hide. Having lived with dysphagia for 9 years, one individual stated that they “would do absolutely anything, whatever it would take”. The patients’ willingness to use a home-based rehabilitation device was further evidenced by their inquisition as to when the tool would be available for use and their offers to participate in future research to further facilitate development in this area. In addition to confirming the need for a tool considerations arose which had not previously been investigated.

### ***How would a tool be used?***

A clear relationship emerged between the impact of dysphagia on users’ lives and tool use. Participants positively described using a home rehabilitation device to reduce the need to attend multiple hospital appointments. Patients described multiple appointments (SLT, physiotherapy, dental, medical) as a burden during acute illness. SLTs additionally described time constraints to providing effective rehabilitation within a hospital setting. A common suggestion across groups was for a link in SLT service which could provide monitoring and support to patients. According to Sharma et al. (2013) patients are highly satisfied to use dysphagia tele-rehabilitation. In fact, following a trial of videoconferencing

assessments 92% of patients perceived benefits of such practice. This suggests that a remote SLT service could effectively allow service provider to monitor performance of patients recuperating at home.

Self-monitoring through device feedback was also highly prioritised across groups. According to Tong et al. (2010) cancer patients with dysphagia cannot accurately judge their swallowing difficulties making self-monitoring impossible. The PDs provided numerous examples of the importance of conceptualising internal processes in facilitating accurate performance. The patients in this study, described how seeing progress motivated them to persevere with rehabilitation. Further, the SLTs described feedback as ‘incomparable’ in facilitating intervention and encouraging treatment fidelity. The use of feedback has been widely found to successfully improve performance and is therefore increasingly being incorporated into rehabilitation devices. Regarding swallowing devices, Robbins et al. (2005; 2007) showed that the IOPI device successfully provided visual feedback to dysphagic patients with benefits to patients’ lingual strength, swallow pressures and penetration-aspiration ratings. Similarly, O’Brien et al. (2014) reported visual feedback provided by OroPress (C) significantly facilitated healthy adults to increase oro-lingual pressures. The incorporation of feedback in a device such as OroPress (R) is therefore clearly supported.

However, further investigation of what mode of feedback is still needed. While SLTs and PDs did briefly mention numerous types of feedback (e.g. visual, audio, tactile) they strongly advocated for the use of visual feedback. This is unsurprising as visual input is a widely applied sensory cue to facilitate motor learning. In contrast, the HN cancer patients preferred another method to facilitate themselves observing the unobservable. They favourably described measuring pressures at the neck level using tactile feedback to provide warnings in the form of ‘pulses’ against the skin. Although ongoing efficacy and safety issues may apply to such a system (Ono et al., 2009), the desire for a non-invasive device is an important finding in relation to end users’ preferences. Subject to appropriate technology being developed, tactile feedback may further offer a means to provide feedback to patients with visual and or cognitive difficulties whom may have difficulty directing their focus to a visual screen (Grierson et al., 2011).

***Preferred tool format***

A few major usability problems were identified in connection with the format of OroPress (R). In contrast to Ní Chualáin et al. (2013), there was low acceptability for the headset format. This was a major finding of the study and indicates a need for format redesign. This discrepancy is best explained by the difference in users between the studies. The users of the current study were patients with physical impairments and comorbidities whom likely had different needs to a healthy population. The patients unexpectedly cited unilateral nerve damage to the head as a surgical complication making a headset device difficult to wear. Across groups, concerns were also found regarding the weight and size of the device. Across groups, a neck type design was preferred as an alternative.

Another significant finding, was the intolerability of an oral sensor by patients. Some patients reported that they would not be able to manipulate their tongue for an oral sensor while others found the sensor extending from the mouth non-discrete. Hence, OroPress (R) may require format and sensor revisions to ensure user-friendliness of the technology (Sharma et al., 2013).

Although these findings pose a number of issues for re-design, it is beyond the scope of this study to examine the technical feasibility of the participants' preferences. In future, it would be interesting to ascertain if views changed following in-depth education on the efficacy of isometric tongue pressures on swallowing function versus the efficacy of neck-type formats.

***Specific thoughts on OroPress***

While the study revealed certain design iterations, there is strong convergence across groups for a wearable device such as OroPress (R). Wearable and ambient technology maximises the independence and participation of individuals with chronic conditions, something which is especially important for home-based applications (Patel et al., 2012). The participants in this study valued the portability and hands free domains the current OroPress model provides. Further taking into account the design priorities and psychosocial factors documented would lead to the development of an innovative swallowing rehabilitation system.

### 6.1 Study strengths & limitations

A strengths of this study was the design and recruitment of a purposeful sample of three different participant groups to represent a mix of views (Mays & Pope, 1996). The FG method provided rich data and all participants gave honest, thoughtful and critical feedback throughout. The data captured is therefore likely to accurately represent their views.

While acknowledging small numbers in each FG mean data saturation may not have occurred, the participants were selected purposefully and their narratives greatly facilitated evaluation of the OroPress (R) prototype. Further research with a larger sample size would be useful to determine whether the themes that emerged from this study were representative of those from other populations with dysphagia. Attempts to recruit a second patient group in this study were faced with issues of cognitive and expressive difficulties. Another methodology may address these users' perspectives in future research.

Ideally, all SLTs would have attended the FG together so that views were appropriately exchanged however a range of both acute and rehabilitation perspectives were still obtained.

### 6.2 Conclusion

The findings of this study provide important implications for designing a home-based swallowing rehabilitation tool, the needs of the potential users and the way in which the device would operate in patients' daily lives. User-centred studies such as this one, provide technology developers with insight into enhancing their designs and subsequently having a meaningful impact on people's lives (Nasr, 2015). OroPress may be further developed as a successful tool by incorporating the described design attributes with the suggested iterations. In the next stages of research, it would be beneficial to involve ethnographic research to observe the prototype being used in a natural environment by its intended user. This may further our understanding of the many physiological, anatomical and psychological variables which can influence the interface between users and new designs (Orpwood et al., 2004). It would also be beneficial to gain perspectives from other dysphagic populations so that a tool could be made as widely applicable as possible.

## 7.0 References

- Archer, S., Wellwood, I., Smith, C., & Newham, D. (2013). Dysphagia therapy in stroke: a survey of speech and language therapists. *International Journal of Communication disorders*, 48 (3), 283–296.
- Corbin-Lewis, K., & Liss, J. (2015). *Clinical Anatomy & Physiology of the swallowing mechanism* (2nd ed.). Connecticut: Cengage Learning.
- Enderby, P. M., John, A., & Petheram, B. (1998). *Therapy outcome measures manual: physiotherapy, occupational therapy, rehabilitation nursing*: Singular.
- Grierson, L. E., Zelek, J., Lam, I., Black, S. E., & Carnahan, H. (2011). Application of a tactile way-finding device to facilitate navigation in persons with dementia. *Assistive Technology®*, 23(2), 108-115.
- Hewitt, A., Hind, J., Kays, S., Nicosia, M., Doyle, J., Tompkins, W., et al. (2008). Standardized instrument for lingual pressure measurement. *Dysphagia*, 23(1), 16-25.
- Kennelly, S., & O'Neill, D. (2012). Management of patients with dysphagia and aspiration pneumonia—an Irish perspective. *European Geriatric Medicine*, 3(5), 323-325.
- Linden, P. (1989). Videofluoroscopy in the rehabilitation of swallowing dysfunction. *Dysphagia*, 3(4), 189-191.
- Logemann, J. (1998). *Evaluation and treatment of swallowing disorders* (2nd ed.). Austin, Texas: PRO-ED.
- Martin, J. L., Clark, D. J., Morgan, S. P., Crowe, J. A., & Murphy, E. (2012). A user-centred approach to requirements elicitation in medical device development: a case study from an industry perspective. *Applied ergonomics*, 43(1), 184-190.
- Mays, N., & Pope, C. (1996). *Qualitative research in health care*. London: BMJ Publishing group.
- McCormack, J. (2013). The OroPress: a pilot study to examine the tool's properties of measurement and use as a biofeedback tool for isometric tongue tasks (MSc). University of Limerick.
- Money, A. G., Barnett, J., Kuljis, J., Craven, M. P., Martin, J. L., & Young, T. (2011). The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC medical informatics and decision making*, 11(1), 15.

- Nasr, N., Leon, B., Mountain, G., Nijenhuis, S. M., Prange, G., Sale, P., et al. (2015). The experience of living with stroke and using technology: opportunities to engage and co-design with end users. *Disability and Rehabilitation: Assistive Technology* (0), 1-8.
- Nicosia, M. A., Hind, J. A., Roecker, E. B., Carnes, M., Doyle, J., Dengel, G. A., et al. (2000). Age effects on the temporal evolution of isometric and swallowing pressure. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, 55(11), M634-M640.
- Nund, R., Ward, E., Scarinci, N., Cartmilli, B., Kuipers, P., & Porceddu, S. (2014). Survivors' experiences of dysphagia-related services following head and neck cancer: Implications for clinical practice. *International Journal of Language and Communication Disorders*, 49(3), 354-363.
- Ní Chualáin, C., Casey, V., Conway, R., & Perry, A. (2013). Clinical utility and safety of a new tool for tongue pressure measurement: OroPress (MSc). University of Limerick.
- O'Brien, T. (2014). Investigating the usefulness of the OroPress as a biofeedback tool (MSc). University of Limerick.
- Ono, T., Hori, K., Masuda, Y., & Hayashi, T. (2009). Recent advances in sensing oropharyngeal swallowing function in Japan. *Sensors*, 10(1), 176-202.
- Orpwood, R., Bjørneby, S., Hagen, I., Mäki, O., Faulkner, R., & Topo, P. (2004). User involvement in dementia product development. *Dementia*, 3(3), 263-279.
- Patel, S., Park, H., Bonato, P., Chan, L., & Rodgers, M. (2012). A review of wearable sensors and systems with application in rehabilitation. *Journal of Neuroengineering and rehabilitation*, 9(1), 21.
- Perry, A., Morris, M., Unsworth, C., Duckett, S., Skeat, J., Dodd, K., et al. (2004). Therapy outcome measures for allied health practitioners in Australia: the AusTOMs. *International Journal for Quality in Health Care*, 16(4), 285-291.
- Robbins, J., Gangnon, R. E., Theis, S. M., Kays, S. A., Hewitt, A. L., & Hind, J. A. (2005). The effects of lingual exercise on swallowing in older adults. *Journal of the American Geriatrics Society*, 53(9), 1483-1489.
- Robbins, J., Kays, S. A., Gangnon, R. E., Hind, J. A., Hewitt, A. L., Gentry, L. R., et al. (2007). The effects of lingual exercise in stroke patients with dysphagia. *Archives of physical medicine and rehabilitation*, 88(2), 150-158.

- Sharma, S., Ward, E. C., Burns, C., Theodoros, D., & Russell, T. (2013). Assessing dysphagia via telerehabilitation: Patient perceptions and satisfaction. *International journal of speech-language pathology*, 15(2), 176-183.
- Steele, C. (2004). Treating dysphagia with sEMG biofeedback. *ASHA leader*, 9, July 20th, p22.
- Stierwalt, J. A., & Youmans, S. R. (2007). Tongue measures in individuals with normal and impaired swallowing. *American journal of speech-language pathology*, 16(2), 148-156.
- Tong, M., Lee, K., Yuen, M., & Lo, P. (2011). Perceptions and experiences of post-irradiation swallowing difficulties in nasopharyngeal cancer survivors. *European journal of cancer care*, 20(2), 170-178.
- Tschesner, U., Rogers, S., Dietz, A., Yueh, B., & Cieza, A. (2010). Development of ICF core sets for head and neck cancer. *Head & neck*, 32(2), 210-220.
- Urquhart, C. (2012). *Grounded theory for qualitative research: A practical guide*: Sage.
- World Health Organisation. (2001). International classification of functioning, disability and health (ICF). . Geneva: WHO.
- Yoshida, M., Kikutani, T., Tsuga, K., Utanohara, Y., Hayashi, R., & Akagawa, Y. (2006). Decreased tongue pressure reflects symptom of dysphagia. *Dysphagia*, 21(1), 61-65.

### Images

DJO Education,. (2015). *Sensor adhered to neck*. Retrieved from  
<http://http:www.djoed.co.uk/cpd-vital-stim.html>

IOPI Medical,. (2013). *Sensor adhered to roof of mouth*. Retrieved from  
[http://http:www.iopimedical.com/Tongue\\_strength.html](http://http:www.iopimedical.com/Tongue_strength.html)

Laryngectomy Association NSW,. (2011). *Sensor held against neck against*. Retrieved from <http://www.stilltalking.org/booklet.html>

# Appendices

## Appendix A: Data collection materials

### **Topic Guide (Product designers)**

Can you each give us your name and a bit about yourself?

- *Objective: Would they use a tool & IF SO, how*

Can you imagine such a tool being useful? If so how?

- *Objective: Preferred Product Format (models and photographs supplied)*

What might be important for a user?

- *Objective: OroPress (photograph of OroPress in situ supplied)*

Ok so if we're looking at this particular tool what do you think? What sort of things do you like/dislike? So we've designed the 'perfect' tool, is there anything else you think that is important in developing this product?

### **Topic Guide (Patients)**

Can you each give us your name and a bit about yourself?

- *Objective: Would they use a tool & IF SO, how*

Tell us how you think patients might use a swallowing tool for rehabilitation?

- *Objective: Preferred Product Format (models and photographs supplied)*

What might be important for a user?

- *Objective: OroPress (photograph of OroPress in situ supplied)*

Ok so if we're looking at this particular tool what sort of things do you like/dislike? So now we've designed the 'perfect' tool, is there anything else that could help you to use this?

### **Topic Guide (Clinicians)**

Can you each give us your name and a bit about yourself?

- *Objective: Would they use a tool & IF SO, how*

Tell us how you think patients might use a swallowing tool for rehabilitation?

- *Objective: Preferred Product Format (models and photographs supplied)*

What might be important for a user?

*Objective: OroPress (photograph of OroPress in situ supplied)*

Ok so if we're looking at this particular tool what sort of things do you like/dislike? So now we've designed the 'perfect' tool, is there anything else that could help you to use this?



**Patient Information Form**

**Name:** \_\_\_\_\_ **Gender:**  Female  Male

**Age:**  18-25years  26-45years  46-65years  >65 years

**Contact details:**

Email: \_\_\_\_\_ Phone number: \_\_\_\_\_

Preferred method of contact:  Email  Phone

Any particular specifications (e.g. only call after 4pm): \_\_\_\_\_

**Site of cancer:** (please specify) \_\_\_\_\_

**Forms of prior treatment:**

Surgery  Other (Please specify) \_\_\_\_\_

Radiotherapy  Chemotherapy

**Employment**

Currently employed (If so please specify) \_\_\_\_\_   
Unemployed

Retired

**Please describe the nature of your swallowing difficulty e.g. food left over in mouth after swallowing, difficulty starting a swallow, tube feeding etc (please specify)**

\_\_\_\_\_

**How does your swallowing difficulty affect your everyday life? (please specify)**



### Clinician Information Form

**Name:** \_\_\_\_\_ **Gender:** Female  Male   
**Age:** 18-25years  26-45years  >45years

**Contact details:**

Email: \_\_\_\_\_ Phone number: \_\_\_\_\_

Preferred method of contact: Email  Phone   
Any particular specifications (e.g. only call after 4pm): \_\_\_\_\_

**Area of work (please tick all boxes that apply):**

Paediatrics  Adults

**Do you have experience with:**  Stroke  Head & Neck cancer  
Other: \_\_\_\_\_

**Place of work:**

Acute  Rehab  Other (Please specify): \_\_\_\_\_

**Demographic of employment (please tick all boxes that apply):**

County: \_\_\_\_\_

Hospital-Based  Community-Based  Private Clinic  Other (Please specify): \_\_\_\_\_

**Experience in the area of dysphagia:**

<1-3years  4-10years  10years +

**Dysphagia training/courses attended (please tick all boxes that apply):**

Undergraduate degree  Postgraduate degree    
CPD  Other \_\_\_\_\_



UNIVERSITY of LIMERICK  
OILSCOIL LUIMNIGH

DEPARTMENT OF  
CLINICAL THERAPIES



### **Product Designer Information Form**

**Name:** \_\_\_\_\_ **Gender:** Female  Male

**Age:** 18-25years  26-45years  >45years

#### **Contact details:**

Email: \_\_\_\_\_ Phone number: \_\_\_\_\_

Preferred method of contact: Email  Phone

Any particular specifications (e.g. only call after 4pm):

#### **Experience in the area of biofeedback tools (e.g. auditory, visual, kinesthetic etc.):**

<1-3years  4-10years  10years +

Please specify:

#### **Experience in the area of medical device product design:**

<1-3years  4-10years  10years +

#### **Training/courses attended (please tick all boxes that apply):**

Undergraduate degree  Postgraduate degree

CPD  Other (please specify) \_\_\_\_\_



## OroPress Rehabilitation tool; Stakeholder perspectives Study information

### ***What are the purposes of this study?***

The purpose is to inform the design of a new clinical tool called OroPress®, for use by adults with dysphagia (a swallowing problem) due to tongue weakness/inco-ordination.

Based on the views of likely users, clinicians (speech and language therapists or SLTs) and design engineers at a series of Focus Groups, a design brief for OroPress® will be developed.

### ***What does this study involve?***

1. If you are interested in taking part in this study, you will be asked to sign a consent form and we will arrange a date and time convenient for you to attend a one hour focus group session at the National Rehab Hospital, Dublin.
2. Each Focus Group will consist of 4-6 clinicians who have experience working with dysphagia and two researcher associates (RAs) - SLT final year students - who will organize and tape record the session.

*The session should take no more than one hour and refreshments (tea, coffee, water) will be provided*

3. At the Focus Group we will ask for your views about using a tool for therapy/practicing tongue movements and tongue strength. We will also ask you about what you would prefer to use in therapy (a mobile phone or a computer, or something else). There will be opportunity for question and discussion and all participants' comments will be tape recorded and notes about the session will be made by one of the RAs.
4. The audiotapes will be transcribed and then sent to you for checking afterwards, as we want to ensure everyone's views are correctly represented. You will have a pre-paid envelope to send back the report, with any amendments or comments, to one of the RAs.

### ***Why is this research important?***

This study will provide information about whether OroPress® can be effectively used for therapy; whether it might help you with a programme of tongue exercises and/or act as a bio-feedback tool.

Such information is important when designing a new tool to help people to undertake tongue exercises, especially where reduced tongue pressure has been linked to swallowing difficulties.

***What will the information I give be used for?***

The information you provide will be recorded and written up as part of a larger study, the results of which will form the basis of the Final Year Projects of two SLT students at the University of Limerick. The results will help us to better design a new rehabilitation tool called OroPress®

The results of this study may also be presented at a national conference and/or printed in a scientific journal but *at no point will you be identified*; all the information you may provide will be anonymized to everyone, except the two SLT researchers and their Supervisor, Prof Alison Perry.

***Are there any risks associated with participating in this study?***

No, there are no risks

***Do I have to participate in this study?***

Your participation in the study is completely voluntary.

***Will I receive any compensation?***

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

***What about my confidentiality?***

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

***What if I want to leave the study?***

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

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

Full Ethical approval has been given 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) 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 (Dean, Faculty of Education and Health Sciences)

**Address:** Dean's Office, Faculty of Education and Health Sciences, University of Limerick.

**Phone:** +353 61 234987

**Email:** 13000616@studentmail.ul.ie  
13012134@studentmail.ul.ie



OroPress Rehabilitation tool - Stakeholder Perspectives

Informed consent

- I have read and clearly understand all the detail provided on the subject information sheet
- 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

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

I consent to participate and have my views documented at a Focus Group

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: \_\_\_\_\_

E-mail Address:

\_\_\_\_\_

Appendix B: Coding Examples

Table 10

Example of Data coding used in analysis under ICF (WHO 2001) and TOMS-UK (Enderby at al., 1998) domains.

Key: Activity=blue, Impairment=yellow, Participation=Orange, Distress & Wellbeing =green

Participant	Transcript extracts	Open Codes	Selective Codes	Themes
P3:	<i>That would depend on each individual, on their surgery wouldn't it. Because I know for instance, I had problems with my bottom teeth sticking into the gum at the top, I had various things made at the dental hospital and a plate or anything in the roof of the mouth, means I then can't swallow properly because the tongue can't manoeuvre.</i>	Individuality; underbite; tongue manipulation difficulties;	Body Structure & Function	Impairment
P3:	<i>Yeah I used that as well but I don't use that anymore (therabite). I found it was beginning to loosen my teeth. And I've nothing there to stop the movement. Initially yeah to get the opening to start but as I said I found it was starting to loosen the teeth. I've had to have the teeth all concreted at the back to stop them moving.</i>	tool complications; dental complications;	Body Structure & Function	Activity
P2:	<i>Does anybody, I suppose we all do to a certain degree, suffer from depression? There's an element of depression having had to have this surgery over the years, sometimes you feel low.</i>	depression related to surgery;	Psychological considerations	Distress/ Wellbeing
P2:	<i>Well eating out is something I tend to turn down now because...or if we're in the restaurant I might face the wall, just in case it runs down my nose or whatever but.. C at home (his wife) she can chop up the food, chop up the meat, bit of beef or whatever and I can just munch that and gulp it down. I'm not chewing it as much as I would of liked to in the past. But in the restaurant, everyones finished their dinner and they're looking at me. It bothers me a little bit but not too much.</i>	social limitations; compensatory strategies; self-consciousness	a) Social Impact	Participation

Table 11

Example of coding used in analysis under themes PU usability (=pink), User Interface (=grey), Format (=orange), OroPress (=yellow) & OBE (=purple)

Participant	Transcript Extracts	Open codes	Selective codes	Themes
D1:	<i>So for example if there's feedback coming to the clinician, the clinician gets an email to say 'yeah X is doing well', then that clinician could email the patient and say I got your readings, everything is fine and we won't need you to come in this week, work away. Or else, we've a concern, can you come in.</i>	feedback; motivation; dual recordings; link in with SLT	<b>6.Clinician Involvement</b>	PU usability
			<b>7.Progress</b>	
D1:	<i>Maybe something that's linked to a screen; a wireless output telling somebody today you did 100 swallows, that's 90% of what we want you to do.</i>	screen; wireless; targets;	7a) Targets	User interface
D4:	<i>If you had actually things that someone could relate to now, you know like a bowl of cornflakes or spoon of cornflakes you know you're improving if you can eat steak or I don't know.</i>	relatable targets;		
D5:	<i>The company I used to work for was neurostimulation and we weren't allowed to put any electrodes transthoracically, you've arteries going right up. So maybe if it's a low level stimulation you would be able to use that. I'm not saying that for definite you need to look that up.</i>	electrode placement; safety; stimulation;	<b>8. Health &amp; Safety</b>	Out of box experience
			<b>10. Product Format</b>	Format
D5:	<i>It could be incorporated into a garment that is worn around the neck.</i>	incorporated into a garment	10c) Neck/chest device	
D5:	<i>Sizing is very important as well.</i>	sizing;	10e) Physical Considerations	
D2:	<i>And weight.</i>	weight;		
D5:	<i>Even an Asian head, what ethnic group are you tackling like? And how much pressure can you put on the head so that there's a clamp force. And you know, let's say you were in that area near the temples that could cause tension. So what are the effects of what you're wearing on the body?</i>	adjustable sizing; ethnic considerations ;		
D5:	<i>It does make you very identifiable.</i>	identifiable;	<b>13. OroPress</b>	
D1:	<i>It's a little bit degrading.</i>	degrading;		
D1:	<i>D1: And even that connector, is that needed? Again it looks over-kill</i>	connector overkill;		

Appendix C: Thematic maps

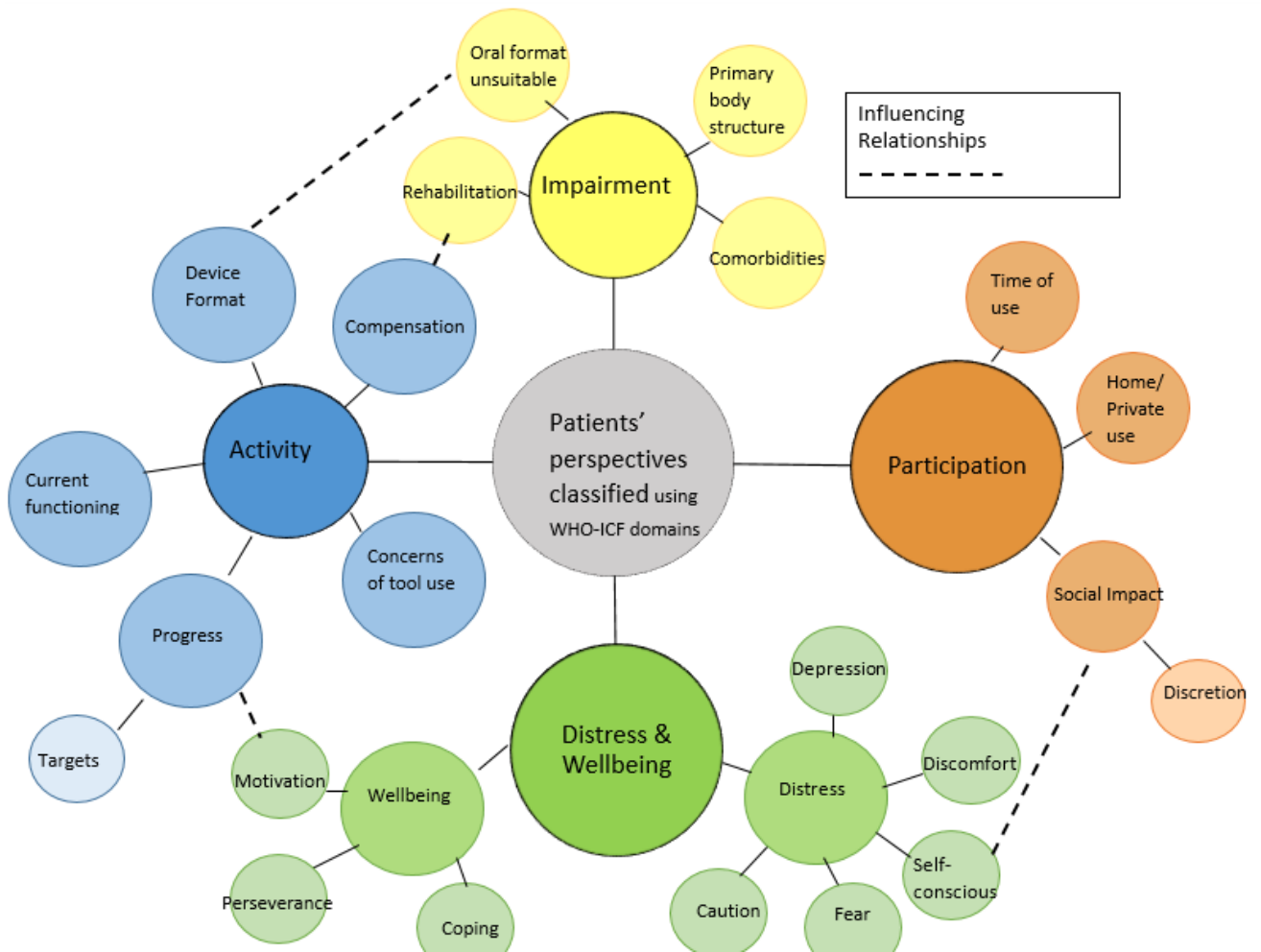


Figure 3 Thematic map of patient data analysed using classifications taken from the WHO-ICF<sup>1</sup> and UK TOMS.<sup>2</sup>

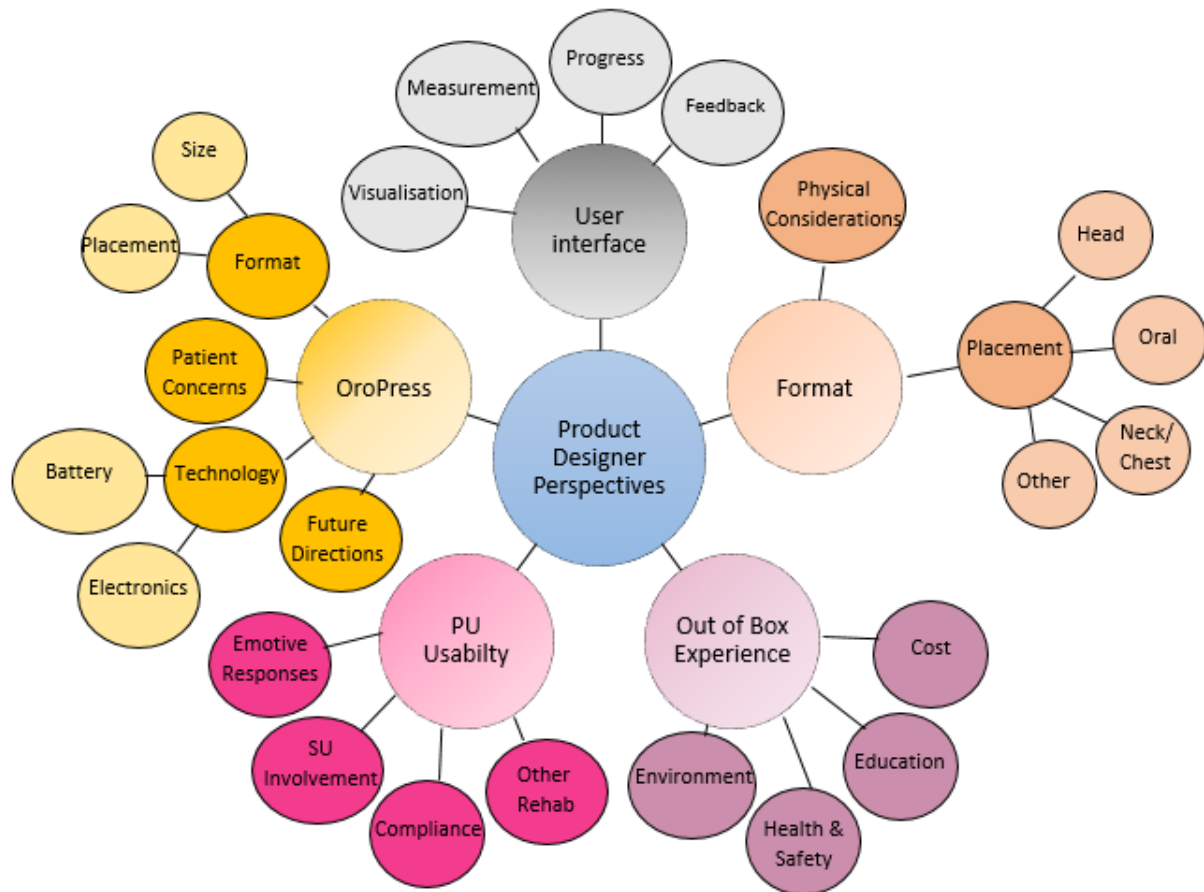


Figure 4. Thematic map of PD discourse analysed using a framework derived from the data.



Figure 5) Thematic map of clinician discourse analysed using a framework derived from the data.



Figure 6. Thematic map of patient discourse, using a framework derived from their data.