Differential diagnosis of pre-swallow pooling: A diagnostic dilemma.

A Thesis Submitted in Partial Fulfilment of the Requirements for the Degree of Doctor of Philosophy

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August 2023

Abstract

Accurate assessment and diagnosis of swallowing disorders is key to providing appropriate intervention. Selection of treatment relies on our diagnostic methodology. If incorrect treatment is selected, then swallowing disorders may not improve. Pre-swallow pooling is a feature of dysphagia that can cause aspiration before or during swallowing. It is presumed to be caused by two different pathophysiological impairments. One is presumed to be a motor impairment, which causes poor bolus containment as a result of oral weakness. This leads to some or all of the bolus entering the pharynx prior to purposeful propulsion of the bolus in the mouth. The other is presumed to be a sensory impairment whereby reduced sensation in the mouth causes a delay or absence of the pharyngeal swallowing response, after the bolus is propelled into the pharynx. However, assessment and diagnosis of pre-swallow pooling is poorly defined in the literature. In clinical practice, observations on videofluoroscopic swallowing studies are used to distinguish between poor bolus containment and delayed pharyngeal swallowing. However, videofluoroscopic swallowing studies allow for observation of biomechanics and cannot provide information regarding a sensory or motor impairment. Therefore, this PhD program investigated the phenomenon of pre-swallow pooling in stroke, to understand how it is differentiated into either poor bolus containment or delayed pharyngeal swallowing and whether a sensory and motor cause of pre-swallow pooling can be established.

This PhD program of research involved four studies and a scoping review. The scoping review findings were included within the literature review for continuity. This identified a large variation of the terms used to describe pre-swallow pooling, the measurement methods, and the methods by which to differentiate poor bolus containment from delayed pharyngeal swallowing. Study one was a normative study on 60 healthy participants. This study evaluated normative and reliability data of a novel oral sensory threshold measurement, and posterior lingual-palatal pressure measurement and the relationship between them. Electrical stimulation was used to establish

sensory thresholds in the mouth including the lips, tongue and faucial palate. Whilst lingual-palatal pressure norms have previously been reported, there is scant data on the posterior position that includes both isometric lingual-palatal pressure and lingual-palatal pressure during swallowing. The relationship between both physiological measures has not previously been investigated. Results suggest that there is some preliminary evidence that these tools can be used to determine a motor or sensory cause of pre-swallow pooling.

Study two was the first study to evaluate the agreement of speech pathologists' current methods for distinguishing poor bolus containment from delayed pharyngeal swallowing. This study evaluated inter- and intra-rater reliability of speech pathologist's current practice in the diagnosis of poor bolus containment and delayed pharyngeal swallowing using videofluoroscopic swallowing studies. Thirty videofluoroscopic thin fluid swallows with five of those appearing twice, were presented via an online survey to examine agreement both between and within raters. Definitions of poor bolus containment and delayed pharyngeal swallowing were provided to one of two groups to evaluate whether this information increased reliability. Reliability was poor for inter and intra-rater reliability for both the group with, and the group without, definitions. This indicated that our current methodology for determining poor bolus containment from delayed pharyngeal swallowing is unreliable. Further, the addition of definitions to guide speech pathologists in determining one from the other did not increase agreement, suggesting that the application or interpretation of measures is too subjective.

Study three was an exploratory study to determine whether distinct groups could be formed based on the physiological data obtained by the oral sensory threshold and posterior lingual-palatal pressure measurements. As there is no "gold-standard" for determining the difference between poor bolus containment and delayed pharyngeal swallowing, cluster analysis methodology was used to identify clusters that could be differentiated into one of potentially 3 groups. The groups were proposed to include a sensory group, a motor group, and a sensory-motor group. The aim was then

to evaluate these groups against speech pathologists' diagnosis of poor bolus containment and delayed pharyngeal swallowing in an attempt to determine whether a sensory and motor cause of pre-swallow pooling could be differentiated by clinicians. However, due to inconsistencies in speech pathologists' diagnosis of poor bolus containment and delayed pharyngeal swallowing, this could not be completed. Since distinct groups could be established via cluster analysis, it is likely that evidence for a sensory and motor cause of pre-swallow pooling exists, however, our current methods for determining this is flawed.

The final study evaluated the groups identified by the cluster analysis against common swallowing measures including oral transit time (OTT), stage transition duration (STD) and the Penetration-Aspiration Scale (PAS). Due to small numbers, most of the statistical methodology could not be applied, and results were presented descriptively.

This research addressed the need for more consistent terminology to describe the two causes of pre-swallow pooling and improved methods for distinguishing between poor bolus containment and delayed pharyngeal swallowing. There is evidence that subjects who have pre-swallow pooling following a stroke can be separated into those who have both a sensory and motor impairment and those who have a motor impairment alone. However, there remains no evidence for linking poor bolus containment with a motor impairment and delayed pharyngeal swallowing with a sensory impairment. New methodologies for determining the cause of pre-swallow pooling are required to ensure correct selection of dysphagia intervention and optimise rehabilitation outcomes.

Acknowledgements

Firstly, I would like to express my deepest appreciation to my primary supervisor, Professor Maggie-Lee Huckabee. I first went to one of your workshops about 20 years ago. Your passion and love for the field of dysphagia inspired me and ever since then, I have wanted to do a PhD. Many years later, I was honoured to have you take me on as a student. The journey has not been easy with personal and worldwide challenges going on at the same time, but the learning that I have received from you has been outstanding. I have come out the other side still loving my topic, wanting to continue research and contribute to the evidence in our field. I am eternally grateful.

This PhD would not have been possible if not for the learning and guidance that I have received from Esther Guiu-Hernandez. The patience you have demonstrated with me in guiding the statistical analysis was so appreciated and I valued my evening discussions with you from abroad so much when no-one else was awake! I am also immensely grateful to Dr Phoebe Macrae, who offered feedback that not only included suggestions, but also explained things that helped me to think differently. I learned so much from your feedback Phoebe, thank you. Special thanks to Associate Professor Karl Ng, who provided invaluable advice and guidance on the neurophysiological components of my research and gave useful feedback from a medical perspective.

I'd like to recognise the contribution of my work colleagues at Royal North Shore Hospital, in particular Mary-Ellen Tarrant, who never stopped encouraging me to pursue a PhD. You always believed in me and supported me through it all. I am also grateful to all my other speech pathology colleagues, who not only volunteered as healthy participants, but also endlessly encouraged me. Special thanks to Meagan Brown and Anita Markey for their contribution to data collection. Thanks also to the nursing and AHP staff and patients of Royal North Shore Hospital who participated in this research and therefore helped to contribute to the evidence in this field. I would also like to

acknowledge the financial support I received from the Ramsay Foundation, the University of Canterbury UC Connect Doctoral Scholarship, and IOPI medical LLC, without which this PhD would not have been possible.

It was an honour to be part of a research lab full of smart, passionate, and dedicated people. Special thanks to Emma Wallace and Katharina Winiker for your help with the scoping review. Thanks also to Keri Darrock, Emma Burnip, Seh Ling, Karen Ng, Paige Thomas, Eloise Smith and all the other students I have met over the years. Thank you for all your assistance and sharing your experiences. Special thanks to Lucy Grieg, Fiona Bellet and Eric Knapp, for making my time at the Rose Centre so exceptional. Thanks also to Margaret Patterson at the University of Canterbury library as well as the librarians at RNSH library, Agnes Wroblewski, Bonnie Cheng and Jackie Edwards. Your guidance and assistance was greatly appreciated.

And lastly to my friends and family. Thank you for your endless support and patience. I'll be making up for lost time now. To my mum, Bernadette Dobson, I truly wouldn't have got through this without you. Thank you for coming to stay and taking over when things got tough, and for your encouragement and pride in me. You have saved my mental health. Finally, to my kids, Oskar and Emilija. This PhD is for you. I hope I've shown you the power of determination and hard work and that no matter what life throws at you, nothing is impossible. Thanks for going on this journey with me, studying with me and believing in me.

Contents

Preface

This thesis is written according to the style described in the Manual of the American Psychological Association, Seventh Edition (2020) and follows spelling consistent with Oxford English Dictionary.

This research was conducted between 2019 and 2022 at the Royal North Shore Hospital in Sydney, Australia. The candidate was enrolled at the Department of Communication Sciences between March 2018 and July 2023 and supervised by Distinguished Professor Maggie-Lee Huckabee, Dr Phoebe Macrae, Ms Esther Guiu Hernandez, all from The Rose Centre for Stroke Rehabilitation and Research and the University of Canterbury, and Associate Professor Karl Ng from Royal North Shore Hospital and Sydney University. Financial support was provided by the University of Canterbury College of Science Doctoral Scholarship and the Ramsey Healthcare Research Grant.

Oral Conference Presentations

- Stroke Rehab: From No-Tech to Go-Tech (2018; Christchurch, New Zealand)
- NSLHD Allied Health Symposium (2018; Sydney, Australia) (Awarded Commendation)
- NSLHD Speech Pathology Professional Development (2019; Sydney, Australia)
- World Dysphagia Summit (2021; Nagoya, Japan)
- Speech Pathology Australia National Conference (2023; Hobart, Australia)
- International Association of Communication Sciences and Disorders World Congress (2023; Auckland, New Zealand)

List of Abbreviations

ANOVA: Analysis of variance

BMI: Body mass index

CPG: Central pattern generator

CPT: Current perception threshold

CN: Cranial nerve

ECR: Endovascular clot retrieval

EMG: Electromyography

FEES: Flexible endoscopic evaluation of swallowing

FOIS: Functional Oral Intake Scale

HREC: Human research ethics committee

HSD: Honestly significant difference

Hz: Hertz

ICC: Intraclass coefficient correlation

IDDSI: International Dysphagia Diet Standardisation Initiative

IOPI: Iowa Oral Pressure Instrument

iSLN: Internal superior laryngeal nerve

kPa: Kilopascals

LAR: Laryngeal Adductor Reflux

mA: Milliamperes

MASA: Mann Assessment of Swallowing Ability

MBSImP: Modified Barium Swallowing Impairment Profile

MCA: Middle cerebral artery

MEG: Magnetoencephalography

mmHg: Millimetre of mercury

MMSE: Mini-mental State Examination

MRI: Magnetic resonance imaging

NA: Nucleus ambiguous

NIHSS: National Institute of Health Stroke Scale

NMES: Neuromuscular electrical stimulation

NTS: Nucleus tractus solitarius

OTT: Oral transit time

PAS: Penetration-Aspiration Scale

PES: Pharyngeal electrical stimulation

PES: Pharyngoesophageal opening

Q-Q PLOTS: Quartile-quartile plots

RLN: Recurrent laryngeal nerve

SD: Standard deviation

SLN: Superior laryngeal nerve

SPECS: Speech Pathology Email Chat Support

STD: Standard deviation

TGA: Therapeutic Goods Administration

tPA: Tissue plasminogen activator

UES: Upper Esophageal Sphincter

VFSS: Videofluoroscopic Swallowing Study

*This thesis was prepared using British spelling conventions. However, direct quotes may contain American Spelling. Additionally, the acronym ‘UES’ (upper esophageal sphincter) is strongly represented in the literature, therefore UES rather than UOS (upper oesophageal sphincter) was used.

Part A: Introduction and Literature Review

Chapter 1 Introduction

Pre-swallow pooling of the bolus in the pharynx prior to the initiation of the pharyngeal swallowing response is a feature of altered swallowing biomechanics seen during videofluoroscopic swallowing studies. If pharyngeal swallowing is not initiated when the bolus is in the pharynx, aspiration can occur prior to, or during swallowing (Logemann, 1998). There are two proposed causes of pre-swallow pooling. One is hypothesised to be a sensory impairment, whereby the information regarding bolus arrival in the pharynx is not adequately detected by the oropharyngeal sensory receptors, and thus a motor response is not appropriately initiated as the bolus enters the pharynx. This is commonly referred to as delayed pharyngeal swallowing. The other is hypothesised to be due to poor oral containment of the bolus secondary to poor glossopalatal approximation. This allows some, if not all, of the bolus to escape prematurely into the pharynx prior to purposeful propulsion. Thus, one cause is considered a sensory impairment and the other, a motor impairment. While these two causes of pre-swallow pooling are commonly recognised, there is currently no accepted method of assessing the pathophysiology of pre-swallow pooling. Thus, there is no empirical evidence to indicate that there are differentiated sensory or motor causes of pre-swallow pooling. Differentiation of these main causes for pre-swallowing pooling is important, as treatment for a motor impairment would presumably require a motor-based approach, and treatment for a sensory disorder, a sensory-based approach.

Pre-swallow pooling is common in acute stroke (Veis & Logemann, 1985) and is associated with a high incidence of complications such as malnutrition, dehydration, and aspiration pneumonia (Martino et al., 2005; Suntrup-Krueger et al., 2018). Accurate identification and management of pre-swallow pooling in acute stroke may prevent prolonged dysphagia and allow patients to return to an oral diet quicker. This in turn, may lead to improved morbidity and mortality in acute stroke. **Therefore, the purpose of this research program was to investigate the phenomenon of pre-**

swallow pooling in acute stroke, to determine whether sensory and motor causes of pre-swallow pooling can be established, and if so, to understand the differential diagnosis of poor bolus containment and delayed pharyngeal swallowing. This is the first study that has attempted to determine a relationship between sensation and strength, and pre-swallow pooling.

Part A of this thesis consists of a literature review which includes normal and disordered swallowing, with a detailed description of the neuromotor control of swallowing, cranial nerve function and biomechanics of swallowing and dysphagia in Chapter 2. Chapter 3 focuses on dysphagia in stroke and introduces the concept of pre-swallow pooling and its two proposed causes: reduced sensation and strength. Chapter 4 then details the mechanisms of oral sensation, deficits of oral sensation in stroke and assessment of oral sensation. Similarly, Chapter 5 reviews the glossopalatal seal and deficits in stroke and the difficulties inherent in the assessment of glossopalatal function.

The literature review identified gaps in our knowledge, assessment, and classification of pre-swallow pooling. Inconsistencies in pre-swallow pooling terminology and measurement methodology makes it difficult to compare across studies or differentiate between delayed pharyngeal swallowing and poor bolus containment. There is an absence of a clear relationship between reduced sensation and delayed pharyngeal swallowing or reduced tongue strength and poor bolus containment. Therefore, this research program attempted to address these gaps.

Part B presents the experimental studies. Chapter 6 details the hypothesis and objectives for the studies. First, normative values of posterior lingual-palatal pressure values and a novel method of obtaining oral sensory perception thresholds in a healthy population were investigated, including the evaluation of reliability of these measures, detailed in Chapter 7. This was to establish normative values of physiological measures of sensation and strength and whether these measures were reliable. In Chapter 8, methods of distinguishing poor bolus containment from delayed pharyngeal swallowing were investigated to determine whether current methodology is reliable within and

between speech pathologists and whether variability was due to the measurement methods, or speech pathologists' knowledge or interpretation of the measurement methods. Chapters 9 and 10, were the main studies of this research program. Chapter 9 used a cluster analysis approach to classify the physiological measures of oral sensation and posterior-lingual pressure into distinct groups. This was to determine if those with pre-swallow pooling could be separated into a sensory or motor group which may assist in establishing evidence for different causes of pre-swallow pooling. Chapter 10 then evaluates swallowing measures such as oral transit time, stage transition duration and the Penetration-Aspiration Scale. Reliability of repeated measures is determined, then the swallowing measures are described within each cluster from study 3 and within the speech pathologists' diagnosis of poor bolus containment and delayed pharyngeal swallowing.

Chapter 11 and 12 discusses the collective findings of these studies to determine whether the tools speech pathologists currently use to classify pre-swallow pooling have any physiological evidence to suggest that one has a motor and one has a sensory cause of pre-swallow pooling. The limitations and implications of this research are presented, with recommendations for future research.

Chapter 2 Normal and Disordered Swallowing

2.1. Neural Control of Swallowing

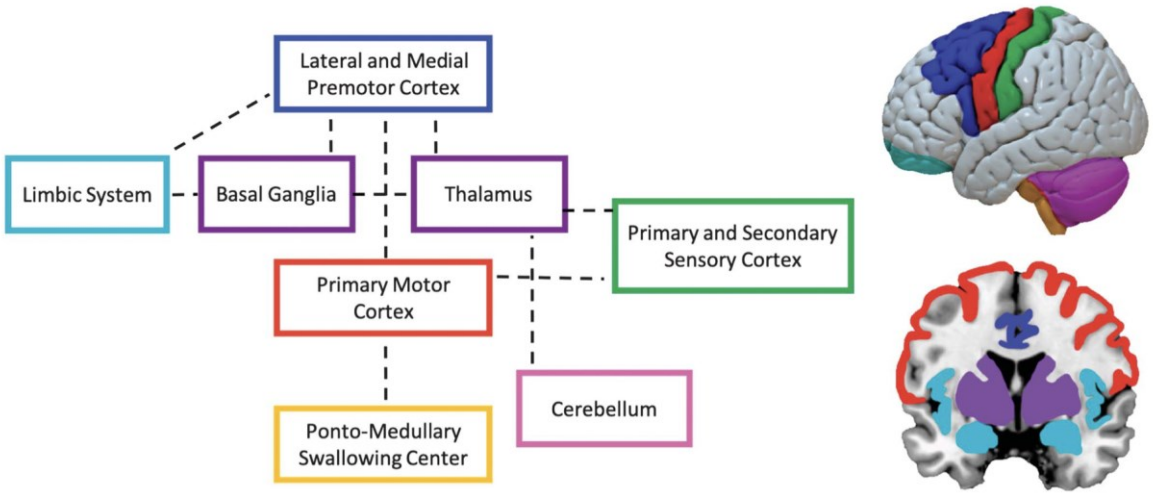
Traditionally, swallowing was described as a purely reflexive function of the brainstem without the need for afferent feedback (Jean, 1984). Early studies used animal models and electrical stimulation to elicit and inhibit swallowing, and consequently identify anatomical regions of interest to elicitation of this response (Doty, 1951; Miller, 1986). As a result of clinical reports of dysphagia occurring outside of the brainstem (Barer, 1989; Stephanie K. Daniels & Anne L. Foundas, 1999; Langdon et al., 2007; Nakamori et al., 2020), cortical stimulation studies (Miller & Bowman, 1977; Sumi, 1969), and functional neuroanatomical imaging studies (Flowers et al., 2011; Li et al., 2009; Mihai et al., 2016), it is now accepted that swallowing is controlled and modulated by a bilateral network of ascending and descending sensory-motor cortical, subcortical and brainstem areas. These require ongoing reciprocal interaction between sensory and motor function (Leopold & Daniels, 2010). As a high-level summary, the areas that are commonly regarded as important in swallowing include:

- the lateral and medial premotor cortex, primary motor cortex, and primary and secondary sensory cortex,
- the limbic system, basal ganglia, and thalamus and
- the cerebellum and brainstem (González-Fernández et al., 2013).

These areas work together to initiate and regulate effective swallowing as shown in **Figure 1** and discussed below.

Figure 1

A Schematic Representation of the Reciprocal Interaction of the Areas of the Brain Involved in Swallowing.



From Wilmskoetter, J., Daniels, S. K., & Miller, A. J. (2020). Cortical and Subcortical Control of Swallowing-Can We Use Information From Lesion Locations to Improve Diagnosis and Treatment for Patients With Stroke? American journal of speech-language pathology, 29(2S), 1030–1043. https://doi.org/10.1044/2019_AJSLP-19-00068. Reproduced with permission.

2.1.1. Supratentorial Control of Swallowing

Swallowing is a complex sequence of events that relies on the interaction of well-coordinated sensory and motor function (Steele & Miller, 2010). While the importance of motor function in swallowing is more obvious, successful swallowing cannot occur without adequate sensory input allowing initiation and modulation of the swallowing mechanism. Critical sensory information is detected from sight and smell, but also via sensory receptors from within the oral cavity and pharynx. The motor response is processed cortically and adapted according to characteristics of the bolus such as viscosity, volume, and taste (Steele & Miller, 2010). For example, the duration of upper oesophageal sphincter opening increases with increased viscosity (Kendall et al., 2001), airway protection manoeuvres occur earlier with larger boluses (Kendall, 2002) and oral

transit times are reduced with a cold/sour bolus (Gatto et al., 2013). Thus, efficient ingestive swallowing cannot take place without sufficient sensory information and corresponding motor response adaptations that occur cortically.

The cortex also has an important role in cognitive processing during swallowing. There is evidence that motor planning for some conditions of swallowing occurs in the premotor and supplementary motor cortices (Huckabee et al., 2003). The sensorimotor cortex plays a major role the execution and regulation of swallowing movements through the feedback loops from the oral sensory receptors via the brainstem. This information is relayed to the primary motor cortex to plan the precise movements involved in swallowing (Wilmskoetter et al., 2020). The primary motor cortex forms the beginning of the corticobulbar pathway, known as the direct activation system or upper motor neuron system. The axons of the upper motor neurons start in their respective hemispheres of the cortex and travel through the thalamus to the posterior limb of the internal capsule and onto the midbrain, pons, and medulla, with fibres exiting at the nucleus for each cranial nerve. Damage to any part of this pathway can cause dysphagia (Wilmskoetter et al., 2020). Most cranial nerves receive innervation via the corticobulbar tracts from both hemispheres (Webb, 2017). This acts as a safety net when damage to one hemisphere occurs: nuclei will still receive innervation from the undamaged hemisphere. The cranial nerves that do not receive bilateral innervation are those that supply the muscles of the lower half of the face (CN VII) and some muscle fibres of the tongue (CN XII). These receive contralateral supply only and explains why single cortical hemisphere strokes commonly cause obvious labial and lingual impairments. Despite the bilateral innervation that most cranial nerves receive, swallowing impairment can still occur due to the unilateral disruption to this pathway, causing a loss of precise and timely skilled execution of swallowing movements (Wilmskoetter et al., 2020).

Other cortical areas important in swallowing include the temporoparietal area (including the posterior insula). This is an important area in attending to and in synthesizing sensory information to

enable perception (Krall et al., 2015). Additionally, the insular cortex is thought to have an important role in the timely integration of sensory and motor swallowing events (Mosier & Bereznaya, 2001). Subcortical areas that have been found to be important in swallowing include the basal ganglia, the internal capsule, the periventricular white matter, and the thalamus. These structures form connections, and relay information between the cortex and brainstem to play a role in the effective sensory-motor integration of swallowing (Wilmskoetter et al., 2020). The supratentorial areas most often activated during swallowing are reported to be the primary motor and sensory cortices, followed by the insula, the cingulate cortex and basal ganglia (Cheng et al., 2022).

2.1.2. Infratentorial Control of Swallowing

Once the bolus reaches the pharynx, a pharyngeal swallowing response occurs. The brainstem centres responsible for the activation of pharyngeal swallowing response are the nucleus tractus solitarius (NTS) and the nucleus ambiguous (NA). The NTS is a network of bilateral afferent cranial nerve nuclei including the facial, glossopharyngeal and vagus nerves located in the dorsal region of the medulla. For the swallowing reflex to occur, sensory information is detected as the bolus is manipulated in the oral cavity, primarily from the sensory receptors within the oral cavity (Steele & Miller, 2010). Touch and taste afferents are received by the facial (VII), glossopharyngeal (IX), and vagus (X) nerves via receptors in the pharynx and larynx and sent directly to the NTS, whereas sensory receptors from the trigeminal (V) nerve are sent to the NTS via the trigeminal nucleus in the pons. When adequate information from multiple areas within the oral cavity is received by the NTS, a motor response is initiated and sent to the nucleus ambiguous (NA), where a pre-programmed series of motor sequences is executed (Doty, 1951). The NA is located in the ventral region of the medulla. It surrounds and includes the NTS and consists of the bilateral motor nuclei of the glossopharyngeal, vagus, and spinal accessory nerves. It also has significant interconnections with the motor nuclei of the hypoglossal, trigeminal and facial nerves. This network of bilateral brainstem nuclei that work together to create the complex series of muscular events for

swallowing is known as the central pattern generator (CPG) (Jean, 2001). Whilst the CPG has a purely reflexive action for saliva swallowing, requiring no voluntary control to initiate a swallowing response (Ertekin, 2011), volitional swallowing during eating and drinking is different. Cortical processing occurs via interconnections through the thalamus to the cortex, to process the characteristics of the bolus. This is then relayed back to the NTS via the corticobulbar pathways (Ertekin, 2011) and directs the NA to initiate swallowing that can accommodate boluses of different consistencies and volumes (Steele & Miller, 2010). The final area within the brain that has a role in swallowing is the cerebellum. The cerebellum ensures movements including swallowing, are smooth, well-coordinated and accurate. Thus, damage to the cerebellum may cause inaccurate, uncoordinated and tremulous movements (Sasegbon & Hamdy, 2021).

At a peripheral level, swallowing involves the coordination of approximately 50 paired muscles (Hennessy & Goldenberg, 2016) that work together to produce values and subsequent pressure to move the bolus from the mouth to the oesophagus (Shaw & Martino, 2013). These muscles are paired, therefore, unless specified otherwise, bilateral contraction of these muscles is inferred in the description below. The muscles receive innervation from 12 pairs of cranial nerves which are responsible for the sensory and motor function of the head, neck, and gut. The cranial nerves most important for sensory and motor functions of swallowing consist of the trigeminal (CN V), facial (CN VII), glossopharyngeal (CN IX), vagus (CN X), and hypoglossal (CN XII), although the optic (CN I) and olfactory (CN II) also contribute. The pharyngeal plexus is formed by the pharyngeal branches of the glossopharyngeal (CN IX) and vagus nerves (CN X) and the cervical sympathetic ganglion (Gutierrez et al., 2021). The ansa cervicalis comprises fibres of CN XII and cervical plexus (Florie et al., 2021). The nuclei for these nerves are contained within the central nervous system (CNS) in the brainstem. The pons contains the trigeminal (CN V), and facial nerves (CN, VII) and the medulla houses the glossopharyngeal (CN IX), vagus (CN X), spinal accessory (CN XI) and hypoglossal (CN XII). The remaining components of the lower motor neuron system are contained within the

peripheral nervous system (PNS). These include the axons, the neuromuscular junctions, and the muscle fibres.

Prior to swallowing, sight (CN II) and smell (CN I) assist in the cortical processing of oral intake as recognition occurs through visualisation of food and drink (Leopold & Kagel, 1997). This, along with oral sensory perception of the bolus, informs masticatory requirements needed to manipulate food into a cohesive bolus and propulsive force required to move it through the pharynx. Sight and smell also trigger saliva production. Saliva is produced by the submandibular and sublingual salivary glands (CN VII) and the parotid salivary glands (CN IX) which aid bolus breakdown and formation, allowing easier bolus transit (Florie et al., 2021; Steele & Miller, 2010). For bolus acceptance, the orbicularis oris, zygomaticus, risorius, labi superioris work together to spread the lips (CN VII), the mouth opens via the anterior belly of the digastric and mylohyoid (CN V) (Florie et al., 2021) and closes via the temporalis and masseter muscles (CN V). The buccinator and the orbicularis oris (CN VII) form an anterior seal of the lips to prevent spillage from the mouth onto the chin. The liquid bolus is collected and held by the intrinsic muscles of the tongue (superior longitudinal, inferior longitudinal, transverse, and vertical) (CN XII), and forms a seal with the alveolar ridge and lateral hard palate via the styloglossus (CN XII) to prevent escape into the anterior or lateral sulci. The palatoglossus (pharyngeal plexus) contracts with assistance from the posterior belly of the digastric and stylohyoid (CN VII). Together they retract the hyoid bone in a superior and posterior manner to achieve glossopalatal closure. This prevents premature spillage of the bolus into the pharynx (Dodds et al., 1990).

Sensory feedback regarding touch, pain and temperature are received by the maxillary branch of CN V for the palate and teeth, and by the mandibular branch of CN V for the mucosa of the mouth, palate, and anterior 2/3rds of the tongue. The sensation of taste from the anterior 2/3rds of the tongue is received by CN VII. This information influences the motor control and adaptations to swallowing biomechanics to accommodate for changes in bolus volume and viscosity.

During chewing of solid foods, the intrinsic and extrinsic muscles of the tongue manipulate the bolus for breakdown by the teeth. This includes the intrinsic tongue muscles such as the superior longitudinal, inferior longitudinal, transverse, and vertical (CN XII). These alter the shape of the tongue during bolus manipulation and control. The genioglossus (CN XII) assists manipulation by protruding the tongue and moving it from side to side. As the jaw moves in an up, down and rotary manner by the lateral and medial pterygoids (CN V), there can be volitional propulsion of the bolus into the pharynx. Well-masticated portions of food may be transported into the pharynx by the intrinsic muscles of the tongue and hyoglossus (CN XII), which depresses and retracts the tongue, whilst ongoing mastication of the remaining bolus takes place. This is referred to as vallecular aggregation (Hiiemae & Palmer, 1999). Contraction of the buccinator (CN VII) along with adequate lingual control prevents entry of food into the lateral sulci. The bolus is volitionally propelled in an anterior-posterior manner by the extrinsic tongue muscles. This is achieved by lowering the posterior tongue via relaxation of the palatoglossus (CN X) followed by contraction of the hyoglossus (CN XII) and which breaks the glossopalatal seal and depresses the tongue base. The bolus is then transferred from the mouth into the oropharynx via sequential anterior-posterior pressure of the tongue with the hard palate. Tactile sensory information about the bolus is received from afferent receptors in the soft palate, adjacent pharyngeal walls, faucial arches and posterior 1/3rd of the tongue, as well as taste from the posterior 1/3rd of the tongue. This information is received by the glossopharyngeal nerve (CN IX) as the bolus moves through the mouth towards the pharynx, and sent to the NTS to accumulate with other sensory input to initiate the pharyngeal swallowing sequence (Jean, 2001). With liquids, oral transit takes between 0.35 to 1.54 seconds (Soares et al., 2015).

As the bolus enters the pharynx, the soft palate elevates to close off the nasopharynx via contraction of the levator veli palatine and the palatopharyngeus muscle (CN X), along with the tensor veli palatini (CN V). As the bolus reaches the pharynx, the anterior and vertical movement of

the hyoid, created by contractions of the anterior belly of the digastric (CN V), mylohyoid (CN V), (Florie et al., 2021) and geniohyoid (ansa cervicalis) (Costa, 2018), pulls the larynx up and forward and with this movement, the epiglottis deflects. The arytenoids approximate the epiglottic petiole as a result of anterior contraction of the thyroepiglottic muscle (McCullagh et al., 2022). This comprises the most superior mechanism of airway closure. The ventricular and true vocal folds close due to the synergistic movement of the thyroarytenoid, lateral cricoarytenoid, and interarytenoid muscles. This completes all four levels of airway closure (Vose & Humbert, 2019). These muscles are all innervated by the recurrent laryngeal nerve (RLN) (CN X). However, the cricothyroid assists in tensing the vocal folds and is innervated by the superior laryngeal nerve (SLN) (CN X) (Uludag et al., 2017). Sensation is important during airway closure to detect and initiate a response to airway penetration or aspiration during swallowing. Sensation to the oropharynx and hypopharynx is detected by the pharyngeal plexus (CN IX, X) (Daniels et al., 2019), the internal branch of the SLN (iSLN) (CN X) receives sensory information from the glottis and supraglottis. The RLN (CN X) receives sensory information from the subglottis and upper trachea including the carina (Wadie et al., 2013).

During laryngeal vestibular closure, respiration stops, although the onset of the apnoeic period can begin much earlier in the swallowing sequence (Martin-Harris et al., 2005). The pharyngeal chamber is narrowed and shortened by the salpingopharyngeus, palatoglossus, palatopharyngeus muscles (pharyngeal plexus CN IX, X) and by the contraction of the pharyngeal constrictors (pharyngeal plexus CN IX, X). Posterior base of tongue contraction towards the pharyngeal wall via the posterior belly of diagastric, stylohyoid (CN VII), and glossopharyngeus (pharyngeal plexus CN IX, X) pushes the bolus inferiorly towards the upper oesophageal sphincter (Dodds et al., 1990). This, along with sequential contraction of the superior, medial and inferior pharyngeal constrictors (CN X), comprises a superior-inferior pressure wave. The upper oesophageal sphincter is comprised of the inferior pharyngeal constrictor (pharyngeal plexus CN IX, X) the cricopharyngeus (recurrent laryngeal nerve CN X/pharyngeal plexus CN, IX, X) and the striated

muscles of the upper oesophagus (recurrent laryngeal nerve CN X) (Matsuo & Palmer, 2008). Upper oesophageal sphincter opening is achieved by anterior movement of the hyoid, pressure of the bolus and relaxation of the cricopharyngeus. The movement of the bolus through the pharynx can take 0.35 to 1.19 seconds (Molfenter & Steele, 2012). Peristaltic movement of the oesophagus is achieved by sequential relaxation and contraction of the smooth muscle fibres of the oesophagus which move the bolus through the 18-25cm long tube which connects to the stomach. Oesophageal transit can take 10.7 seconds for a 20ml liquid bolus (Miles et al., 2016).

2.2. Dysphagia

Dysphagia can occur when structural, neurological, gastrointestinal, iatrogenic or functional impairments, among others, cause a disruption in swallowing (Malandraki & Robbins, 2013). These conditions can be developmental, such as cerebral palsy or birth defects; acquired, such as brain injury or head and neck cancer; structural, such as spinal surgery or laryngeal surgery; or neurological such as progressive neurological conditions or brain lesions or infections (Rommel & Hamdy, 2016).

Dysphagia is characterised by any difficulty in the transport of solids and liquids from the mouth into the stomach. It can range from impaired mastication or lip closure which may make eating and drinking slower or messier, to severe difficulties where no food or fluids are able to be swallowed (Bhattacharyya, 2014). The implications of dysphagia can be serious. Dysphagia can cause aspiration, where food or fluids pass below the vocal folds and enter the lungs. Colonised oral bacteria contained within the aspirated contents can then cause pneumonia (Marik, 2001). Pneumonia is associated with poorer outcomes including increased morbidity and mortality (Cabre et al., 2010). Dysphagia can also lead to malnutrition and dehydration due to inadequate food and fluid intake. This, in turn, can lead to further medical implications such as urinary tract infections, constipation and renal failure (Mentes & Gaspar, 2020). In addition to the health implications,

dysphagia can also considerably compromise quality of life (Ekberg et al., 2002; Namasivayam-MacDonald et al., 2022).

Signs of dysphagia are generally divided into oral signs, pharyngeal and oesophageal signs. Signs of oral difficulties include poor mouth opening and closing, poor mastication, residue on the tongue, floor of mouth, buccal sulci or adhering to the palate. Poor bolus control can lead to loss of the bolus anteriorly, laterally into the buccal sulci, or posteriorly into the pharynx prior to purposeful propulsion (with possible penetration or aspiration). There can also be poor initiation of the anterior-posterior propulsion of the bolus in the oral cavity with subsequent holding of the bolus in the mouth. Pharyngeal signs include poor velopharyngeal closure leading to nasopharyngeal regurgitation. Delayed initiation of swallowing can lead to penetration or aspiration before or during hyolaryngeal excursion. Reduced hyolaryngeal excursion can result in poor airway closure with possible penetration and aspiration during swallowing. Reduced base of tongue to posterior pharyngeal wall approximation and poor pharyngeal contraction can lead to vallecular and pyriform fossae residue, and reduced upper oesophageal sphincter opening can lead to residue in the pyriform fossae. This residue can lead to possible aspiration after swallowing (Malandraki & Robbins, 2013). Many of these signs are impossible to assess without instrumentation.

2.2.1. Assessment of Dysphagia

Dysphagia can be assessed clinically or with instrumentation. Clinical assessment consists of integration of case history information, assessment of cranial nerve function, some physiological tests where available such as cough reflex testing, cough strength, and tongue strength, and observation of signs of dysphagia during eating and drinking. There is no consensus regarding what should be included in a clinical assessment, although some features of assessment are more closely related to swallowing impairment. Dysphonia (Horner et al., 1988), impaired gag, weak cough (Horner et al., 1990), wet hoarse voice quality, absent voluntary cough (Linden et al., 1993) dysarthria and wet voice or cough after swallowing (Daniels et al., 2000) have all been used as

clinical indicators of dysphagia. A clinical reasoning process takes place whereby the information from the case history, cranial nerve findings and clinical signs of dysphagia on eating and drinking are integrated into a hypothesis to predict the biomechanical breakdown causing the detectable signs of dysphagia. However, clinical assessment is mostly non-standardised and has variable accuracy. Clinical assessment can only detect the more obvious signs of dysphagia. When silent aspiration occurs, 67% of aspirators may be missed (Daniels et al., 1998). The more obvious signs of dysphagia include poor stripping of a utensil or spillage of the bolus from the lips, oral residue, prolonged mastication, struggling behaviour, coughing, choking, and multiple swallows. Whilst some of the causes of these signs might seem obvious, e.g., lip weakness, many other signs could have multiple causes (Daniels et al., 2019). For example, coughing may be due to penetration or aspiration of the bolus into the airway due to:

- poor oral control due to orolingual weakness and entry of food or fluids into the airway prior to or during swallowing.
- poor sensation causing a delayed pharyngeal swallowing response and subsequent entry into the airway prior to or during swallowing.
- poor hyolaryngeal range of movement causing reduced airway closure with entrance of food or fluids into the open airway during swallowing.
- or oropharyngeal weakness or incoordination causing residue with entrance of food or fluids into the airway post swallowing.

Thus, instrumental assessments allow for more accurate observation of swallowing biomechanics. The most common and clinically available instrumental methods used for assessing and diagnosing dysphagia are the videofluoroscopic swallowing study (VFSS) and the flexible endoscopic evaluation of swallowing (FEES) (Zhou et al., 2018). FEES has been reported to have a greater sensitivity in the detection of residue and aspiration (Kelly et al., 2007; Kelly et al., 2006) whereas VFSS has a greater specificity in the biomechanics of dysphagia (Pisegna & Langmore,

2016). However, instrumental assessments of swallowing remain subjective due to interpretation required by the observer. Efforts have been made to increase objectivity with the use of rating scales such as the MBSImp (Martin-Harris et al., 2008). The MBSImp (Martin-Harris et al., 2008) divides the swallowing process into 17 components. These components of swallowing can be evaluated during videofluoroscopic swallowing studies and are rated on a descriptive scale that ranges from 0-2, to 0-4. The components include a mix of observed biomechanical movements as well as bolus observations. Whilst this increases reliability between and within raters, this measurement technique has not been norm-referenced and therefore it is not clear how the scores relate to a normal or abnormal swallowing presentation.

Other swallowing measures include displacement measurements such as hyolaryngeal range of movement (Kim & McCullough, 2010; Kraaijenga et al., 2017) and temporal measurements such as oral transit time or stage transition duration (Kim et al., 2005; Soares et al., 2015). There are a wide range of normative data on both temporal and displacement measures and significant variability of individual swallowing measurements (Lof & Robbins, 1990; Molfenter & Steele, 2012). However, VFSS only allows for description of biomechanics and quantification of residue or timing events; it does not identify the pathophysiological cause that may be underlying the biomechanics of dysphagia (Daniels et al., 2019). Since rehabilitation is targeted to the underlying pathophysiology, for example, strength-based exercises for weakness, assessment of pathophysiology is important to determine so that improvements in swallowing can be realised. The physiological causes for dysphagia are presumed to be related to impairments in neuromuscular function and therefore, seemingly may consist of impaired sensation, strength, range of movement, speed, and coordination of movement. These features may be assessed in a thorough assessment of cranial nerve function during a clinical assessment, and then related to observable signs of dysphagia to predict physiological causes. However, there has yet to be determined a direct link between physiological impairments and swallowing impairments. Therefore, treatments are provided based on assumed

pathophysiology and success is evaluated based on improvements in signs of dysphagia observable on VFSS.

2.2.2. Current Treatments for Dysphagia

Treatments that are designed for reduced sensation include both compensatory and rehabilitative approaches. Compensatory treatments include changes in bolus viscosity, positioning changes, or the addition of strategies to reduce residue or improve neuromuscular control and delays which may be the result of reduced sensation. Changes to viscosity are one of the most common compensatory strategies used in the management of dysphagia (Cichero et al., 2013; Garcia et al., 2005) as they do not require cognitive function to warrant their use. Increasing viscosity can increase the duration of swallowing events such as pharyngeal contraction (Dantas, Kern, et al., 1990), laryngeal vestibular closure (Lazarus et al., 1993), total swallowing time (Dantas & Dodds, 1990; Reimers-Neils et al., 1994) as well as oral transit duration (Robbins et al., 1992) and containment (Palmer et al., 1992). Therefore, increasing the consistency of fluids may compensate for delays or poor control of the bolus that may otherwise enter the airway prior to or during the pharyngeal stage of swallowing. There is evidence that thickening fluids reduces aspiration (Leder et al., 2013; Masuda et al., 2022; Newman et al., 2016); however, evidence for their use in reducing aspiration pneumonia is lacking (Kaneoka et al., 2017; Logemann et al., 2008). Furthermore, there are also negative consequences of thickening fluids, including poorer quality of life (Swan et al., 2015), dehydration and associated complications (Robbins et al., 2008) and poorer outcomes if aspirated (Nativ-Zeltzer et al., 2018; Nativ-Zeltzer et al., 2021).

Changes in positioning are also widely used compensatory approaches in dysphagia management. The most common position utilised in dysphagia management is the “chin tuck” (Speyer, Sandbekkbraten, et al., 2022). The chin tuck position was originally described by Logemann (1983) to compensate for delayed swallowing by widening the vallecular space and thus allowing the bolus to collect there prior to the onset of airway closure. However, it has also been shown to be

useful in reducing vallecular residue by retracting the base of tongue more proximal to the posterior pharyngeal wall (Oh et al., 2022). Despite the physiological benefits that the chin tuck can provide, it does not necessarily ensure prevention of aspiration, particularly if the pre-swallow pooling reaches the pyriform fossae (Shanahan et al., 1993).

Rehabilitative treatments for weakness use principles of exercise-based regimes to increase muscle mass and endurance by considering intensity, load, and specificity (Steele, 2012). The Mendelsohn manoeuvre is also an exercise that aims to increase the duration of UES opening. (McCullough et al., 2012; McCullough & Kim, 2013). However, observation of the Mendelsohn manoeuvre during VFSS has shown that performing the exercise is difficult for patients to achieve (Azola et al., 2015). Ultrasound may provide a suitable biofeedback technique to assist patients to perform the Mendelsohn manoeuvre, however the accuracy has not been confirmed with VFSS (Kwong et al., 2021; Peng & Pauloski, 2022). Like the Mendelsohn manoeuvre, the effortful swallow has also been transformed from a compensatory strategy into a rehabilitation exercise in an attempt to improve pharyngeal pressure and thus reduce pharyngeal residue; however, evidence for achieving this in a dysphagic population is limited. Park et al., (2019) reported that the effortful swallow improved both anterior and posterior lingual-palate strength and improved oral phase swallowing as measured with the Videofluoroscopic Dysphagia Scale. However, they did not detail what these improvements were. Other researchers have found improvements in oral tongue strength (Oh, 2022) laryngeal elevation (in conjunction with electrical stimulation) (H. S. Park et al., 2019) and pharyngeal constriction ratio (H. Kim et al., 2017). But these improvements were not related to improvements in swallowing safety or efficiency. Additionally, the effortful swallow has been found to decrease hyoid range of movement (Bulow et al., 1999), which may contribute to worsening swallowing function (Daniels et al., 2019).

In summary, both compensatory and rehabilitative techniques have been used to treat dysphagia with presumed sensory and motor causes. However, outcomes have not always been

favourable. There does not seem to be a process whereby sensation and strength are assessed as the cause for biomechanical impairments with subsequent matching of sensory or strength-based treatments. It is reasonable to suggest that outcomes may improve should there be a more robust method of assessing whether signs of dysphagia seen on VFSS are caused by a motor or sensory impairment. This would allow for improved research to establish outcomes for different treatments for different pathophysiological swallowing impairments.

Chapter 3 Stroke

Stroke is the second leading cause of death in the world after ischaemic heart disease, with a world-wide incidence of 12.2 million and a prevalence of 101 million in 2019. Both incidence and prevalence of stroke is increasing (Feigin et al., 2022). In 2019, most strokes were ischaemic (62.4%). Ischaemic strokes result from a loss of oxygen via blood supply to the brain, resulting in tissue death. Haemorrhagic stroke (bleeding within the brain tissue) contributed to 27.9% of strokes and sub-arachnoid haemorrhage (bleeding within the layers of the linings of the brain) to the remaining 9.7% (Feigin et al., 2022). The most common risk factors for stroke are (in order) a high systolic blood pressure, high BMI, diabetes, pollution, and smoking (Feigin et al., 2022).

Stroke severity is often measured using a stroke scale such as the National Institute of Health Stroke Scale (NIHSS) (Brott et al., 1989; Lyden et al., 1999). This is a 15-item scale that measures impairment across a range of motor and sensory functions and can evaluate neurological outcome and recovery post stroke. The NIHSS can predict recovery post-stroke as well as ongoing care after acute hospitalisation. For example, those with a NIHSS of ≥ 16 are more likely to have to have a severe disability or death, whereas those with ≤ 6 were more likely to have a good recovery (Adams et al., 1999), and those with a NIHSS score ≥ 13 administered within the first 24 hours post-stroke, are more likely to require rehabilitation and be discharged to a nursing facility (Schlegel et al., 2003).

3.1. Dysphagia in Stroke

Dysphagia following stroke is well-documented (Banda et al., 2022; Martino et al., 2005). Historically, it was believed that dysphagia in stroke was found only in those with brainstem (i.e., bulbar) or bilateral cortical strokes where bilateral damage is considered necessary to cause bulbar dysfunction (i.e., pseudobulbar) (Bickerstaff, 1973; Walton, 1985; Patten, 1977; in Gordon, 1987). However, through animal and human studies that utilise both ablation and functional imaging techniques (Mihai et al., 2016), it is now acknowledged that dysphagia can occur in unilateral cortical

strokes (Gordon et al., 1987; Hamdy et al., 1997; Veis & Logemann, 1985). Indeed, functional MRI studies show multiple areas in the cortex that are associated with dysphagia post stroke (Wilmskoetter et al., 2019).

It is estimated that between 50-80% of patients with acute stroke will have dysphagia (Kidd et al., 1995; Mann et al., 2000; Martino et al., 2005; Meng et al., 2000). This figure varies according to the definitions and methods of detecting of dysphagia. For example, Martino et al., (2005) identified rates of 37% to 45% of stroke patients with dysphagia when screening techniques were used, 51% to 55% when clinical assessment was performed, and 64% to 78% when instrumental assessment techniques were used.

Although over 80% will recover within the first two weeks following stroke (Gordon et al., 1987; Smithard et al., 1997), dysphagia in stroke is associated with a high incidence of complications such as malnutrition, dehydration, and aspiration pneumonia (Martino et al., 2005; Suntrup-Krueger et al., 2018). This leads to increased morbidity and mortality, and for those who have persisting dysphagia, increased costs and dependence on healthcare and social services, and reduced quality-of-life (Bonilha et al., 2014; Katzan et al., 2007). Thus, the early detection and appropriate treatment of dysphagia is important for people recovering from a stroke.

Dysphagia following stroke is commonly first detected using swallowing screening upon admission to hospital. Screening tools are designed to be administered before any food, drinks or medications are given, and have been shown to reduce the incidence of aspiration pneumonia following stroke (Yang et al., 2021). Clinical evaluation of dysphagia by a speech pathologist may also reduce the incidence of post-stroke pneumonia (Eltringham et al., 2018). However, clinical assessment of dysphagia has variable sensitivity and specificity, especially for the detection of silent aspiration (Ramsey et al., 2003). Standardisation of clinical assessment tools can increase the sensitivity to detect aspirators. The Mann Swallowing Assessment Tool (MASA) has a reported 93% sensitivity to detect aspirators, and the 3-ounce water swallow test has a sensitivity of 96.5% to

detect aspiration (Mann, 2002; Suiter & Leder, 2008). However, both tests have a high false-positive rate of 55% and 51.3% respectively, meaning that many non-aspirators fail the tests, requiring further instrumental assessment before they can commence oral intake. Cough reflex testing has also been used to increase the detection of those who may silently aspirate (Miles et al., 2013). Cough reflex testing has a reported sensitivity to detect silent aspirators of between 19% to 87.1% (true positive rate) and a specificity to detect non silent aspirators of 60% - 90% (true negative rate) (Wallace et al., 2022). These large differences may be due to variances in cough reflex protocol. However, since cough reflex testing is a test of sensation rather than a test for aspiration, it has little use for detecting aspiration in a population.

Instrumental assessment of dysphagia is considered the gold standard in dysphagia assessment (Cohen et al., 2016). The most widely used instrumental assessments remain Video-Fluoroscopic Swallowing Study (VFSS) and Flexible Endoscopic Evaluation of Swallowing (FEES). FEES is more sensitive to aspiration (Colodny, 2002; Kelly et al., 2007); however, VFSS allows measurement of biomechanical movements in dysphagia (Daniels et al., 2019). The reported biomechanical characteristics of dysphagia in acute stroke are diverse. Terre and Mearin (2006) found increased transit time (27%), reduced lingual control (39%), piecemeal deglutition (20%), and reduced glossopalatal approximation (20%) in dysphagia post-stroke (Terre & Mearin, 2006). Some researchers report more severe and prolonged dysphagia with a higher incidence of pharyngeal phase swallowing difficulties in brainstem stroke, including pharyngeal residue and laryngopharyngeal paresis (Aydogdu et al., 2001; Kim et al., 2014). Oral stage problems such as oral residue, anterior bolus loss and disordered lingual movements are more frequently reported in supratentorial stroke (Han et al., 2005; Kim et al., 2014). Some biomechanical impairments are difficult to differentiate with VFSS because they have similar observable signs on VFSS. An example of this is pre-swallow pooling.

3.1.1. Pre-swallow Pooling

Pre-swallow pooling is described as hesitation of the bolus in the pharynx between the oral and pharyngeal phases of swallowing and is referred to as an impairment of timing in swallowing (Kim et al., 2019) and may lead to aspiration of the bolus before or during swallowing (Logemann, 1998). Pre-swallowing pooling is commonly assumed to be caused by two impairments: poor bolus containment or delayed initiation of pharyngeal swallowing (Steele et al., 2016). Poor bolus containment is considered a motor impairment whereby the bolus fails to be contained in the oral cavity, due to reduced tongue control and an ineffective glossopalatal seal. This allows some of the bolus to escape into the pharynx before purposeful posterior movement of the tongue for volitional transfer. In contrast, delayed initiation of pharyngeal swallowing is considered a sensory impairment, whereby the bolus is propelled from the oral cavity into the pharynx and a pharyngeal swallowing response is not initiated in a timely manner (Daniels et al., 2019). Differentiation of these main causes of pre-swallowing pooling is important as treatment for a motor impairment would logically require a motor-based approach and treatment for a sensory disorder a sensory-based approach.

Logemann (1983; 1998) provided a method of distinction between poor bolus containment and delayed pharyngeal swallowing which involved identifying the head of the bolus. Logemann defined the head of the bolus as the leading edge of the main part of the bolus, disregarding any part of the bolus which may have separated from the bolus before or during oral transit (Logemann, 1983). Delayed pharyngeal swallowing was defined as a delay between the head of the bolus reaching the inferior ramus of the mandible until the pharyngeal swallow was initiated. Whereas poor bolus containment (referred to as pre-swallow spill by Logemann), was defined as some or all of the bolus entering the pharynx prior to the onset of oral transit (Logemann, 1983; Logemann, 1998). However, the distinction between these two definitions of pre-swallow pooling is poorly addressed in the literature.

One of the difficulties in understanding the cause of pre-swallow pooling is the terminology used to describe it. There are many different terms used to describe pre-swallow pooling. These can be separated into terms used to describe delayed pharyngeal swallowing, and terms used to describe poor bolus containment. However, due to inconsistencies in terminology and in how the terms are measured, it is sometimes difficult to tell if the terms refer to delayed pharyngeal swallowing or poor bolus containment, or if the authors even acknowledge two causes of pre-swallow pooling. Therefore, it is possible that some researchers use a term to describe delayed pharyngeal swallowing but due to poor definitions or measurement techniques, may actually be measuring poor bolus containment. In order to be replicable, the measurements need to be specific. If the measurements are not specific, there may be small variations in the way measurements are taken, which means that any differences may be due to measurement error and not true change or absence of change in swallowing function. This has implications for clinical practice, as therapy techniques may be selected or disregarded due to research findings. It also makes comparing treatment outcomes between studies difficult.

In order to investigate how pre-swallow pooling is defined and described in the literature, a scoping review was undertaken (manuscript in preparation). Published methodology was followed (Arksey & O'Malley, 2005; Levac, Colquhoun, & O'Brien, 2010). The checklists from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) were used for reporting (Tricco et al., 2018). See **Appendix 1** for terms used for search strategy and **Appendix 2** for PRISMA diagram of methodology. From this review, the terms used in the literature to describe delayed pharyngeal swallowing are summarised in **Table 1**. The most commonly used term is "pharyngeal delay time". The terms used in the literature to describe poor bolus containment are summarised in **Table 2**. "Premature bolus loss" is the most commonly used term to describe this impairment.

Table 1.

Terms Used to Describe Delayed Pharyngeal Swallowing

Terms	Authors
Pharyngeal delay time	(Abraham & Yun, 2002; Ayala & Logemann, 2010; Bingjie et al., 2010; Bisch et al., 1994; Denk et al., 1997; Hirai et al., 2010; Kang et al., 2016; Kang et al., 2011; Kim & Kim, 2012; Kim et al., 2020; Kim et al., 2016; Kim et al., 2010; Kim et al., 2005; Kim et al., 2019; Y. H. Kim et al., 2015; Kiyohara et al., 2018; Kweon et al., 2016; Lazarus et al., 1993; Lee, Kim, Kim, Kim, et al., 2012; Lee, Kim, Kim, & Lee, 2012; Lee et al., 2014; Logemann et al., 1995; Maruo et al., 2014; McConnel et al., 1998; Min et al., 2013; Miyaji et al., 2012; Newman et al., 2002; Oh et al., 2020; Ohashi et al., 2019; J. W. Park et al., 2013; Park et al., 2016; Pauloski & Nasir, 2016; Regan et al., 2010; Seo et al., 2011; Su et al., 2015; Terre & Mearin, 2006, 2009a, 2009b, 2012; Terre et al., 2013; Warabi et al., 2008; Yoshida et al., 2019)
Delayed triggering	(Han et al., 2001; Kim et al., 2012; Kim & Kim, 2012; Kim et al., 2014; Kreuzer et al., 2000; Logemann, 1985; Logemann et al., 1995; Logemann et al., 2006; Lundy et al., 1999; Mendell & Logemann, 2007; Miyaji et al., 2012; J. W. Park et al., 2013; Perez et al., 1998; Saconato et al., 2016; Sellars et al., 1999; Seo et al., 2011; Terre & Mearin, 2009a, 2009b; Terre et al., 2013; Triadafilopoulos et al., 1992; Veis & Logemann, 1985)
Delayed swallow	(Daniels et al., 2007; Kim et al., 2019; Leonard & McKenzie, 2006; Oommen et al., 2011; Saito et al., 2016; Suh et al., 2009; Triadafilopoulos et al., 1992; Yamamoto et al., 2013)
Delayed onset	(Clark et al., 2019; Dietsch et al., 2019; Humbert et al., 2009; Karnell & Rogus, 2005; Keeling et al., 2010; H. R. Kim et al., 2015; Kim & McCullough, 2007; Leonard & McKenzie, 2006; Martin-Harris et al., 2007; Mok et al., 2003; Nagy et al., 2013; Ohki & Kikuchi, 2018)
Delayed response	(DeVita & Spierer-Rundback, 1990; Leonard & McKenzie, 2006; Linden et al., 1989; Moon et al., 2019; Nativ-Zeltzer et al., 2014; Oommen et al., 2011; Sdravou et al., 2012; Terre & Mearin, 2009a)
Delayed pharyngeal swallow	(S. K. Daniels & A. L. Foundas, 1999; Daniels et al., 1996; Furuya et al., 2014; Keage et al., 2020; Kim et al., 2010)
Delayed transition	(Byeon & Koh, 2016; Daniels et al., 2009; Kim & McCullough, 2007; Kim et al., 2005; Stephen et al., 2005)
Delayed initiation	(Feinberg & Ekberg, 1990; Ford & Cruz, 2004; Han et al., 2016)
Latency	(Cantarella et al., 2001; Zhang et al., 2016)
Swallowing hesitation	(Saito et al., 2016)
Impaired swallowing reflex	(Han et al., 2005)

Table 2.

Terms Used to Describe Poor Bolus Containment

Terms	Authors
Premature bolus loss	(Han et al., 2001; Kang et al., 2011; Kim et al., 2012; H. R. Kim et al., 2015; Kim et al., 2019; Y. H. Kim et al., 2015; Lee, Kim, Kim, & Lee, 2012; Moon et al., 2012; Oh et al., 2020; B. H. Park et al., 2013; J. W. Park et al., 2013; Park et al., 2016; Rhie et al., 2016; Seo et al., 2011)
Premature spillage	(Cook et al., 1989; Fattori et al., 2016; Hsiao et al., 2003; Keeling et al., 2010; Nagy et al., 2013; Steele et al., 2013; Steele et al., 2016; Sulica et al., 2002)
Reduced palatoglossal closure	(Terre & Mearin, 2006, 2009a, 2009b, 2012; Terre et al., 2013)
spillage	(Furuya et al., 2014; Iida et al., 2011; Miyaji et al., 2012; Tabaee et al., 2006)
Posterior spillage	(Clark et al., 2019; Kang et al., 2011; Santos et al., 2014)
Premature entry	(Feinberg & Ekberg, 1990; Palmer et al., 1992)
Premature posterior spillage	(S. K. Daniels & A. L. Foundas, 1999; Parreira et al., 2020)
Pre-swallow pooling	(Kocdor et al., 2015; Sellars et al., 1999)
Premature leakage	(Huggins et al., 1999; Wu et al., 1997)
Premature spill-over	(Morton et al., 1997)
Leaking	(Denk et al., 1997)
Loss of bolus	(Pauloski et al., 1994)
Oral posterior escape	(Santos et al., 2014)
Pooling	(Perez et al., 1998)
Pre-swallow leakage	(Han et al., 2005)
Leakage	(Feinberg & Ekberg, 1990)
Early spillage	(Moon et al., 2019)
Pre-swallow spillage	(Sellars et al., 1999)

There are discrepancies between researchers on definitions used to describe poor bolus containment vs. delay. For example, Iida, Katsumata & Fujishita (2011) use the term “spillage” but define it as “when a drop of material on the base of the tongue was observed on VFSS images before initiation of swallowing”. Similarly, Han et al., (2001) describe “premature bolus loss” as “bolus drop into the pharynx from the oral cavity before the swallowing reflex”. Both of which could be descriptions of delay or poor bolus containment.

Descriptions for measuring delayed pharyngeal swallowing are similar amongst researchers. Most use the difference between the arrival of the bolus in the pharynx until the initiation of the pharyngeal swallow. Yet there appear to be discrepancies in how these two things are measured.

Some measure from the arrival/first sign of barium in the pharynx (Daniels et al., 2009; Daniels et al., 2007; Dietsch et al., 2019); however, this would include any part of the bolus that may separate from the main part of the bolus before purposeful propulsion, which would otherwise differentiate it from poor bolus containment. Most researchers use the term "the head of the bolus", yet few define it. Of those who do, there are some who refer to it as the leading edge of barium (Martin-Harris et al., 2007; Martin-Harris et al., 2005; Maruo et al., 2014; Newman et al., 2002; Yamamoto et al., 2013), and some who refer to it as the leading edge of the main part of the bolus (B. H. Park et al., 2013). Kim et al., (2005) define the head of the bolus by specifying that "trickle down barium was not counted in this measure. Rather, the tongue must have been actively pushing the barium into the pharynx for the first part of this measure to be counted" (pg. 292). This would exclude any loss of the bolus that may occur from poor bolus containment and is consistent with Logemann's differentiation of delayed pharyngeal swallowing and poor bolus containment. Park et al., (2013) also referred to identifying the "main bolus" from "premature bolus loss" but did not specify how to differentiate them. One group of researchers differentiate pre-swallow pooling by measuring "reduced palatoglossal closure" and "pharyngeal delay time" (Terre & Mearin, 2006, 2009a, 2009b, 2012; Terre et al., 2013). Reduced palatal closure was defined as "when some of the bolus falls into the pharynx prematurely; before activation of the swallowing reflex" (Terre & Mearin, 2009b), pg. 924) and pharyngeal delay time was defined by "the arrival of the head of the bolus at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered" (pg. 924). However, despite identifying the two causes of pre-swallow pooling, the head of the bolus was not defined.

In addition to inadequate definition of the head of the bolus, there is also poor definition of how the onset of pharyngeal swallowing should be determined. Many do not describe how to judge the onset of pharyngeal swallowing. Kim et al., (2005) described the onset of laryngeal elevation as "the first superior movement of the thyroid cartilage that actually results in a swallow; any up and

down movements of the larynx before the onset of the swallow were ignored" (pg. 292). Oommen et al., (2011) described the onset of hyoid elevation as the "onset of maximum hyoid excursion" (pg. 320). Yoshida et al., (2019) described laryngeal elevation as "the start of laryngeal elevation in the context of completion of swallowing" (pg. 200). Daniels et al., (2009) described the onset of laryngeal elevation as "initiation of the maximum superior movement of the hyoid bone" (pg. 76). See **Appendix 3** for full details of extracted data for the scoping review.

In addition to the difficulties in determining the difference between poor bolus containment and delayed pharyngeal swallowing, the underlying pathophysiology that is responsible for the impaired biomechanics cannot be determined using VFSS. Cranial nerve assessment may suggest an underlying pathophysiology such as impaired strength or sensation; however there has, as yet been no empirical evidence to link the biomechanical impairments seen on VFSS to impaired physiology such as reduced lingual strength or oral sensation.

Chapter 4 Oral Sensation

The oral cavity is the first part of the swallowing and digestive system and comprises the lips anteriorly, the faucial arches posteriorly, the cheeks laterally, the floor of mouth inferiorly and the palate superiorly (Çelebi & Yörükan, 1999). The mouth and face are densely and diversely innervated with sensory receptors (Sessle & Squire, 2009) resulting in a highly developed and well-defined sensory system (Haggard & de Boer, 2014). The mouth can receive and differentiate senses of touch, temperature, pain, proprioception, and taste (Jacobs, Wu, Van Loven, et al., 2002). Changes to oral sensation are known to occur with age (Braun et al., 2022; Calhoun et al., 1992), and women have lower thresholds than men resulting in increased oral sensitivity (Heft & Robinson, 2010; Won et al., 2017).

Mechanoreceptors are responsible for the detection of touch, proprioception, vibration and pressure (Trulsson & Johansson, 2002). There are different types of nerve endings found in the mucosa. These include free nerve endings, Pacinian corpuscle, Meissner corpuscle, and Merkel discs (Haggard & de Boer, 2014). The oral mucosa is composed of connective tissue, covered by wet epithelium and has one of three functions: masticatory mucosa, lining mucosa, or specialised (taste) mucosa (Gartner, 1994) as shown in **Table 3**.

Table 3.

Mucosal Types of the Oral Cavity

Masticatory	**Lining**	**Specialised**
Gingiva	Lining of the vestibule	Dorsal surface of the tongue
Hard palate	Lining of the cheeks	Near the palatoglossus folds-soft palate
Filiform papillae of the tongue	Gingival sulcus	

Alveolar mucosa

Soft palate

Uvula

Ventral surface of the tongue

Floor of mouth

Adapted from Gartner L. P. (1994). Oral anatomy and tissue types. *Seminars in dermatology*, *13*(2), 68–73.

All mechanoreceptors are found in these areas of the oral mucosa except for the Pacinian corpuscle mechanoreceptors, which may be present in the dental pulp, although this is controversial (Haggard & de Boer, 2014). Each of these mechanoreceptors have different receptor fibres which respond to different sensations. For example, Merkel cells have slowly adapting fibres which respond to static stimulus, and Meissner corpuscle have fast adapting fibres which respond to the initial sensation at the onset of stimulation (Haggard & de Boer, 2014). Most of the oral cavity is innervated by fast adapting mechanoreceptors which makes it highly sensitive. Innervation density within the mucosa varies according to site and function. Tactile sensitivity also varies, with the lowest sensitivity to light touch occurring on the hard palate and anterior tongue (Capra, 1995). The anterior and middle parts of the tongue are more sensitive than the lateral and posterior areas (Trulsson & Essick, 1997). Two-point discrimination is impaired when topical anaesthesia is applied to the tongue, suggesting an involvement of superficial mechanoreceptors in discriminating between two points on the tongue (Haggard & de Boer, 2014).

4.2. Assessment of Oral Sensation

Multiple sensory areas in the oral cavity and pharynx have been shown to be important in swallowing (Jean, 1984; Mansson & Sandberg, 1974; Pommerenke, 1928). Direct stimulation of the

glossopharyngeal nerve (GPN) elicits swallowing when stimulated in the cat (Sinclair, 1970). Anaesthetisation of the internal superior laryngeal nerve (iSLN) produces a globus sensation and increased difficulty in initiating swallowing (Jafari, Prince, Kim, & Paydarfar, 2003) and anaesthetisation of the larynx causes increased premature spillage, pharyngeal residue and laryngeal penetration (Sulica, Hembree, & Blitzer, 2002). However, oral sensation is not routinely assessed during assessment of swallowing. Oral sensation can be assessed through the sensation of touch, temperature, and taste (Boliek et al., 2007). Touch can be assessed with vibration (Fucci & Petrosino, 1995; Rolke et al., 2006) and light touch (Boliek et al., 2007; Komiyama et al., 2008). Proprioception can be assessed with two point discrimination tasks (Boliek et al., 2007; Grossman, 1964; Won et al., 2017) and oral stereognosis tests (Essick et al., 1999; Müller et al., 1995). Temperature can be assessed using hot and cold items (Boliek et al., 2007; Rolke et al., 2006), and taste by using solutions of differing concentrations of basic tastes (Boliek et al., 2007; Salata et al., 1991). For swallowing to be initiated in the pharynx, adequate sensory information is required to reach the nucleus tractus solitarius (NTS) for the central pattern generator (CPG) to initiate a swallowing response. However, it is unknown how much sensory information is required to reach the NTS before a swallowing response is initiated nor how much sensory loss can alter the swallowing response. Pommerenke (1928) showed that there are multiple areas in the mouth that are responsible for eliciting swallowing but the area most sensitive to the initiation of swallowing was the anterior faucial arch, followed by the posterior pharyngeal wall when the stimulus was stronger. The least important areas for stimulating swallowing were found to be the soft palate and uvula (Pommerenke, 1928) (**Figure 2**). Thus, when evaluating oral sensation methods, the ability to assess the anterior faucial arch is paramount.

Figure 2

Areas of the Oral Cavity Most Sensitive to Elicit Swallowing

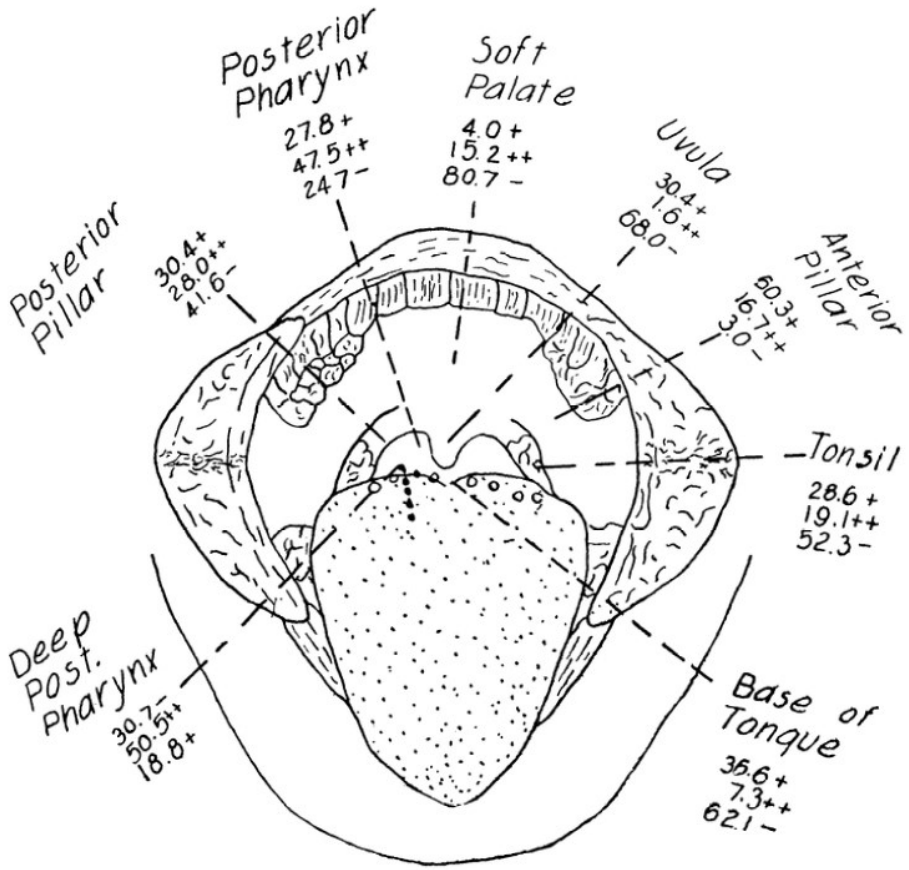


Illustration showing the areas that elicit swallowing. The numbers represent percentage. The "+" indicates to a swallow was elicited in response to a light stimulus, the "++" indicates a swallow was only elicited with strong touch over a larger area, and "-" indicates that no swallowing response was elicited. Pommerenke, W.T. (1928). A Study of the Sensory Areas Eliciting the Swallowing Reflex. *American Journal of Physiology, 84,* 36-41. Reprinted with permission.

The most common assessment of touch is the Semmes-Weinstein monofilament sensory test (Semmes-Weinstein Aesthesiometer ®, Stoelting, IL, USA) (Jacobs, Wu, Van Loven, et al., 2002). This test is a standardised system used to determine a threshold level based on the detection of different sized plastic monofilaments. The monofilaments bend with different degrees of force when

pressed against the skin at right angles. A threshold is established by determining the lightest monofilament that can be detected. It has been used successfully to assess sensation on the lips, tongue, and hard palate (Cordeiro et al., 1997; Grushka et al., 1987; Komiyama & De Laat, 2005; Komiyama et al., 2008), but not faucial arches. Bearelly and Cheung (2017) used a specially modified (non-commercially available) monofilament which unlike the Semmes-Weinstein monofilaments, are not mounted on a right-angled handle (which make accessibility to the posterior mouth difficult). Their monofilaments were inserted into single-use ureteral catheters. With these custom-built monofilaments, they were able to assess sensation as far back as the pharyngeal wall, however they did not assess the faucial arches (Bearelly & Cheung, 2017). In addition to access difficulties, the monofilaments have a pre-determined threshold value, therefore small differences are unable to be captured and the lowest monofilament exerts a force of 0.08mN which is higher than other reports of tongue mucosa sensory threshold of 0.03mN (Trulsson & Essick, 1997).

Two-point discrimination tasks are used to discriminate spatial acuity between two points of touch (Lundborg & Rosén, 2004). Thresholds can be established by asking the subjects whether they feel one point or two, while gradually decreasing the distance between the two points. Norms have been established for the tongue at 3-6mm using a commercial tool known as the MacKinnon-Dellon Disk-criminator © (Mackinnon & Dellon, 1985) (Boliek et al., 2007). However, this is difficult to position in the oral cavity to assess other sites due to its size (Jacobs, Wu, Goossens, et al., 2002). Two-point discrimination has also been assessed with callipers or a paperclip which may make it more suitable for use in the posterior oral cavity. There are few studies that have addressed reliability in the oral cavity. Won et al., (2017) reported significant variation within and between subjects on the anterior tongue, and reliability on the tongue dorsum has been shown to be poor (Lass & Park, 1973). Other tests such as vibration (Fucci & Petrosino, 1995; Rolke et al., 2006), taste (Boliek et al., 2007; Salata et al., 1991) and temperature (Boliek et al., 2007; Rolke et al., 2006) have

been shown to be reliable on the tongue but there are no reports of the feasibility of measuring sensory thresholds of the faucial arch with these methods and it would seem difficult to execute.

Electrical stimulation has been used extensively to detect cutaneous sensory perception thresholds for a variety of purposes including sensory impairments in spinal nerve injury, peripheral neuropathy and stroke (Ellaway & Catley, 2013; Gaudreault et al., 2015; Hedman & Sullivan, 2011; Leong et al., 2009; Leong et al., 2010; Pitei et al., 1994; Savic et al., 2006). The use of electrical stimulation in this manner generates a measure known as current perception threshold (CPT) which is used to determine the sensory threshold of sensation to the skin. Stimulation is provided via electrodes to the surface of the skin and frequency is commonly delivered at 5Hz, 250Hz and 2000Hz. These values have been selected due to theories that 5Hz stimulates unmyelinated fibres (C-fibres) and 250Hz stimulate thin myelinated fibres (a∂-fibres) (Zhou et al., 2018). Both of these fibres are seen in free nerve endings. The 2000Hz frequency is believed to stimulate thick myelinated fibres (AB-fibres) which are seen in the Pacinian corpuscle, Meissner corpuscle, and Merkel discs. However the use of frequency-related sensory stimulation is controversial (Martins et al., 2013). Felix et al., (2009) report that stimulation at 5Hz, activates all a∂-, AB-, and C fibres.

The use of electrical stimulation in the mouth is uncommon. Park et al., (1997) used electrical stimulation delivered to the soft palate to investigate whether it had an effect on swallowing function in four participants, post-stroke. A palatal prosthesis embedded with stimulating electrodes was used to deliver a stimulus that started at 0.5mA and increased in 0.2 mA increments until the participant's tolerance was reached. Detection was reported at between 10 and 14mA for one participant and 3.8 mA for another. The other participant's detection thresholds were not reported; however maximum stimulation reached 39.5 mA for one participant (Park et al., 1997). Similarly, Power et al., (2006), delivered electrical stimulation to the faucial pillars to investigate its effect on swallowing in post-stroke participants. Intensity started at 0.5 mA and was increased in 0.2

mA increments until the participants' tolerance was reached. They reported the mean sensory threshold of the faucial pillars was 4.1 ± 0.5 mA (Power et al., 2006).

There are some reports of electrical stimulation to establish sensory perception thresholds in the mouth (Ogawa et al., 2017; Ogura et al., 2007; Seno, 2011) (**Table 4**). Seno (2011) established sensory perception threshold to the mouth and lips using electrical stimulation on 120 healthy young subjects with a mean age of 22.56 (female) and 22.0 (male) years. Stimulation was delivered by a purpose-built stimulation device (PainVision PS-2100, Oshachi, Japan). A current was gradually delivered from 0 – 256 mA at 50 Hz, until a stimulus was detected. The perception threshold was recorded as the lowest detected stimulus. Intensity threshold means were recorded for upper and lower lips, upper and lower gums and tip, body, and base of tongue. These ranged from 5.73 mA (females tip of tongue) to 20.18 mA (males base of tongue).

Ogura et al., (2007) and Ogawa et al., (2017) established palatal thresholds using the same method of electrical stimulation. Electrical stimulation was delivered using the Neurometer (Neurotron Incorporated, Baltimore) to the hard palate via a custom-made oral prosthesis. The Neurometer presents a constant alternating current, sinusoidal waveform stimuli delivered at either 2000Hz, 250Hz and 5Hz with an electrical current range of between 0.01mA to 9.99mA. The electrical current was increased slowly from 0mA, in 0.01mA increments until a sensation was perceived by the participant. The Neurometer was then able to deliver random implemented sensations above and below this initial threshold to determine the exact perception threshold. Ogura et al., (2007) recorded anterior palate thresholds for the nasopalatine nerve and posterior palate threshold for the greater palatine nerve. Ogawa et al., (2017) did not report by sex. These values are shown in **Table 4** below.

Table 4.

Oral Sensory Perception Thresholds

Author	Electrical Parameters	Site	Sex	Threshold
Seno, 2011 (Selected sites only shown)	50Hz, mA	upper central lips	male	9.57 +/- 3.71
		lower central lips	male	8.95 +/- 3.12
		central tongue	male	14.97 +/- 6.19
		base of tongue	male	20.18 +/- 10.28
		upper central lips	female	8.39 +/- 3.39
		lower central lips	female	7.82 +/- 2.52
		central tongue	female	12.50 +/- 5.81
		base of tongue	female	14.53 +/- 8.47
Ogura, 2007	5Hz, mA	anterior palate	male	8.2 (+/- 6.1)
	250Hz			11.8 (+/- 6.8)
	2000Hz			29.4 (+/- 10.6)
	5Hz	posterior palate	male	13.3 (+/- 6.3)
	250Hz			17.0 (+/- 6.7)
	2000Hz			38.2 (+/- 11.5)
	5Hz, mA	anterior palate	female	6.7 (+/- 4.6)
	250Hz			9.5 (+/- 4.9)
	2000Hz			24.0 (+/- 6.8)
	5Hz, mA	posterior palate	female	9.8 (+/- 4.6)
	250Hz			14.4 (+/- 5.9)
	2000Hz			32.3 (+/- 9.0)
Ogawa, 2017	5Hz, mA	posterior palate	N/A	16.3mA (+/- 18.6)
	250Hz			26.8mA (+/- 31.0)
	2000Hz			40.0mA (+/- 27.6)

In summary, oral sensation has not previously been assessed in relation to delayed pharyngeal swallowing. However, it is reasonable to suggest that reduced sensation will causes changes to swallowing biomechanics, given what we know about the importance of sensation in swallowing. Different methods have been used to assess oral sensation; however, most methods are unable to assess sensation at the faucial arch, which may be the most important location to assess. Electrical

stimulation can assess sensation at the faucial arch. It can also quantify a threshold for establishment of normative data.

4.2. Oral Sensory Impairment in Stroke

Most research which addresses oral sensory impairments post-stroke is limited to cheiro-oral syndrome (An et al., 2008; Arboix et al., 2005; Satpute et al., 2013; Sekine et al., 2011), and an absence of the gag reflex (Nakajima et al., 2010; Nishiwaki et al., 2005; Oliveira et al., 2015; Ramsey et al., 2005; Schroeder et al., 2006; Terre & Mearin, 2006). Schimmel et al. (2017) studied oral sensitivity post-stroke to identify the impact that reduced sensation has on masticatory function. There were 27 stroke patients matched with 27 controls. Unfortunately, those with acute risk of aspiration or who were tube-fed were excluded, biasing the population to the more mildly impaired subgroup. Two methods of oral sensation were assessed:

1. Tactile detection thresholds using von Frey filaments on three bilateral sites – the outer surface of the lip (approximately halfway between philtrum and oral commissure), the dorsum of the tongue opposing the second premolar and the cheek opposing the second premolar tooth. Tactile detection threshold is established by the smallest filament perceived on the detection site. Both infra- and supra-thresholds were established, and the mean of these results were used in the evaluation.
2. Two-point discrimination thresholds using a medical calliper. This threshold is obtained by the subjects' ability to detect two simultaneously presented punctiform stimuli that ranged from 0-15mm. The smallest separation where the subject is able to detect two stimuli is recorded as the threshold. There were two sites: the extraoral surface of the lip bilaterally and the dorsum of the tongue opposing the second pre-molar tooth bilaterally.

Bite force and masticatory function were assessed using an occlusional force meter and chewing gum colour-mixing ability test respectively. Results showed that thresholds for two-point discrimination and tactile detection thresholds were higher on the contra-lesional side for the stroke

group compared to the control group, indicating reduced sensation. Furthermore, within the stroke group, the contra-lesional side had higher thresholds for all sites except for the lips, which had higher thresholds on both sides indicating a crossover of sensory fibres in the lips. There was no difference between the stroke group and the control group in bite force, indicating no differences in motor ability of the trigeminal nerve. However, masticatory function was significantly lower in the stroke group compared to the control, which, given the absence of impaired motor jaw function, is presumed to be due to muscle weakness within the tongue. However, it could also be the result of poor sensation. Again, the authors did not look at the impact of this in dysphagia and related outcome measures (Schimmel et al., 2017). Therefore, it remains unknown whether reduced sensation is the cause of dysphagia in these subjects.

4.3. Sensory-based treatments

Despite the lack of relationship between impaired swallowing biomechanics and reduced sensation, sensory-based interventions are well-established in dysphagia rehabilitation. Thermal-tactile stimulation, which is a sensory-based treatment that uses cold touch as both a compensatory and rehabilitation approach to improve delayed pharyngeal swallowing, has shown varied success. It was first described by Logemann (1983) to reduce “pharyngeal delay time” by increasing sensory stimulation to the faucial arches. This was proposed to increase sensory information reaching the CPG to initiate a timelier swallow. It was initially used as a compensatory approach with evidence that it facilitates immediate changes to swallowing in healthy participants (Kaatzke-McDonald et al., 1996; Sciortino et al., 2003) although there are studies that found opposing outcomes (Ali et al., 1996). There are also mixed results in studies with dysphagic participants. Some studies have shown an immediate reduction of pharyngeal stage delay (de Lama Lazzara et al., 1986; Nakamura & Fujishima, 2013; Regan et al., 2010; Rosenbek, Roecker, et al., 1996; Sciortino et al., 2003) although outcome methods were variable. For example, de Lama Lazzara et al., (1986) stimulated the base of the faucial arches of 25 neurologically impaired patients who had delayed pharyngeal swallowing.

Delayed pharyngeal swallowing was defined as “when the bolus fell over the back of the tongue into the pharynx without eliciting any response in the pharynx” p.74. The “delay” was at least 1.5 seconds. Improvements were demonstrated in 23/28 participants. However, the outcome measure used to measure improvement was pharyngeal transit time rather than pharyngeal delay time, therefore it is unclear whether improvements were due to a quicker pharyngeal swallowing response or faster transfer through the pharynx (or both). Nakamura and Fujishima (2013) examined the effect of thermal stimulation to the faucial arches in 24 participants following stroke and cerebrovascular disease. Their results also showed improvements in triggering a pharyngeal swallow response. However, participants were cued to swallow, which is known to alter the bolus position at the onset of swallowing response (Daniels et al., 2007). Furthermore, they measured the swallowing response between the time from the cue to swallow and the rapid elevation of the thyroid cartilage. This may have included a delay in the oral transfer of the bolus +/- a pharyngeal delay. In studies where thermal-tactile stimulation has been used as a rehabilitative intervention; results have been less promising. Lim et al., (2009) reported improved pharyngeal transit time (which is not a measure of delay) in response to thermal-tactile stimulation used in conjunction with neuromuscular electrical stimulation (NMES). NMES was delivered for 1 hour per day, 5 days per week for four weeks. Thermal-tactile stimulation was also carried out for 5 days per week for four weeks, however there was no description of how long the faucial arches were stimulated. A control group was provided with thermal-tactile stimulation only. The authors reported that pharyngeal transit time decreased in the experimental group but not the control group. It is therefore possible that the thermal-tactile stimulation component to the treatment had no effect on the pharyngeal transit time. Furthermore, there was no description of how pharyngeal transit time was measured. Rosenbek et al., (1991) failed to report an improvement in delayed pharyngeal swallowing over a two-week period of intervention for dysphagia patients who had multiple strokes. The faucial arches were stimulated 15-25 times during each session, for a maximum of 8 sessions per day. Stage

transition duration was used to measure the onset of the pharyngeal swallow. This was described as the time between when the head of the bolus reaches the ramus of the mandible to the beginning of maximal hyoid elevation. However, since the head of the bolus was not defined, it is possible that poor bolus containment was included in the measurements. This may theoretically not improve with thermal-tactile stimulation and may explain a lack of improvement. Indeed, in all these studies, there was poor description of subject selection, poor detail of stimulation methods, varying outcome methods, and no consideration of a distinction between poor bolus containment and delayed pharyngeal swallowing. Therefore, it's possible that some participants may have had poor bolus containment rather than delayed pharyngeal swallowing. It continues to remain unclear whether thermal-tactile stimulation is an appropriate treatment for delayed pharyngeal swallowing.

Other sensory-based treatments have shown success in the treatment of dysphagia. A sour bolus has been shown to reduce pharyngeal delay time. Pauloski and Nasir (2016) used taste to determine a relationship between taste sensation and the onset of pharyngeal swallowing. A shorter pharyngeal delay time was associated with greater tendency to detect the sour tastes for paste boluses adding some evidence to support that (taste) sensation is associated with a delay. They also found that a longer pharyngeal delay time was correlated with a lower detection threshold for sweet taste for liquids, suggesting that poor detection of sweet taste may increase pharyngeal delay time. Taste has also been shown to increase swallowing frequency. Brady et al., (2016) used FEES to investigate the relationship between taste and spontaneous swallowing frequency. They found that the use of a spearmint flavoured oral strip placed in the mouth, significantly increased swallowing frequency. Whilst this doesn't suggest a link with shorter pharyngeal delay time, it does suggest that taste increases the signal to the brain to swallow, further adding evidence for the importance of sensation in swallowing. Other studies have had similar findings: A combination of cold and sour has been shown to reduce oral transit time (Gatto et al., 2013) reduce swallowing delay/initiate

swallowing at a higher bolus location (Gatto et al., 2021) and reduce pharyngeal transit time (Cola et al., 2010).

Yet it's not just timing measures that have demonstrated improvement with the use of taste sensation. Pelletier and Steele (2014) found that high-intensity sour stimuli increased anterior lingual-palatal pressure and submental muscle contraction during swallowing. Similarly, Dietsch et al., (2019) found that a combination of sweet and sour increased tongue-base retraction, pharyngeal shortening, hyoid elevation, and improved PAS scores in those with sensory dysphagia, defined as a delay in initiation of swallowing, or poor response to residue or penetration/aspiration (Dietsch et al., 2019). These studies suggests that sensation may also have a role in determining strength during swallowing. Ding et al., (2003) explain how sensation increases strength: They argue that increased sensation increases the input to the NTS. The NTS then sends a stronger signal to the NA with subsequent activation of cranial nerve nuclei which initiates faster and stronger swallowing.

More recently, pharyngeal electrical stimulation (PES) has been used as a treatment for dysphagia. This intervention uses nasogastric tubes modified with electrodes to deliver an electrical current (0.2 -ms pulses, 280 V, 5Hz) for a ten-minute period to the pharynx for three days (Fraser et al., 2002). Results regarding swallowing improvements are limited, with most reporting no difference between treatment and sham (Bath et al., 2016; Essa et al., 2017; Vasant et al., 2016), although under-treatment may have been a factor (Bath et al., 2016). There has been some evidence that PES improves swallowing duration measures (Fraser et al., 2002) and improved outcomes on the penetration-aspiration scale (Restivo et al., 2013). Dziewas et al., (2018) demonstrated that PES can lead to higher rates of decannulation according to a FEES based decision protocol. The protocol determines that participants are not ready for decannulation when they that have less than one swallow per minute, massive pooling of secretions or no sensation of the laryngeal vestibule when contacted by the endoscope. Use of PES compared to sham led to 40% of the treatment group being

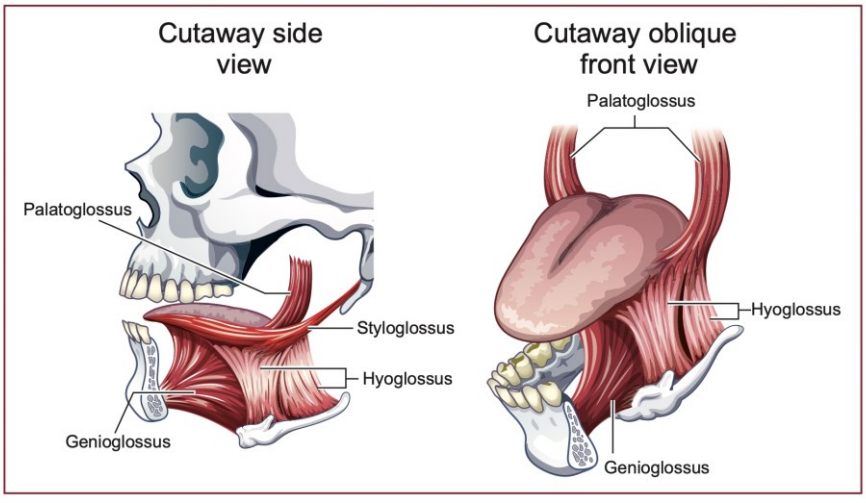
decannulated compared to 9% of the sham group. This suggests that PES increases swallowing frequency, reduces pooled secretions, and improves sensation in the laryngeal vestibule.

Chapter 5 Glossopalatal Approximation

Glossopalatal approximation is achieved by contact of the posterior tongue and soft palate, presumably by exerting adequate opposing force. The tongue is mostly comprised of muscle. There are four paired intrinsic muscles and four paired extrinsic muscles as described previously. The intrinsic muscles of the tongue assist in manipulating and controlling food and fluids; whereas the extrinsic muscles of the tongue enable the tongue to protrude, depress, elevate, and retract. The soft palate is made up of five paired muscles. These include the palatoglossus, palatal levator, uvulus, tensor palatine, and pharyngopalatine (Weismer et al., 2020). Glossopalatal approximation is achieved primarily by the glossopalatine muscle which elevates the posterior tongue blade and depresses the soft palate so that they approximate each other. However, other muscles as shown in **Figure 3**, also have a role. These include the styloglossus muscle which retracts and elevates the tongue superiorly and posteriorly, and the stylohyoid and posterior belly of the digastric muscles (considered suprahyoid muscles) which elevates the tongue (Daniels et al., 2019).

Figure 3

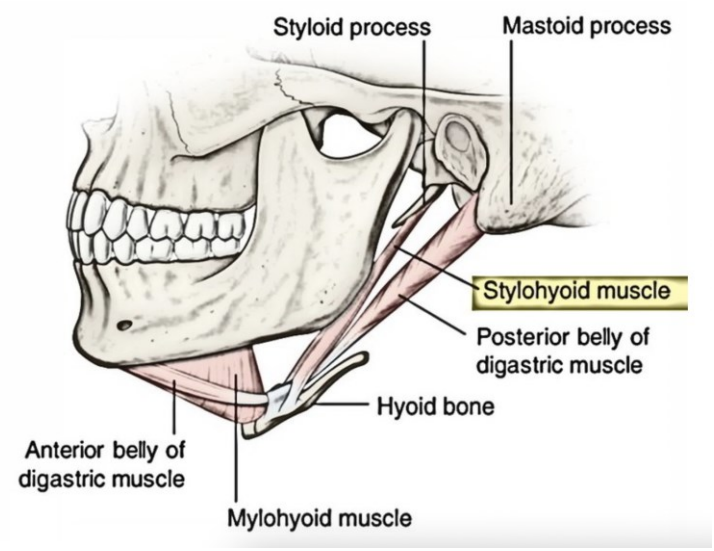
Extrinsic Muscles of the Tongue



From Weismer, G., Story, B., & Hoit, J. (2020). *Foundations of speech and hearing: Anatomy and physiology*. Plural Publishing, Incorporated. Reproduced with permission.

Figure 4

Suprahyoid Muscles



Retrieved from: https://www.earthslab.com/anatomy/styloid-gear/ Reproduced with permission.

The palatoglossus is described as a sphincter, similar to the lips, forming a near complete circle at the junction between the oral and pharyngeal cavities (Gick et al., 2014). The fibres of the paired palatoglossus blend closely with the longitudinal fibres of the dorsal tongue. They traverse superiorly and medially towards the palate, forming the faucial arches (Weismer et al., 2020). On acceptance of the bolus into the mouth, the central tongue depresses to contain the bolus and the posterior tongue elevates to approximate the palate and maintains a seal to prevent early entry of the bolus into the pharynx. Whilst greater depression of the tongue occurs with increasing bolus volume, glossopalatal pressure does not increase, requiring just 0-2mm Hg to maintain a seal (Dantas, Dodds, et al., 1990).

5.1. Assessment of Glossopalatal Function

It is difficult to assess competence of the glossopalatal seal. Incompetence is usually inferred during VFSS when bolus escape from the oral cavity into the pharynx is observed prior to purposeful movement of the tongue (Dodds et al., 1990). Although there is no evidence to demonstrate

glossopalatal approximation during maximum isometric posterior lingual-palatal pressure tasks, it is reasonable to suggest that it is achieved. Palmer et al., (2008) demonstrated glossopalatal approximation during a lingual-palatal pressure task. EMG needle electrodes were inserted transorally directly into the tongue, floor of mouth, velum, and cheeks to assess activation of the velum, intrinsic tongue muscles, genioglossus, anterior belly of the diagastric, mylohyoid, and geniohyoid during anterior lingual-palatal pressure tasks. Increased muscle activity was seen in all muscles but less so in the intrinsic tongue muscles and medial pterygoid. The strongest relationship was seen with the floor of mouth muscles and the posterior genioglossus demonstrating that glossopalatal approximation is achieved during a lingual-palatal pressure task (Palmer et al., 2008).

Whilst other devices have been used to assess and rehabilitate lingual-palatal pressure (Hori et al., 2005; Juan et al., 2013; McCormack et al., 2015; Todd et al., 2013), perhaps the most commonly used device is the Iowa Oral Pressure Instrument (IOPI) (IOPI Medical LLC, Redmond, WA), an air-filled bulb attached to a manometer that measures tongue to palate pressure in kilopascals (kPa). It has been used to measure tongue to palate pressure in the anterior position (Vanderwegen et al., 2013; Youmans & Stierwalt, 2006; Youmans et al., 2009) and less so in the posterior position (Oh et al., 2017; Wu et al., 2020).

The IOPI has demonstrated improvements in lingual-palatal pressure generation (H. D. Kim et al., 2017; McKenna et al., 2017; Steele et al., 2016) but few studies have evaluated specific changes to muscle mass and activation. Park et al., (2019) showed an increase in muscle mass of the mylohyoid and digastric muscles following a lingual-palatal pressure training program, and anterior (Oh, 2022) and posterior (Reis et al., 2017) tongue pressure training has been found to improve suprahyoid muscle activation as detected by sEMG.

In summary, glossopalatal function during lingual-palatal pressure assessment or training has not been assessed and therefore its activation during lingual-palatal pressure assessment or training is unknown. However, we infer lingual-palatal strength measured with pressure devices such

as the IOPI is indicative of glossopalatal approximation. Further, since the lingual muscles work together to control and manipulate the bolus, it is feasible to consider that reduced glossopalatal function will lead to reduced tongue to palatal pressures as assessed by the IOPI.

5.2. Reduced Lingual-Palatal Pressure in Stroke

Reduction in lingual-palatal pressure is well-documented in stroke patients with dysphagia (Hirota et al., 2010; Hori et al., 2005; Konaka et al., 2010; Lee et al., 2016; Nakamori et al., 2016; Smaoui et al., 2022). Nakamori et al., (2016) examined the relationship between lingual-palatal pressure and pneumonia in stroke patients. Lingual-palatal pressure was assessed with a balloon type bulb and established via 3 repetitions of maximum isometric lingual-palatal pressure generation tasks. Dysphagia diagnosis was based on the modified MASA when the score was less than 95. Of a total of 220 subjects, 98 scored less than 95 on the modified MASA. The mean lingual-palatal pressure was 22.8±14.6 kPa. Pneumonia occurred in 35 subjects. Those who developed pneumonia had significantly lower lingual-palatal pressure than those who did not. However, those who developed pneumonia had a greater stroke severity than those who didn't, therefore reduced lingual-palatal pressure may simply identify patients who are generally more unwell and thus more likely to get pneumonia.

Hori et al., (2005), studied 10 patients following stroke in a rehabilitation ward, with 5 control subjects. A T-shaped sensor sheet fitted to the hard palate measured lingual-palatal pressure during dry swallowing. A diagnosis of dysphagia was made based on a timed water swallow test where two groups were formed based on the mean swallowing time of the sample and then separated into 'better than average' or 'worse than average'. Lingual-palatal pressure was reported to be higher in subjects with 'better than average' scored on timed water swallowing test (Hori et al., 2005). However, there was high variability between subjects and a small sample size, therefore these results may not be translated to a post-stroke dysphagic population. In a similar manner and from the same group of researchers, Konaka et al., (2010) investigated the relationship between

reduced lingual-palatal pressure and dysphagia in 64 patients with stroke, 30 of which were determined to have dysphagia using a water swallow test. Using a T-shaped sensor attached to the palate to measure lingual-palatal pressure, results indicated that the maximum lingual-palatal pressure was significantly lower in the stroke patients who had dysphagia compared with the stroke patients who did not have dysphagia. However, their diagnosis of dysphagia was based on a water swallow test; no instrumental swallowing assessment was evaluated. Therefore, the accuracy of the findings is questionable. These studies suggest that there is a link between reduced lingual-palatal pressure and dysphagia post-stroke. However, as instrumental assessment of swallowing was not used to describe the biomechanical impairment leading to dysphagia, it is unclear how reduced lingual-palatal pressure during swallowing resulted in dysphagia.

Lee et al., (2016) investigated the relationship between maximal isometric lingual pressure in anterior, posterior, and lateral positions using the IOPI, and indicators of dysphagia using videofluoroscopy in a cohort of 96 patients with a stroke in the subacute phase. Results indicated that reduced isometric lingual-palatal pressure in both the anterior and posterior positions was associated with all elements of oral phase dysphagia including bolus formation, premature bolus loss, mastication, oral transit time, and tongue to palate contact (Lee et al., 2016). In contrast, Smaoui et al., (2022) investigated maximum anterior lingual-palatal pressure in six participants with a three-month history of stroke. Whilst all subjects presented with dysphagia, there was no consistent swallowing profile between them. However, with a study size of only six participants, it may be difficult to draw any meaningful conclusions from this study.

5.3. Strength-based Treatments for Tongue Control

Oral motor exercises are one of the longest-standing approaches to dysphagia rehabilitation (Logemann, 1983), although more evidence to support their use in improving swallowing function is needed (Lazarus et al., 2011; McKenna et al., 2017). Lingual-palatal exercises are the most common oral motor rehabilitation technique reported in the literature. There is sufficient evidence to suggest

that maximum lingual-palatal pressures increase following a lingual-palatal training intervention (Franciotti et al., 2022; Lin et al., 2022). However, translation into improvements in swallowing is less convincing (McKenna et al., 2017). Steele et al., (2016) did not find any improvement in stage transition duration following a lingual strengthening program to evaluate improved oral tongue control and bolus containment in the mouth. They proposed that since an increase in stage transition duration can be the result of either poor bolus containment or delayed pharyngeal swallowing, an absence of change may suggest that stage transition duration was measuring delayed pharyngeal swallowing rather than poor bolus containment in their cohort, and therefore was not an appropriate measure for poor bolus containment (Steele et al., 2016). Clearly there is a need for assessment methods to be able to differentiate between poor bolus containment and delayed pharyngeal swallowing.

Summary

Pre-swallow pooling is a feature of dysphagia that has two proposed causes: a sensory cause that leads to a delay in initiating the pharyngeal swallowing sequence, and a motor cause, resulting in poor containment of the bolus in the mouth with subsequent loss of some of the bolus into the pharynx before prior to purposeful propulsion. However, there has been no evidence to clearly link impaired sensation with delay or reduced lingual-palatal pressure with poor bolus containment, and thus not enough evidence to differentiate two causes of pre-swallow pooling. There is some evidence that there is reduced oral sensation and reduced lingual-palatal pressure in stroke associated with dysphagia, however evidence for how this leads to dysphagia is lacking. Despite this, both strength-based and to a lesser extent, sensory-based treatments are common in the treatment of people with dysphagia post stroke. Lack of success in some studies may be due to poor participant selection due to difficulties in differentiating between sensory and motor causes of dysphagia.

Assessment of oral sensation with electrical stimulation may be a useful measure of sensation to assist in the evaluation of delayed pharyngeal swallowing. Assessment of posterior

lingual-palatal pressure using the IOPI is a well explored method and may provide insight into glossopalatal function for bolus containment. If both are found to be reliable and predictive in the differentiation of delayed pharyngeal swallowing from poor bolus containment, then these simple tools may be useful to assist in the identification of appropriate therapeutic techniques for dysphagia rehabilitation post stroke.

Chapter 6 Objectives and Hypotheses

This programme of research will systematically evaluate the concept of pre-swallow pooling and how it relates to physiological measures of strength and sensation. These research questions will be evaluated in four studies which will determine whether there is empirical evidence for differentiated sensory and motor causes of pre-swallow pooling and whether our current methods for determining the differences between them are valid.

6.1. Reliability of Posterior Lingual-Palatal Pressure and Oral Sensory Thresholds (Study 1)

Statement of problem:

There are no empirical data that have linked the physiological impairment of sensation to a diagnosis of delayed pharyngeal swallowing, or an impairment of lingual-palatal pressure to a diagnosis of poor bolus containment. This may, in part, be due to poor assessment techniques of oral sensation and glossopalatal function. This study investigated the use of electrical stimulation to assess sensory perception thresholds in the oral cavity and the IOPI to assess posterior lingual-palatal pressure. From these data, normative data will be established, and the reliability of these techniques will be evaluated.

Research questions:

1. Are measures of posterior lingual-palatal pressure using IOPI and oral sensation using electrical stimulation reliable?
2. What are the oral sensory thresholds of the top lip, bottom lip, anterior tongue and faucial arch in a representative sample of healthy community-dwelling females and males of different age-ranges in a metropolitan area?

3. What are the posterior isometric lingual-palatal pressure and the posterior lingual-palatal pressure values during swallowing values in a representative sample of healthy community-dwelling females and males of different age-ranges in a metropolitan area?

Primary objectives:

The primary aim of this study was to determine the reliability of oral sensory perception thresholds using electrical stimulation presented via pudendal electrode and posterior lingual-palatal pressure using the IOPI device in a healthy population. A secondary aim was to determine the relationship, if any, of the sensory perception measures to the posterior lingual-palatal pressure measures to determine the level of dependence. Should these methods prove reliable, normative data for oral sensory perception thresholds and posterior lingual-palatal pressure could be used in further studies to identify potential dysphagia.

Proposed Hypotheses:

1. There will be at least moderate reliability (ICC 0.50 – 0.75) (Koo & Li, 2016) within each session for oral sensation measures.
2. There will be at least moderate reliability (ICC 0.50 – 0.75) (Koo & Li, 2016) within each session for posterior lingual-palatal pressure measures.
3. There will be less than 10% change in mean between trials within each session for oral sensation measures.
4. There will be less than 10% change in mean between trials within each session for posterior lingual-palatal pressure measures.
5. There will be at least moderate reliability (ICC 0.50 – 0.75) (Koo & Li, 2016) between sessions for oral sensation measures.
6. There will be at least moderate reliability (ICC 0.50 – 0.75) (Koo & Li, 2016) between sessions for posterior lingual-palatal pressure measures.
7. There will be less than 10% change in mean between sessions for oral sensation measures.

8. There will be less than 10% change in mean between sessions for posterior lingual-palatal pressure measures.

Significance:

Normative values are required as a reference by which to judge abnormal values. The posterior tongue has been selected due to its function in glossopalatal approximation during bolus control. IOPI norms exist for isometric lingual-palatal pressure in the anterior and posterior position (Adams et al., 2013; Vanderwegen et al., 2013; Youmans et al., 2009). Norms also exist for lingual-palatal pressure during swallowing (Fei et al., 2013; Nicosia et al., 2000; Robbins et al., 1995; Todd et al., 2013; Youmans & Stierwalt, 2006). However, only Todd et al., (2013) Robbins et al., (1995) and Nicosia et al., (2000) reported on posterior lingual-palatal pressure during swallowing. Todd et al., (2013) used the Kay Pentax system which is no longer available, and Robbins et. al., (1995) and Nicosia et al., (2000) had very small sample sizes. Furthermore, norms have been found to differ in different populations (Vanderwegen et al., 2013). There is only one study that has evaluated oral sensory thresholds to electrical stimulation in young adults (Seno, 2011). Therefore, further exploration and establishment of norms are needed to include older adults. Norms for oral sensation and lingual-palatal pressure will need to be obtained in the same cohort as a baseline by which the dependent studies can be evaluated.

Should these tools be shown to be reliable, they may be useful in the assessment of oral sensation and glossopalatal function. This may then assist in the differential diagnosis of pre-swallow pooling as either a motor or sensory impairment which would enable the appropriate sensory or strength-based treatment to be selected for people with dysphagia and thus influence their subsequent successful recovery.

Proposed study:

Healthy participants will undergo assessments of oral sensory perception thresholds and posterior lingual-palatal pressure. A selection of 20% of recruited participants will repeat the assessments with

the same assessor and a further 20% will repeat the assessments with a different assessor, one week after the initial assessments. Estimated percentage change of the mean, inter-rater reliability and test-retest reliability of both assessments will be calculated within and between sessions. Means and confidence intervals for normative values will be described according to age and sex as described in chapter 7.

6.2. Reliability of Speech Pathologists' Classification of Pre-Swallow Pooling (Study 2)

Statement of problem:

There is currently no validated method for determining poor bolus containment from delayed pharyngeal swallowing, the two presumed causes of pre-swallow pooling. Current methods rely on observation of swallowing biomechanics and bolus flow on videofluoroscopic swallowing studies. These movements include the separation of the glossopalatal seal, the purposeful movement of the tongue to move the bolus back in the mouth, the head of the bolus reaching the point where the posterior ramus of the mandible crosses the base of tongue, and the initiation of hyolaryngeal movement. How the bolus flows in relation to these movements determines a diagnosis. Poor bolus containment is diagnosed when some of the bolus breaks away from the main part of the bolus and enters the pharynx before or during the purposeful movement of the tongue during oral transfer. Delayed pharyngeal swallowing is diagnosed when a cohesive bolus is propelled into the pharynx but hyolaryngeal excursion is not initiated by the time the bolus reaches the point where the posterior ramus of the mandible crosses the base of the tongue. However, in clinical practice, this distinction may prove difficult. Therefore, this study will investigate the reliability of this measurement technique both within raters and between raters.

Research questions:

1. How reliable is the clinical diagnosis of pre-swallow pooling as poor bolus containment or delayed swallowing between speech pathologists?
2. How reliable is the clinical diagnosis of pre-swallow pooling as poor bolus containment or delayed pharyngeal swallowing by the same speech pathologist?
3. Does reliability improve when given clear definitions of the measurement technique?

Primary objectives:

The primary objective of this study is to determine whether the methods for determining poor bolus containment from delayed pharyngeal swallowing are reliable between and within raters and whether the provision of definitions for the measurement of each measure increases reliability.

Hypotheses:

1. Speech pathologists will achieve:
    a. Moderate kappa ($k > .60$) intra- rater reliability when deciding between a diagnosis of poor bolus containment and delayed pharyngeal swallowing.
    b. Moderate kappa ($k > .60$) inter-rater reliability when deciding between a diagnosis of poor bolus containment and delayed pharyngeal swallowing (McHugh, 2012).
2. Speech pathologists'
    a. Intra-rater reliability will increase when provided with definitions of how to distinguish between poor bolus containment and delayed pharyngeal swallowing.
    b. Inter-rater reliability will increase when provided with definitions of how to distinguish between poor bolus containment and delayed pharyngeal swallowing.

Significance:

Should intra-rater reliability be acceptable when inter-rater reliability is poor, then it can be determined that clinicians are consistent with their measurement methods despite poor agreement

across clinicians. This would suggest that the measurement methods are inadequate and/or require better training. Should inter-rater reliability be poor in the group who are not provided with the definitions, but acceptable for the group who are provided the definitions, then it can be determined that the methods for measurement are adequate for determining one from the other. However, if inter-rater reliability is poor for both groups, then it can be determined that the current methods for determining poor bolus containment from delayed pharyngeal swallowing are unreliable for clinical differentiation of one over the other.

Proposed study:

Speech pathologists who report that they are competent in the assessment of dysphagia using videofluoroscopic swallowing studies were invited to participate in an online survey. The online survey consisted of 30 videos of stroke patients with dysphagia swallowing a single bolus of thin fluids. Five videos will be presented twice for intra-rater reliability. The speech pathologists will be randomly assigned to two groups. One group will be given measurement methods of poor bolus containment and delayed pharyngeal swallowing and the other group will not receive measurement methods. The speech pathologists will be asked to diagnose the swallowing as either poor bolus containment, delayed pharyngeal swallowing, both poor bolus containment and delayed pharyngeal swallowing or neither of these. Inter- and intra-rater reliability will be calculated under both circumstances as described in chapter 8.

6.3. Classification of Sensory and Motor Causes of Pre-Swallow Pooling using Physiological Assessment of Posterior Lingual-Palatal Pressure and Oral Sensation (Study 3)

Statement of problem:

As there is no 'gold standard' for differential diagnosis of the two causes of pre-swallow pooling, this exploratory research will categorize participants, using outcomes of physiological measures of oral sensation and posterior lingual-palatal pressure, via a cluster analysis method to determine whether distinct clusters exist that align with impaired sensation and impaired lingual-palatal pressure and whether these clusters align with clinician diagnoses of poor bolus containment and delayed swallowing.

Research question:

Using a cluster analysis approach, can measures of isometric posterior lingual-palatal pressure, posterior lingual-palatal pressure during swallowing and oral sensory perception measures, define unique groups that align with clinician judgements of poor bolus containment and delayed pharyngeal swallowing?

Hypothesis:

1. There will be at least moderate reliability (ICC 0.50 – 0.75) (Koo & Li, 2016) and percentage change in mean <10% between trials for
    a. Oral sensation measures
    b. Posterior lingual-palatal pressure measures
2. There will be four distinct clusters discriminating between sensation and strength. Patients will be allocated to the following clusters depending on their presentation:
    a. Good strength and good sensation.
    b. Good strength and poor sensation.

c. Poor strength and good sensation

d. Poor strength and poor sensation

3. Clusters will align with clinician diagnosis:

    a. Participants with reduced lingual-palatal pressure (poor strength good and sensation cluster) will align with clinician diagnosis of “poor bolus containment”.

    b. Participants with reduced oral sensation (good strength and poor sensation cluster) will align with clinician diagnosis of “delayed pharyngeal swallowing”.

    c. Participants with both reduced oral sensation and reduced lingual-palatal pressure (poor strength and poor sensation cluster) will align with clinician diagnosis of “delayed pharyngeal swallowing and poor bolus containment”.

    d. Participants with neither reduced oral sensation nor reduced lingual-palatal pressure (good strength and good sensation) will align with clinician diagnosis of “neither delayed pharyngeal swallowing nor poor bolus containment”. It is assumed that healthy participants will be allocated to this cluster.

Significance:

As there is currently no established link between those diagnosed with poor bolus containment and lingual weakness or those diagnosed with delayed pharyngeal swallowing and reduced oral sensation, this research could greatly improve our understanding of the pathophysiology of pre-swallow pooling. If this research validates clinician presumptions, treatment approaches based on clinician assessment can be tailored more effectively, leading to improved swallowing outcomes, reduced pneumonia, and dysphagia-related complications for individuals’ post-stroke. If this research identifies that our clinical presumptions are incorrect, our clinical practice will require re-evaluation and new methods for diagnosing the cause of pre-swallow pooling will need to be identified.

Proposed study:

Participants with an acute stroke will be invited to participate in this study. Measurements of oral sensation and lingual-palatal pressure in the posterior position will be collected as well as assessment of swallowing using VFSS. An exploratory cluster analysis approach will be used to determine whether distinct groups are formed. Healthy participants from study 1 will be included in the cluster analysis. The clusters will then be compared to speech pathologists' diagnosis or poor bolus containment or delayed pharyngeal swallowing, to determine whether the groups align with speech pathologists' diagnosis as detailed in chapter 9.

6.4. How Does Impaired Sensation or Impaired Lingual-Palatal Pressure Align with Measures of Functional Swallowing Biomechanics (Study 4)

Statement of Problem:

Swallowing measures such as oral transit time (OTT), stage transition duration (STD) and the penetration aspiration scale (PAS) are measures used clinically and in dysphagia research to evaluate the severity of dysphagia and response to dysphagia rehabilitation. There are no studies that have evaluated how physiological measures such as reduced sensation or lingual-palatal pressure relate to swallowing measures commonly used in the assessment of dysphagia.

Oral transit time has been shown to decrease after tongue strengthening exercises (Robbins et al., 2007). There are mixed results with sensory treatments. A sour bolus (Logemann et al., 1995) and a cold-sour bolus (Gatto et al., 2013) have been shown to decrease OTT, however carbonation has not demonstrated a reduction of OTT (Sdravou et al., 2012). There is some evidence to suggest that reductions in lingual-palatal pressure are related to increased OTT (Lee et al., 2016).

STD has been associated with reduced sensation. As discussed in Chapter carbonation and sour and sour-cold boluses have been found to reduce STD (Cola et al., 2010; Logemann et al., 1995;

Pauloski & Nasir, 2016; Sdravou et al., 2012). Conversely, Steele et al., (2016) did not find an association between increased lingual-palatal pressure with reduction in stage transition duration. Therefore, it may be logical to assume that oral sensory impairments can predict increased STD and reduced lingual-palatal pressure can predict OTT. Therefore, this study investigated the relationship between swallowing measures (OTT, STD, PAS) and physiological measures of oral sensation and lingual-palatal pressure. As there are no physiological data to identify a link between oral sensation and OTT, STD and PAS, this research provides empirical data to determine a relationship between reduced oral sensation and swallowing measures.

Research questions:

1. Which oral sensation perception threshold site predicts greater stage transition duration (STD)?
2. Is increased oral transit time (OTT) due more to reduced sensory thresholds, reduced lingual-palatal pressure, or both?
3. Is increased stage transition duration (STD) due more to reduced sensory thresholds, reduced lingual-palatal pressure, or both?
4. Are higher penetration-aspiration scale (PAS) scores due more to reduced sensory thresholds, reduced lingual-palatal pressure, or both?

Secondary objectives will be to evaluate reliability of swallowing measures (OTT, STD, PAS) between raters.

Primary objectives:

This research will provide empirical data to determine a relationship between oral sensation and/or reduced lingual-palatal pressure to OTT, STD and PAS. A secondary objective will be to determine intra-rater reliability of the swallowing measures (OTT, STD, PAS).

Hypotheses:

1. Faucial arch sensation will have a larger effect size than all the other sensation threshold sites for stage transition duration.

2. Participants who are assigned to a cluster with good strength measures will have lower mean OTT than those who are assigned to a cluster with poor strength measures.
3. Participants who are assigned to a cluster with good sensation measures will have lower mean STD than those who are assigned to a cluster with poor sensation measures.
4. Participants who are assigned to a cluster with good sensation and good strength measures will have better PAS scores than those who are assigned to a cluster with poor sensation and poor strength measures.
5. Speech pathologists will achieve good (ICC 0.75 – 0.90) (Koo & Li, 2016) intra-rater reliability of:
    a. Oral transit time.
    b. Stage transition duration.
    c. Penetration-Aspiration Scale.

Significance:

Understanding how oral sensation and lingual-palatal pressure measures relate to swallowing measures will help to determine the association of reduced physiological measures of oral sensation and lingual-palatal pressure with swallowing impairments as measured by OTT, STD and PAS and which oral sensation site is more predictive of swallowing difficulties. If oral sensation and lingual-palatal pressure measurements are predictive of changes in swallowing measures, they may be helpful in the evaluation of dysphagia.

Proposed study:

Participants who have had an acute stroke will be invited to participate in this study. Measurements of oral sensation and lingual-palatal pressure in the posterior position will be collected as well as assessment of swallowing using VFSS. Oral transit time, stage transition duration, and the Penetration-Aspiration Scale (Rosenbek, Robbins, et al., 1996) will be measured for each participant. Physiological measures will be compared to swallowing measures to evaluate the relationship between them as outlined in chapter 10.

Part B: Experimental Studies

Chapter 7 Reliability of Posterior Lingual-Palatal Pressure and Oral Sensory Thresholds.

7.1. Introduction

For treatment approaches to be successful, interventions need to match the underlying pathophysiology (Logemann, 1998). Applying the incorrect treatment due to difficulties in diagnosis may lead to lack of improvement and prolonged dysphagia, with associated increased healthcare costs and reduced quality of life for individuals with dysphagia.

Success in swallowing intervention studies is shown through the use of outcome measures. Stage transition duration (STD) is an outcome measure which determines the duration between the oral and pharyngeal phases of swallowing (Lof & Robbins, 1990). Hence it can be prolonged when pre-swallow pooling occurs. However, stage transition duration cannot distinguish between poor bolus containment and delayed pharyngeal swallowing and thus may not change if dysphagia treatment is directed to delayed pharyngeal swallowing when poor bolus containment is the impairment or vice versa. Steele et al. (2016) acknowledged this in their randomised controlled study on tongue pressure resistance training in post-stroke dysphagia. Stage transition duration and the penetration-aspiration scale were used as outcome measures to determine improvement in bolus containment following a lingual-palatal pressure resistance training protocol. Neither outcome measure showed an improvement despite a 21 kPa increase in lingual-palatal pressure. Steele et al. (2016) suggest that these measures were therefore not sensitive to show improvements in bolus containment. This may indicate that the pre-swallow pooling for the participants in this study may have been due to delayed initiation of pharyngeal swallowing rather than poor bolus containment. Therefore, the ability to differentiate poor bolus containment from delayed pharyngeal swallowing as causes of pre-swallow pooling is important for translation of meaningful research data and the

success of dysphagia rehabilitation programs. This differentiation requires identifying a sensory or motor impairment in the underlying pathophysiology.

Lingual weakness is presumed to be the cause of many signs of dysphagia, including poor bolus containment and oral residue (Logemann, 1988); however, it is unknown how much lingual weakness is required to directly result in dysphagia. Therefore, quantifying lingual weakness in the context of dysphagia may be useful in determining a cause of dysphagia symptoms.

The Iowa Oral Pressure Instrument (IOPI) (IOPI Medical LLC, Redmond, WA) is a universally available tool that consists of an air-filled bulb attached to a manometer that measures tongue to palatal pressure in kilopascals (kPa). It has been used to measure lingual-palatal pressure in the anterior position (Vanderwegen et al., 2013; Youmans & Stierwalt, 2006; Youmans et al., 2009) and less so in the posterior position (Oh et al., 2017; Wu et al., 2020).

Norms for maximal isometric lingual-palatal pressure are reported to range between 43 – 78 kPa when using the IOPI (Adams et al., 2013; Robbins et al., 1995; Vanderwegen et al., 2013; Youmans et al., 2009). Therefore, maximum isometric lingual-palatal pressures below this have been considered weak. However, norms for lingual-palatal pressure during swallowing are significantly lower and, unlike maximal isometric lingual-palatal pressure, are not found to decrease with age (Nicosia et al., 2000) thereby illustrating the submaximal nature of lingual-palatal pressure during swallowing. Fei and colleagues (2013) used the Kay-Pentax swallowing signals lab to measure lingual-palatal pressures for saliva swallows. In the under 40 age-group, results ranged from 105 to 135 mmHg for females (equivalent to 14-18 kPa) and 133 to 183 mmHg for men (18-24kPa) for men. In the over 60 age-group, this reduced to 104 to 132 mmHg for men (14-18 kPa), whilst means for women in this age group did not change. In water swallows, pressures ranged from 77 to 98 mmHg (10-13 kPa) for females and 102 to 145 mmHg (14-19 kPa) for males in the under 40 age group and in the over 60 age group, pressures remained the same for females but reduced to 77 to 104 mmHg

(10-14 kPa) for males (Fei et al., 2013) (**Table 5**). As such, lingual-palatal pressure during swallowing may be a more important function to measure to predict dysphagia.

Table 5.

Normative Values for Posterior Lingual-Palatal Pressure (kPa).

Authors	**Age range (number)**	**Sex**	**Task**	**Values**		
				male	female	
Kays et al., 2010	young 20-35 (11) old 65-82 (11)	6 female 5 male 6 female 5 male	max isometric	50.00 (7.90) 61.40 (8.80)	62.50 (14.50) 49.00 (12.60)	young old
Clark & Solomon, 2012	young 18–29 (68) middle 30–59 (60) old 60–89 (42)	25 male 43 female 35 male 25 female 28 male 15 female	max isometric	young 52.3 (13.2) middle 57.9 (14.0) old 47.4 (16.7)		
Gingrich et al., 2012	18-34 (62)	32 female 30 male	saliva swallows	women 18.52 (8.71) men 15.30 (6.64)		
Oh et al., 2017	20-26 (60)	30 men 30 women	max isometric	46.5 (10.3)		
Oh, 2018	21-24 (13)	5 women 8 men	max isometric	64.6 (10.25)		
Park, 2019	65-84 (23)	17 female 6 male	max isometric	39.17 (11.65)		
Wu et al., 2020	20-29 (67) 30-39 (23) 40-49 (30) 50-59 (18) >60 (10)	101 female 49 male	max isometric saliva swallow water swallow	53.23 (12.24) 48.11 (14.91) 43.38 (15.42)		

Oral sensation has a well-recognised role in the initiation of the pharyngeal swallow response as described in Chapter 4. However, there are no established methods for assessing oral sensation and its relative role in dysphagia. It is not known how much loss of sensation is required for dysphagia to exist, nor whether signs of dysphagia are worse with worsening oral sensation. Therefore, this study establishes norms for oral sensory thresholds of the mouth and posterior tongue strength in a community-dwelling population of healthy individuals.

7.2. Methodology

Participants and Recruitment

This was a prospective observational analytical cross-sectional study. A target of 120 subjects (30 per age group 20-39, 40-59, 60-79, 80+; gender equally represented) were invited to participate in a normative study of posterior lingual-palatal pressure and oral sensation. A sample of 20% of these participants were invited to return for reliability testing. Participants were selected for reliability testing based on their ability to return exactly one week later. Exclusion criteria, based on participant report, included any history of neurological disorder including numbness in the tongue, impaired sensitivity, poor circulation, or inability to keep the tongue in one position for a period of time; open wounds, abrasions or dental work in the mouth within the 3 months prior to the study; pregnancy; and use of any substances that may affect perception including alcohol, drugs or caffeine in the 12-hour period prior to the study. Participants were recruited via work-place advertisements, community and work-place presentations and in-house email invitation. Participants received verbal and written information and the opportunity to ask questions prior to providing written consent. Participant demographic information was recorded including age and sex. Measurements were taken in the outpatient department of a large tertiary hospital. Ethical approval was obtained by the appropriate regional human ethics committee, reference number 2019/ETH00413.

Instrumentation

Assessment of oral sensory perception thresholds was conducted using the Natus® Synergy software on a Nicolet® SDX electrodiagnostics and monitoring system. Disposable pudendal nerve electrodes were used to deliver the stimulus, attached to a gloved finger (**Figure 5**). Posterior lingual-palatal pressure was assessed using the Iowa Oral Pressure Instrument (IOPI) (IOPI Medical LLC, Redmond, WA) (**Figure 6**).

Figure 5

Pudendal Nerve Electrode attached to gloved finger

Figure 6

Iowa Oral Pressure Instrument (IOPI)

Study Preparation

As the instrumentation for the oral sensory perception measurements is a novel method for establishing sensory thresholds, trial of equipment placement, pressure, and methodology took place over some months by local researchers to discuss and standardise methods and measurement techniques. Initially, a dental pulp tester was considered as this is designed specifically for the mouth (Chen & Abbott, 2009). However, it was determined that the ability to determine thresholds would be limited by pre-programmed levels of electrical stimuli.

Different electrical stimulation devices were also considered such as the Digitimer DS7 used by Park (1997) and Power (2006), however the cost of purchasing this equipment was not feasible for a PhD project. Through discussions with the manufacturers of the Digitimer equipment and neurophysiology advisors it was determined that current available equipment used in the Neurophysiology Department at Royal North Shore Hospital would be suitable to deliver an electrical stimulus suitable for determining sensory thresholds.

Different electrodes were considered including ball electrodes such as that pictured in **Figure 7**. However, due to cost and the single use nature of all electrodes and previous reporting of the use

Figure 7

Ball Electrode

of the pudendal nerve electrode (Park et al., 1997; Power et al., 2006), the pudendal nerve electrode was selected. The pudendal nerve electrode is designed for stimulation and recording of the pudendal nerve, located in the anus. Due to the novel use of this electrode in the mouth, permission was sought and granted from the Therapeutic Goods Administration (TGA) Australia.

As most of the superficial nerve fibres in the oral cavity are fast adapting, stimulating oral structures with electrical stimulation produce a sense of vibration at a precise location, whereas slowly adapting nerve fibres respond to pressure (Haggard & de Boer, 2014). Fast adapting nerve fibres respond to frequencies of 0-50Hz, whereas slow adapting nerve fibres require a much higher frequency. Therefore, to target the superficial, fast-adapting nerve fibres, a frequency of 10Hz was selected. This also controls for the sensation of pressure applied by the finger to the skin as the participant is oriented to detect the sensation of vibration rather than pressure. To determine whether pressure applied by a finger would influence the perception thresholds, a pilot study was

undertaken. The pudendal nerve electrode was used under two conditions; with light pressure and with firm pressure, randomly presented over the same sites as the experimental studies. Twelve participants completed the study. A paired t-test showed no significant difference between the two conditions.

There are two methods of detecting thresholds in electrical stimulation protocols. These are known as the method of levels and the method of limits. The method of levels requires the participant to answer yes or no to randomly delivered stimuli. The response is used to determine if the next stimuli is higher or lower than the first. This method was not selected due to the capabilities of the equipment in delivering pre-determined accurate stimuli as well as concern that a stimulus delivered too high in an area where thresholds are unknown may cause localised damage. Alternatively, the method of limits requires a stimulus to be delivered gradually until detected by the participant. The stimulus is then gradually decreased, and the participant is required to indicate when the stimulus is no longer detected (Chong & Cros, 2004). This method was not selected in favour of the staircase model which is a variation of the method of limits. It was determined to be the most appropriate for this study based on its simplicity, which may be relevant when examining participants who may have cognitive or communication deficits. This method requires the stimulus to be gradually increased until the participant engages the stop signal. This establishes the appearance threshold. When the participant detects the stimulus, the stimulus is stepped down, and then redelivered until detected (Cornsweet, 1962). The mean of appearance thresholds determines the threshold (Chong & Cros, 2004). However, for this research all trials were taken to investigate reliability. Ultimately, the method of threshold determination is not considered to be significant for the outcomes of this programme of research, considering that both the normative study and experimental study used the same methodology.

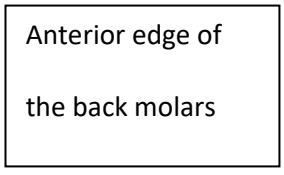
Procedure

Participants were seen in the outpatient department of a large teaching hospital. The participants were oriented to the current delivered by the electrode on their forearm and the stop protocol prior to task commencement. The stimulus was continuously delivered at 10Hz with a square wave duration of 200ms, starting at 0.0mA and gradually increasing in increments of 0.1mA until it was perceived by the participant. When the participant detected the stimulus, they were required to engage a hand-held switch to stop delivery of the current. Once the current was stopped, the stimulus was reduced by 0.4mA and redelivered in the same manner until stopped again by the participant. The second result was taken for analysis. This was repeated three times. Four sites were assessed: the dry vermillion of the medial upper and lower lip, posterior dorsal surface of the tongue in line with the posterior molars and either faucial arch, randomly selected. Each site was assessed three times with the finger remaining in place until all results were obtained. All measures were taken for analysis.

Assessments of isometric posterior lingual-palatal pressure and posterior lingual-palatal pressure during regular saliva swallows were obtained. The IOPI tongue bulb was held in place by the lead investigator so that the straight edge of the IOPI bulb was located at the anterior edge of the participants' back molars. Three measurements each of maximal posterior lingual strength during the isometric task and during saliva swallowing were obtained to assess within session variability. All three measurements were taken for analysis.

Figure 8

Image of Posterior Placement of IOPI Bulb



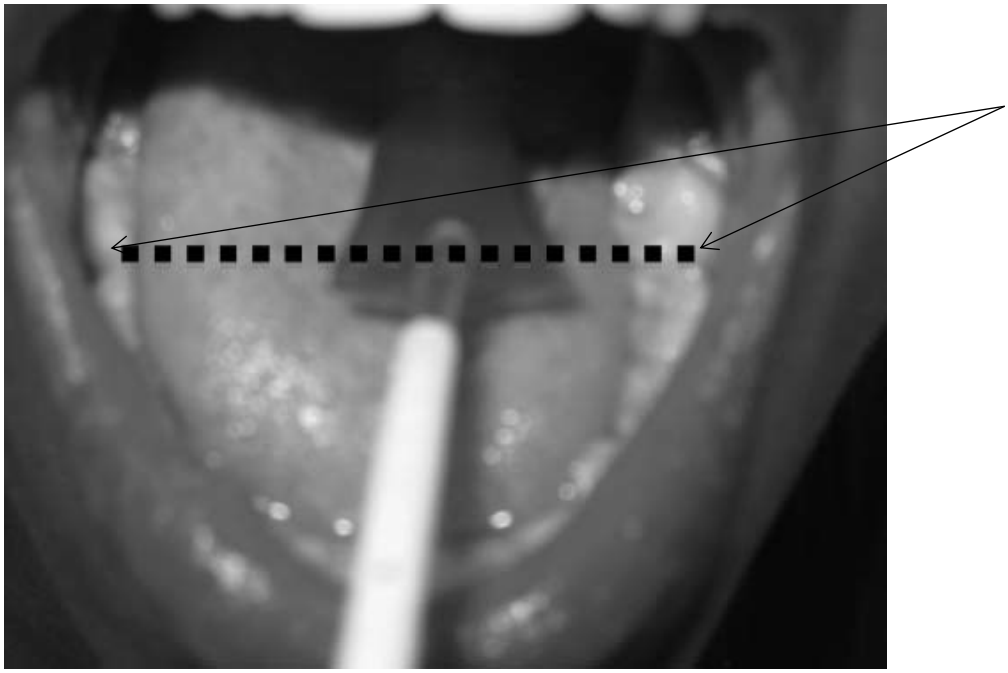


Image from Gingrich, L. L., Stierwalt, J. A., Hageman, C. F., & LaPointe, L. L. (2012). Lingual propulsive pressures across consistencies generated by the anteromedian and posteromedian tongue by healthy young adults. J Speech Lang Hear Res, 55(3), 960-972. https://doi.org/10.1044/1092-4388(2011/10-0357). Image reproduced with permission.

Safety

Electrical stimulation has been used inside the mouth (Park et al., 1997; Power et al., 2006) and pharynx (Restivo & Hamdy, 2018; Vasant et al., 2016) without adverse effects. The Natus EDX device and pudendal nerve electrodes are approved by the Therapeutic Goods Administration (TGA) of Australia and approval was gained to use the pudendal nerve electrodes in the mouth.

Statistical Analysis

Descriptive and inferential statistical analyses were completed using R (RCoreTeam, 2021) Means and standard deviations (SD) were calculated for all measures across participants and are reported by trial and by session.

Within and between sessions reliability

Reliability was investigated using two different analyses:

a) *Percentage of change in the mean* within sessions (between trials) and between sessions was assessed to evaluate learning effects and sampling error. The percentage of change in the mean for each site was derived from mixed effects models using the lmer function from the lme4 package in R (Bates et al., 2014). To derive the percentage of change in the mean between trials, a separate model was used for each session. In both models, trial was entered as a fixed effect, while a by subject random intercept was included as a random effect to account for the repeated measures. For the percentage of change in the mean between sessions, a model that included session as a fixed effect and a by subject random intercept as random effect was evaluated. In both models, the response variable was log-transformed. Post-hoc analysis was performed using emmeans package with Tukey adjustment for multiple comparisons. Model coefficients were exponentiated (*(exp(coefficient) – 1) * 100*) to transform them back to their original scale, obtaining the percentage of change in the mean. The percentage of change in the mean, 95% CI and p-values are reported. Residual versus fitted plots were visually inspected to identify potential deviation from homoscedasticity; and quantile-quantile plots (Q-Q plots) of the residuals were reviewed to evaluate normality. A p-value of 0.05 was considered significant. Interpretation of change in mean within and between sessions was considered acceptable if ≤ 10% (Hopkins, 2000).

b) *Intraclass correlation coefficients (ICC)* within sessions (between trials) and between sessions were used to investigate repeatability of the results among the trials and sessions (ICC [3, k]). ICC's were calculated using the lmer package (Bates et al., 2014). Reliability between trials for each session was evaluated using a model where trial was entered as a fixed effect and a by participant intercept as a random effect. A separate model was used for each session obtaining two different ICC's. Reliability between sessions was calculated by averaging the trials of each session and using a model where session was entered as a fixed effect and by participant intercept as a random effect. The ICC for both within and between sessions was calculated by dividing the between participant's variability by the total variability. Since the ICC depends on both measurement error and

homogeneity of the sample (Bartlett & Frost, 2008), between-subject variance was reported as a measure of the sample homogeneity. A bootstrap distribution was calculated from which the 95% confidence intervals for each ICC was obtained. Residual versus fitted plots were visually inspected to identify potential deviation from homoscedasticity; and quantile-quantile plots (Q-Q plots) of the residuals were reviewed to evaluate normality. For interpretation of the ICC results, criteria reported by Interpretation of reliability findings was based on published criteria: Poor reliability (ICC < 0.50); moderate (ICC 0.50 – 0.75) good (ICC 0.75 - 0.90) and excellent reliability (ICC < 0.90) (Koo & Li, 2016).

Correlation

There is no universal agreement as to what constitutes an acceptable ICC. Therefore, measures that had at least moderate reliability (ICC > .70) which is considered a minimal standard for a test to be useful (Portney, 2020) were required for measures for calculation of correlation between oral sensation and lingual-palatal pressure measures. Measures with a lower ICC were discarded. A Pearson's correlation coefficient (r) was selected to determine the relationship between the identified measures, if any were selected for analysis. First, the assumptions of a Pearson's correlation analysis are checked. Significant outliers were checked and in case of measurement error discarded, then a scatter plot of both selected measures visualized to assess whether the relation between the two variables is linear. Q-Q plots were used to assess normality of the data. If the assumptions of a Pearson's correlation analysis were violated, a nonparametric Kendall's correlation coefficient (tau) was calculated. Published guidelines will be used for interpretation (Allen, 2017).

7.3. Results

A total of 60 healthy participants completed the normative study. This was half of the planned participant recruitment. The study was ceased in 2020 due to the restrictions put in place at the Hospital as a result of covid-19.

Reliability study

Nineteen females and 5 males completed the study protocol. This resulted in 40% of the total participants recruited for the normative study. Participants ranged in age from 22 to 84 years (mean 41.9). All attended for a second session exactly 7 days later. Means and standard deviations across participants for all measurement sites within sessions are depicted in **Table 6** (session 1) and **Table 7** (session 2) and between sessions in **Table 8**. First, within session analysis was performed to evaluate reliability of repeated measures between trials for each session.

Within session analysis:

a) *Percentage of change in the mean:*

Visual inspection of the residual plots revealed a deviation from homoscedasticity for the oral sensory perceptual thresholds of the posterior tongue for session 1. Therefore, this measure for session 1 is not reported. No other differences or violation of assumptions were found for the rest of the measures. The sensation threshold for the top lip measurement in trial 1 was higher when comparing it to trial 2 and trial 3 for session 1 (percentage of change in the mean between Trial 2-1: -19.18 (-31.62, -5.97), p-value = 0.004); (percentage of change in the mean between Trial 3-1: -16.39 (-28.70, -1.95), p-value = 0.024) and for session 2 when comparing it to the third trial (percentage of change in the mean between Trial 3-1: -10.55 (-19.97, -0.03), p-value = 0.050). For the bottom lip, the sensation threshold was higher when comparing trial 2 to trial 1 in session 2 (percentage of change in the mean between Trial 2-1: -14.78 (-27.28, -0.12), p-value = 0.047) suggesting a systematic error on those measures. Percentage change in mean was above 10% for all these measures.

b) Intraclass correlation coefficients (ICC)

ICC for oral sensory perception threshold of the faucial arch, posterior lingual-palatal pressure and posterior lingual-palatal pressure during swallowing was good for both the first and second session (ICC > 0.78). ICC for oral sensory perception threshold of the top lip was moderate for the first

session (ICC 0.51) and good for the second session (ICC 0.84), and ICC for oral sensory perception threshold the bottom lip was good for the first session (ICC 0.85) but poor for the second session (ICC 0.39). However, due to the systematic error evident in the top and bottom as reported above, these measures and subsequent analysis of these measures must be interpreted with caution. ICC for oral sensory perception threshold of the posterior tongue was excellent in the first session (ICC 0.93) and good in the second session (ICC 0.71), however assumptions for ICC calculation were not met for the model for oral sensory threshold of the posterior tongue, as homoscedasticity of residuals was violated, and thus ICC for this measure and subsequent analysis must also be interpreted with caution.

Between session analysis:

Due to the systematic error evident in the first trial of the oral sensory perception measures for the lips, the first trial for all measures was used as a practice trial and the following two trials was averaged for the between sessions calculation.

a) *Percentage of change in the mean:*

No assumptions were violated for any of the measures. The sensory thresholds for the top lip and posterior tongue were higher on trial 1 when compared to trial 2 (top lip percentage of change in the mean between trial 2-1: -11.68 (-20.08, -2.39), p-value = 0.016); (posterior tongue percentage of change in the mean between trial 2-1: -12.20 (-21.69, -1.56), p-value = 0.024) suggesting a practice effect (systematic error). The mean percentage change was above 10% for both measurements.

b) Intraclass correlation coefficients (ICC):

Between-session reliability was poor for the oral sensory perception thresholds for the top lip (ICC 0.42) and bottom lip (ICC 0.44), and moderate for the oral sensory perception measures of the posterior tongue (ICC 0.53), faucial arch (ICC 0.57) and lingual-palatal pressure during swallowing (ICC 0.66). Between session reliability was good for maximum isometric lingual-palatal pressure (ICC 0.76)

Table 6

Within Session Reliability. Session 1

	Mean +/- SD						
Outcome measures	**Trial 1**	**Trial 2**	**Trial 3**	**Estimated % change per trial (95% CI)**		**ICC (95% CI)**	**Between participants SD (95% CI)**
Sensation top lip (mA)	0.85 +/- 0.16	0.71 +/- 0.23	0.72 +/- 0.18	Trial 2-1	-19.81 (-31.62, -5.97) *	0.51 (.24, .70)	0.14 (0.09, 0.20)
				Trial 3-2	4.27 (-11.08, 22.27)		
				Trial 3-1	-16.39 (-28.70, -1.95) *		
Sensation bottom lip (mA)	0.75 +/- 0.29	0.67 +/- 0.27	0.7 +/- 0.25	Trial 2-1	-13.17 (-28.02, 4.73)	0.85 (0.71, 0.93)	0.25 (0.18, 0.33)
				Trial 3-2	8.72 (-9.87, 31.14)		
				Trial 3-1	-5.61 (-21.75, 13.87)		
Sensation posterior tongue (mA)	1.03 +/- 0.55	0.94 +/- 0.59	0.95 +/- 0.59	Trial 2-1		0.93 (0.86, 0.96)	0.56 (0.42, 0.75)
				Trial 3-2	Assumptions not met		
				Trial 3-1			
Sensation faucial arch (mA)	1.66 +/- 0.54	1.52 +/- 0.51	1.54 +/- 0.70	Trial 2-1	-8.66 (-22.02, 6.98)	0.85 (0.72, 0.92)	0.54 (0.40, 0.73)
				Trial 3-2	-5.80 (-19.57, 10.34)		
				Trial 3-1	-13.96 (-26.54, 0.78)		
Posterior lingual-palatal pressure (kPa)	45.2 +/- 14.1	45.4 +/- 13.5	46.5 +/- 13.1	Trial 2-1	1.10 (-7.69, 10.73)	0.85 (0.72, 0.93)	12.52 (9.27, 16.97)
				Trial 3-2	2.33 (-6.56, 12.08)		
				Trial 3-1	3.46 (-5.53, 13.31)		
Posterior lingual-palatal pressure during swallowing (kPa)	21.8 +/- 11.2	23.0 +/-14.5	23.3 +/-14.7	Trial 2-1	-0.97 (-19.71, 22.13)	0.80 (0.64, 0.90)	12.13 (8.89, 16.55)
				Trial 3-2	0.08 (-18.85, 23.44)		
				Trial 3-1	-0.89 (-19.64, 22.24)		

Table 7

Within Session Reliability. Session 2.

	Mean +/- SD						
Outcome measures	**Trial 1**	**Trial 2**	**Trial 3**	**Estimated % change per trial (95% CI)**		**ICC (95% CI)**	**Between participants SD (95% CI)**
Sensation top lip (mA)	0.7 +/- 0.21	0.65 +/- 0.20	0.63 +/- 0.21	Trial 2-1	-8.92 (-18.51, 1.80)		
				Trial 3-2	-1.79 (-12.13, 9.76)		
				Trial 3-1	-10.55 (-19.97, -0.03) *	0.84 (0.71, 0.92)	0.19 (0.14, 0.26)
Sensation bottom lip (mA)	0.75 +/- 0.36	0.63 +/- 0.20	0.63 +/- 0.17	Trial 2-1	-14.78 (-27.28, -0.12) *		
				Trial 3-2	3.42 (-11.76, 21.20)		
				Trial 3-1	-11.87 (-24.80, 3.29)	0.39 (0.03, 0.16)	0.16 (0.08, 0.24)
Sensation posterior tongue (mA)	0.83 +/- 0.31	0.78 +/- 0.31	0.76 +/- 0.32	Trial 2-1	-6.36 (-17.47, 6.24)		
				Trial 3-2	-4.24 (-15.60, 8.65)		
				Trial 3-1	-10.33 (-20.97, 1.74)	0.71 (0.52, 0.85)	0.27 (0.19, 0.37)
Sensation faucial arch (mA)	1.56 +/- 0.60	1.42 +/- 0.59	1.40 +/- 0.61	Trial 2-1	-10.81 (-23.91, 4.53)		
				Trial 3-2	-2.02 (-16.40, 14.83)		
				Trial 3-1	-12.62 (-25.44, 2.42)	0.83 (0.70, 0.91)	0.55 (0.40, 0.744)
Posterior lingual-palatal pressure (kPa)	46.8 +/- 10.7	45.7 +/-12.8	47.8 +/-13.2	Trial 2-1	-3.82 (-10.89, 3.81)		
				Trial 3-2	4.81 (-2.89, 13.12)		
				Trial 3-1	0.80 (-6.61, 8.80)	0.81 (0.66, 0.91)	11.10 (8.16, 15.10)
Posterior lingual-palatal pressure during swallowing (kPa)	23.8 +/-9.82	21.3, +/-10.5	23.1 +/-11.2	Trial 2-1	-16.80 (-31.76, 1.44)		
				Trial 3-2	11.28 (-8.73, 35.67)	0.78 (0.63, 0.89)	
				Trial 3-1	-7.41 (-24.06, 12.88)		9.34 (6.82, 12.75)

The ICC's shown in red should therefore be interpreted with caution due to the systematic error between trials.
* p > 0.05. ICC derived from mixed models by dividing variability participants/total variability, CI derived from bootmer

Table 8

Between Session Reliability

Outcome measures	Mean +/- SD Session 1	Mean +/- SD Session 2	Estimated % change between session (95% CI)	ICC (95% CI)	Between session SD (95% CI)
Sensation top lip (mA)	0.76 +/- 0.20	0.66 +/- 0.21	-11.68 (-20.08, -2.39) *	0.42 (0.04, 0.73)	0.11 (-0.18, -0.02)
Sensation bottom lip (mA)	0.70 +/- 0.27	0.66 +/- 0.26	-4.91 (-15.67, 7.23)	0.44 (0.08, 0.71)	0.15 (-0.14, 0.06)
Sensation posterior tongue (mA)	0.81 +/- 0.07	0.71 +/- 0.06	-12.2 (-21.69, -1.56) *	0.53 (0.21, 0.77)	0.32 (-0.36, -0.01)
Sensation faucial arch (kPa)	1.39 +/-0.12	1.28 +/- 0.11	-7.71 (-19.4, 5.69)	0.57 (0.26, 0.80)	0.42 (-0.33, 0.10)
Posterior lingual-palatal pressure (kPa)	44.2 +/- 2.48	44.8 +/- 2.52	1.43 (-5.28, 8.61)	0.76 (0.53, 0.89)	10.66 (-2.33, 4.53)
Posterior lingual-palatal pressure during swallowing (kPa)	22.7 +/- 13.4	22.7 +/- 10.4	3.33 (-11.54, 20.7)	0.66 (0.37, 0.84)	9.14 (-3.82, 3.82)

* $p > 0.05$. The ICC's shown in red should therefore be interpreted with caution due to the systematic error between trials.

Normative data

Participants were grouped by age (young vs old) and sex (male vs female). There were 20 men, of which only 2 were over 60, and 39 women of which 9 were over 60. This represents just half of the intended sample size. Due to incomplete data (inability to initiate a swallow with the IOPI bulb in position), 1 participant (male 60+) was removed. Based on the reliability findings, trial 1 was omitted and trials 2 and 3 were averaged. Mean and standard deviation of both sensory and strength measures are summarised in **Table 9**. As the sensory measures for top and bottom lip were not shown to be reliable, these measures should be interpreted with caution.

Table 9

Mean and Standard Deviation of Normative Data

	Men		Women	
	Young 20-59 (N=18)		**Young 20-59 (N=30)**	**Old 60+ (N=9)**
Mean age (SD)	31.3 (8.25)	**Old 60+ (N=1)**	35.2 (11.93)	72.6 (8.73)
(min, max)	(23, 56)	68	(22, 59)	(62, 85)
Top lip sensation (mA)	0.82 +/- 0.23	0.8	0.74 +/- 0.24	0.72 +/- 0.16
Bottom lip sensation (mA)	0.84 +/- 0.28	0.65	0.7 +/- 0.20	0.91 +/- 0.16
Posterior tongue sensation (mA)	1.09 +/- 0.42	0.8	0.96 +/- 0.72	1.46 +/- 0.78
Faucial arch sensation (mA)	1.82 +/- 0.51	2.6	1.36 +/- 0.63	2.4 +/- 1.03
Isometric posterior lingual-palatal pressure (kPa)	47.06 +/- 15.16	25.5	41.31 +/- 9.37	46.72 +/-15.78
Posterior lingual-palatal pressure during swallowing (kPa)	19.58 +/- 13.40	18.5	18.69 +/- 9.76	35.72 +/- 15.36

*note: values in red are not reliable and should be interpreted with caution

Correlation

Oral sensory perception measure of the faucial arch and maximum isometric lingual-palatal pressure from the first session were selected to determine a relationship between strength and sensation as they achieved ICC > 0.70. First, assumptions were checked for Pearson's correlation. As the normal distribution for maximum isometric lingual-palatal pressure was right-skewed, Kendall´s Tau correlation was used to determine the relationship between the strength and sensation measures. There was a non-significant correlation between variables -0.10 [95%CI (-0.36, 0.16)].

7.4. Summary

Reliability measurements of oral sensory perception thresholds and posterior lingual-palatal pressure during swallowing were evaluated using percentage change in mean and intraclass coefficient correlation both within and between sessions. Test-retest measures identified acceptable within and between session reliability and percentage of change of mean for measures of electrical sensory threshold of the faucial arch and isometric posterior lingual-palatal pressure and posterior lingual-palatal pressure during swallowing. The other sites were unable to be reliably evaluated due to violation of homoscedasticity of residuals for the oral sensory threshold measures of the posterior tongue and a systematic error for the top and bottom lip oral sensory perception threshold measurements. There was a non-significant correlation between sensation and strength measures.

Chapter 8 Reliability of Speech Pathologists' Classification of Pre-Swallow Pooling.

8.1. Introduction

Accurate identification of swallowing impairments is required to select appropriate treatment. Since pre-swallow pooling has two hypothetical causes, one sensory and one motor, determining between them is important prior to commencing treatment. Diagnosis of poor bolus containment vs delayed pharyngeal swallowing relies on interpretation of swallowing biomechanics seen on videofluoroscopic swallowing studies. Although many researchers do not acknowledge a difference between the two causes of poor bolus containment (see chapter 3), it has been defined by Logemann (1983; 1998). Logemann defined delayed pharyngeal swallowing as a delay between the head of the bolus reaching the inferior ramus of the mandible and the initiation of pharyngeal swallowing. Poor bolus containment (referred to as pre-swallow spill by Logemann), was defined as some or all of the bolus entering the pharynx prior to the onset of oral transit (Logemann, 1983; Logemann, 1998). There is no previous research that has evaluated the reliability of speech pathologists' current methods of determining pre-swallow pooling as either poor bolus containment or delayed pharyngeal swallowing. Therefore, this study has been undertaken to evaluate the reliability of speech pathologists' determination of pre-swallow pooling as either poor bolus containment or delayed pharyngeal swallowing.

8.2. Methodology

Participants and Recruitment

This was a prospective experimental study. Participants were invited to participate via an advertisement in the listserv of an international special interest group: Speech Pathologists Email Chat Support (SPECs). This special interest group was selected as it has a large population of speech pathologists who treat people with swallowing disorders. Speech pathologists were invited to

participate if they had achieved self-reported competency in using videofluoroscopic swallowing assessments (VFSS) and performed them regularly. Those who were interested in participating in the study were invited to read the information sheet attached to the email and contact the primary researcher if they wanted to participate. They were then sent an invitation from the Qualtrics email distribution list. Inclusion criteria was any speech pathologist with competency in analysing and reporting videofluoroscopic swallowing studies. Participants were excluded if they were not qualified speech pathologists or speech pathologists who indicated that they were not competent in the analysis of videofluoroscopic swallowing studies or did not do them regularly. A sample size of 4 (minimum) to 6 (maximum) participants for each survey and 35 videos was selected which exceeds the sample size of 28 - 24 for a moderate (.40 - .60) (Landis & Koch, 1977) kappa co-efficient with a probability of .30 (Donner & Rotondi, 2010). Ethics was obtained through the University of Canterbury Human Research Ethics Committee reference HREC 2022/59/LR-PS.

Procedure

Participants were randomly split into two groups, one of which received definitions to support their interpretation, the other was not. The same videos were provided for both groups. The following was provided to the group that were given definitions:

1) "Poor bolus containment is defined as entry of part of the bolus into the pharynx prior to the purposeful anterior-posterior movement of the tongue for oral transfer of the bolus in the mouth (i.e., prior to the onset of the "oral phase")".
2) "Delayed pharyngeal swallowing is defined as when the bolus has been purposefully transferred from the mouth and the bolus has past the point where the ramus of the mandible crosses with the base of tongue, but a pharyngeal swallow has not been initiated".

The online survey was designed with Qualtrics (Provo, UT) Copyright © October 2022. Each question consisted of a video and four diagnostic options that the participant was instructed to select from:

1. Poor bolus containment.

2. Delayed pharyngeal swallowing.
3. Both poor bolus containment and delayed pharyngeal swallowing.
4. Neither both poor bolus containment nor delayed pharyngeal swallowing.

These formed the four categories for reliability analysis. The videos were taken from study 4, investigating the relationship between swallowing measures and diagnoses with oral sensory perception thresholds and posterior lingual-palatal pressure in patients who had dysphagia in the acute phase of stroke. There were 30 unique swallows which each represented a bolus of a sip of thin fluid, volume determined by the participant. There was no cue to swallow. The videos were presented randomly. Five videos were presented twice which enabled evaluation of intra-rater reliability, therefore there were 35 videos for scoring overall. The videos were able to be watched as many times as needed. Although frame by frame analysis was not possible, it was possible to stop and start the video in quick succession, thereby replicating a frame by frame analysis.

Statistical analysis

Descriptive analysis was used to describe trends in diagnosis of each survey question. Percentage agreement was described by each variable and overall. The Kappa statistic was used to determine agreement between and within raters. In the inter-rater study, the same set of coders (n = 6) rated all videos (fully crossed design), therefore Light's Kappa was used (Hallgren, 2012). Light's Kappa is equal to the mean of the n(n-1)/2 kappas obtained from each pair of raters. The function lkappa from psy library in R, was used to compute Light's Kappa for agreement between the six raters. The 95% confidence intervals were obtained from a bootstrap distribution. In the intra-rater study, Cohen's kappa was used to compare all videos rated as a group between the first and second rating by each rater. Interpretation of Kappa was according to published criteria where 0 -.20; none; .21 -.39; minimal; .40 -.59; weak; .60 -.79; moderate; .80 -.90; strong; and above .90; almost perfect (McHugh, 2012).

8.3. Results

A total of 12 unique speech pathologists completed the surveys. There were 6 speech pathologists in each group. All participants rated all 35 videos which resulted in 210 responses for each survey.

1) Frequency of diagnoses. Of the four diagnostic categories, “neither poor bolus containment nor delayed pharyngeal swallowing” was the most frequent and “both poor bolus containment and delayed pharyngeal swallowing” was the least frequent diagnosis in both groups.

Table 10

Frequency of Diagnoses.

Diagnoses	Control group n (%)	Experimental group n (%)
1. Poor bolus containment	56 (26.7)	52 (24.8)
2. Delayed pharyngeal swallowing	50 (23.8)	57 (27.1)
3. Both poor bolus containment and delayed pharyngeal swallowing	26 (12.4)	28 (13.3)
4. Neither poor bolus containment nor delayed pharyngeal swallowing	78 (37.1)	73 (34.8)

2) Percentage agreement. The agreement was calculated as agreements/agreements + disagreements x 100% (Araujo & Born, 1985). For the control group there were 139 occasions of agreement out of a total 210 occasions. Therefore, overall agreement was 0.66, or 66%. For the experimental group, there were 140 occasions of agreement out of a total 210 occasions. Therefore, overall agreement was 0.67, or 67%.

3) Intra-rater reliability for each rater and comparison within raters is represented in **Appendix 4**. Intra-rater reliability was moderate for both the control group (k = 0.67, p>.001, 95% CI, 0.46-0.88) and the experimental group (k = 0.71, p>.001, 95% CI, 0.50-0.92). Contingency tables for intra-rater agreement are shown in **Table 11**. The most frequent agreement occurred for the diagnosis of “neither poor bolus containment or delay”, followed by "delay”. The most disagreement occurred between “neither poor bolus containment or delay”, and “delay” in group 1. The frequency of disagreements was less in the experimental group suggesting that agreement improved with the provision of definitions.

Table 11

Intra-Rater Contingency Tables

Control Group

		Rating 2			
		Both	**Delay**	**Neither**	**Poor Bolus Containment**
Rating 1	**Both**	2	1	0	1
	Delay	0	6	0	1
	Neither	0	3	11	1
	Poor Bolus Containment	0	0	0	4

Experimental Group

		Rating 2			
		Both	**Delay**	**Neither**	**Poor Bolus Containment**
Rating 1	**Both**	3	0	0	0
	Delay	1	5	2	0
	Neither	1	1	11	1
	Poor Bolus Containment	0	0	1	4

2. Inter-rater reliability: As percentage agreement does not account for chance agreement, the kappa statistic was calculated. First, each possible rater pair was compared, which resulted in 15 unique pairs (**Appendix 5**). Cohen's kappa was used for this calculation as there were two consistent raters and the data was categorical. The kappa's for these pairs are represented in **Appendix 6**. Reliability between pairs was slight to fair in both groups (k = 0.01 to k = 0.55 in the

control group and k = 0.14 to k = 0.49 in the experimental group). On closer examination of contingency tables illustrating agreement within pairs (**Appendix 7**), there is more agreement between pairs for "neither poor bolus containment nor delay". The most common disagreement is between "delay" and "neither poor bolus containment nor delay". This is particularly evident in the control group with rater 6. To calculate overall inter-rater reliability, Light's kappa was used. Light's kappa is a variation of Cohen's kappa where there are more than 2 consistent raters. Light's kappa was calculated by taking the mean of each Cohen's kappa calculation. Inter-rater reliability of speech pathologists' diagnosis of poor bolus containment and delayed pharyngeal swallowing was minimal (k = 0.29, p>.001, 95% CI, 0.21-0.40) when not given definitions. There was little difference in reliability when given definitions (k = 0.33, p>.001, 95% CI, 0.24-0.42).

8.4. Summary

This study evaluated the agreement of speech pathologists' determination of pre-swallow pooling as either delayed pharyngeal swallowing or poor bolus containment. Agreement between speech pathologists was poor indicating that the current methods for determining the difference between poor bolus containment and delayed pharyngeal swallowing are unreliable. Further, the addition of definitions to guide speech pathologists in determining one from the other did not increase agreement, suggesting that the application or interpretation of measures is too subjective.

Chapter 9 Classification of Sensory and Motor Causes of Pre-Swallow Pooling using Physiological Assessment of Lingual-Palatal Pressure and Oral Sensation.

9.1. Introduction

As discussed in prior chapters, there is no 'gold standard' for differential diagnosis of pre-swallow pooling, therefore this exploratory research will categorize outcomes of physiological measures of oral sensation and lingual-palatal pressure using cluster analysis methods. If clusters differentiate sensory impairments from motor impairments, it can be presumed that there are indeed two physiological causes of pre-swallow pooling. The resulting clusters will then be evaluated against clinician judgements of the cause of pre-swallow pooling. If a sensory cluster aligns with delayed pharyngeal swallowing, the presumed sensory cause of pre-swallow pooling, and the motor cluster aligns with poor bolus containment, the presumed motor cause of pre-swallow pooling, then this will provide evidence that our current methods for determining the two causes of pre-swallow pooling are satisfactory. If this research identifies that separate sensory and motor clusters do not exist and our clinical presumptions are incorrect, our clinical practice will require re-evaluation and new methods for diagnosing the cause of pre-swallow pooling will need to be identified.

9.2. Methodology

Participants and Recruitment

This was a prospective observational cohort study. Patients admitted to the Royal North Shore Hospital in Sydney with an acute ischaemic or haemorrhagic stroke who failed the swallowing screen were invited to participate. Inclusion criteria included any participant who had the ability to participate in swallowing assessment and had adequate alertness for oral intake. Participants were reconsidered for inclusion into the study if/when alertness improved. Participants with aphasia or

cognitive impairments were not excluded from participating; however, assessment of cognition was completed to determine whether participants were able to make an informed decision regarding consent. The Mini Mental State Examination (MMSE) was used for any participant where cognition was reported in the medical file to be impaired. The participants next of kin was approached for consent if MMSE was scored below 18 (Gregory et al., 2007; Pucci et al., 2001).

A sample size of 60 participants was considered appropriate for cluster analysis of potentially 3/4 clusters. Twenty observations in each subgroup has been shown to result in sufficient power to detect subgroups with k-means provided that subgroups were roughly equal sized and cluster separation variation was 4 or over (Dalmaijer et al., 2022). Data were collected over a 12-month period. Healthy participants from study 1 were used as the control group. It was anticipated that this group would form a cluster who have both good sensation and good strength.

Procedure

Healthy participants were evaluated as described in study 1 (page 79). Stroke participants who had failed the hospital swallow screening tool (**Appendix 8**) were first assessed following receipt of consent, with Flexible Endoscopic Evaluation of Swallowing (FEES). This was used as a screening tool to identify the presence of pre-swallow pooling. FEES was completed at bedside on the ward where the participant was admitted. Pre-swallow pooling was identified by a single examiner and was defined as any amount of the bolus which progressed beyond the valleculae prior to the onset of the pharyngeal swallowing response as identified by whiteout. Those who presented with pre-swallow pooling received further assessment using videofluoroscopic swallowing evaluation followed by measurement of physiological measures of oral sensation and posterior lingual palatal pressure. Those who did not have pre-swallow pooling on FEES, received physiological measurement only. Thus, they formed a group whereby oral sensation and posterior lingual-palatal pressure could be evaluated in those who do not present with pre-swallow pooling. This could identify whether strength or sensation was impaired in those who did not have pre-swallow pooling.

All the physiological assessments were completed on the same day. Assessments of isometric posterior lingual-palatal pressure and posterior lingual-palatal pressure during saliva swallowing were obtained using the Iowa Oral Pressure Instrument (IOPI) as described previously (pg. 81). Oral sensation was tested using electrical stimulation as described previously (pg 80). Areas stimulated included the medial posterior tongue, and bilateral faucial arches for the glossopharyngeal nerve. The lips were not assessed due to poor reliability identified in test-retest study (chapter 7). There were 3 trials taken for all physiological measures. All three trials were included in analysis. Monitoring of localised tissue damage was performed post measurement of electrical stimulation. The Faces Pain Scale (Hicks et al., 2001) was used for any participant who had difficulty communicating.

All videofluoroscopic swallowing studies (VFSS) were completed within a week of the physiological tests. The VFSS consisted of the following procedure in lateral view:

- 3 x single sips of thin barium
- 3 x spoonful of barium-coated diced peaches

Videofluoroscopic images were acquired at 30 pulses per second (pps) and recorded at 30 frames per second (fps) with a Philips Multidiagnost Eleva with Flat Detector. The liquid consistency was compliant with IDDSI 0 (thin fluid) and made using a mixture of 152g of Liquibar (1.25g/ml) and water to achieve 250mls in total. This provided a 40% barium w/v solution to ensure adequate density for visualisation. The peaches were partially drained and coated in EZ-HD (98% w/w) barium powder. Instructions given to the participants were to: “take a sip or mouthful and swallow as you would normally”. There was no prompt to hold the bolus in the mouth and specific bolus size was not measured so as to capture usual swallowing behaviour for each participant. Those who aspirated and were unable to clear the aspiration, completed the procedure with thickened fluids. The videofluoroscopic images were analysed by three trained speech pathologists with self-reported documented evidence of competency in VFSS and at least 2 years’ experience in videofluoroscopic

analysis. The speech pathologists were blinded to the results of the physiological tests. Each swallow was assigned a diagnosis of

i) poor bolus containment,

ii) delayed pharyngeal swallowing,

iii) neither poor bolus containment nor delayed pharyngeal swallowing or

iv) both poor bolus containment and delayed pharyngeal swallowing.

Where there was not 100% agreement, the speech pathologists reviewed the videos together to reach a consensus diagnosis. If no agreement was able to be reached, then that participant was excluded from the analysis.

Other relevant medical information that is routinely collected during admission, was recorded for further post hoc exploration of the data. This included age, sex, medical history details, medical imaging tests and results (location and size of lesion), National Institute of Health Stroke Scale (NIHSS) (Appelros & Terént, 2003; Jeyaseelan et al., 2015), and Functional Oral Intake Scale (Crary et al., 2005).

Statistical analysis

Descriptive data were obtained to evaluate the characteristics of participants.

Reliability of physiological data

Reliability of repeated measures of the physiological data was analysed with intraclass coefficient correlation (ICC 3,1) and percentage change in mean. Evaluation of measurement reliability determined whether the physiological measures were reliable for inclusion in the cluster analysis.

a) Percentage of change in the mean

Percentage of change in the mean was evaluated in the same manner as for study 1 (see page 82). Interpretation of change in mean between trials was considered acceptable if ≤ 10% (Hopkins, 2000).

b) Test-retest reliability of physiological measures

Intraclass correlation coefficients (ICC [3, 1]) were used to investigate repeatability of the results among the trials in the same manner as for study 1 (see page 83). Interpretation of the ICC results was based on published criteria: Poor reliability (ICC < 0.50); moderate (ICC 0.50 – 0.75) good (ICC 0.75 – 0.90) and excellent reliability (ICC < 0.90) (Koo & Li, 2016).

Cluster analysis

Only the physiological measures that have moderate to excellent reliability (ICC >.50 and percentage change in mean <10%) were used in the cluster analysis. As the scale for lingual-palatal pressure measures was different to the oral sensory perception threshold scale, the data were standardised using z scores. This was calculated by subtracting the mean from each value and then dividing this new value by the standard deviation of the sample. Standardisation transforms the data so that the values have a mean of 0 and standard deviation is 1. A correlation scatterplot was used to detect any strong collinearity between the variables which could bias the results. Those with a correlation over 0.75 (Portney, 2020) were considered to significantly increase the weight of the concepts and thus bias the results. Thus, any variable with high collinearity (above 0.75) was removed from the variables. The remaining variables were selected for the cluster analysis.

A k-means cluster analysis with four clusters to represent the four hypothesised diagnoses was used as the clustering algorithm. K-means cluster analysis is the most often used unsupervised machine learning approach for dividing a given data set into a collection of k groups (i.e., k clusters), where k denotes the number of pre-specified clusters. The k-means algorithm divides the data into several clusters, with the goal of making objects from the same cluster as similar as possible (high intra-class similarity), and as diverse from one another (low inter-class similarity). Each cluster in k-means clustering is represented by its centroid, which is the mean of the points allocated to the cluster and serves as its centre. A descriptive analysis was then performed which identified the characteristics of the subjects within each group according to their results of oral sensory perception

and lingual-palatal pressure tests to describe the characteristics within a diagnostic category as hypothesised.

Speech pathologists' diagnosis of the cause of pre-swallow pooling.

Diagnosis of delay vs poor bolus containment was established via consensus between 3 speech pathologists experienced in analysis of VFSS. The videos were presented de-identified and the speech pathologists were blinded to the results of the physiological tests. Each speech pathologist independently classified pre-swallow pooling as either:

- Poor bolus containment,
- Delayed pharyngeal swallowing,
- Both poor bolus containment and delayed pharyngeal swallowing, or
- Neither poor bolus containment nor delayed pharyngeal swallowing.

Cohen's kappa was used to evaluate inter-rater reliability between pairs of speech pathologists' diagnosis of poor bolus containment or delayed pharyngeal swallowing prior to consensus. Light's Kappa (Hallgren, 2012) was used to determine overall agreement between all three raters. Interpretation was based on published literature where ≤ 0 indicated no agreement, 0.01–0.20; slight, 0.21–0.40; fair, 0.41– 0.60; moderate, 0.61–0.80; substantial, and 0.81–1.00; almost perfect agreement (Landis & Koch, 1977).

Relationship between the two diagnostic methods

If the hypothesised categories were discovered in the cluster analysis, a chi-square test of independence was used to evaluate whether clinician diagnostic categories (poor bolus containment, delayed pharyngeal swallowing, both or neither) were associated with the cluster categories obtained by the clustering algorithm. A p-value of less than .05 indicates a reliable statistical relationship between the two diagnostic methods.

9.3. Results

Descriptive data

Participant demographics are represented in **Table 12**.

Table 12

Participant Demographics

	Stroke n=24
Age (years):	
Mean +/- SD	72.4 +/- 7.57
Range	50-87
Sex:	
Male	19 (79%)
Female	5 (21%)
Stroke lesion location:	
Cortical	12 (50%)
Subcortical	3 (13%)
Cortical-brainstem	2 (8%)
Brainstem	7 (29%)
NIHSS:	
No symptoms	1 (4%)
Minor	10 (42%)
Moderate	10 (42%)
Moderate-severe	1 (4%)
Severe	2 (8%)
FOIS:	
7	22 (92%)
6	2 (8%)

	Healthy n =18
Age (years):	
Mean +/- SD	64 +/- 11.30
Range	50-85
Sex:	
Male	2 (11%)
Female	16 (89%)

Healthy participant demographics

There were 60 healthy participants who completed physiological data as per study 1. As mentioned in study 1, only 60 out of the 120 anticipated participants were recruited due to hospital restrictions imposed by covid-19. A greater proportion were in the younger age range. Participants ≥50 years were selected to match the stroke participants as closely as possible.

Stroke participant demographics

Due to disruption of data collection associated with covid-19, only 29 of the anticipated 60 stroke participants were recruited. Two participants could not complete the physiological tasks to command. Both presented with left MCA strokes with aphasia/apraxia of speech and thus a language comprehension or motor planning deficit may have impacted on their ability to perform the tasks. Three further participants were excluded as they could not complete the lingual-palatal pressure during swallowing task. The remaining 24 participants completed all tasks. Stroke participants were admitted to Royal North Shore Hospital, Sydney between 30/9/2020 to 5/5/2022.

Comparison of the healthy participants with the stroke participants revealed predominantly women in the healthy group (89%) and predominantly men (79%) in the stroke group. Post-hoc analysis identified a statistically significant association between group and gender X^2 (1, N= 41) =13.496, p = < 0.001. Mean age was lower in the healthy group (64 +/- 11.30) compared to the stroke group (72.4 +/- 7.57). Post-hoc analysis identified that this difference was not statistically significant, t(39) = -2.412, p = 0.02. FOIS pre-admission was 6 (8%) or 7 (92%), suggesting no pre-existing dysphagia.

Of the 24 stroke participants, 13 (54.2%) were identified as having pre-swallow pooling on FEES and proceeded to VFSS. All participants completed the VFSS protocol including three sips of thin fluids and three spoonful's of diced peaches. The demographic variables of those who had pre-swallow pooling are compared with those who do not have pre-swallow pooling in **Table 13**. In summary, participants who had pre-swallow pooling had a range of stroke locations, and greater number of moderate strokes than those without pre-swallow pooling.

Table 13

Patient Demographics by Presence of Pre-Swallow Pooling

	Pre-swallow pooling absent (n=11)	Pre-swallow pooling present (n=13)
Age (years):		

Mean +/- SD	70.2 +/- 10.06	74.2 +/- 7.35
Range	50-81	63-87
Sex:		
Male	10 (91%)	8 (62%)
Female	1 (9%)	5 (38%)
Stroke lesion location:		
Cortical	8 (73%)	4 (31%)
Subcortical	0 (0%)	3 (23%)
Cortical-brainstem	0 (0%)	2 (15%)
Brainstem	3 (27%)	4 (31%)
NIHSS:		
No symptoms	1 (9%)	0 (0%)
Minor	7 (64%)	3 (23%)
Moderate	1 (9%)	9 (69%)
Mod-severe	1 (9%)	0 (0%)
Severe	1 (9%)	1 (8%)

Reliability of stroke participant repeated measures of physiological data

All measures met assumptions for statistical analysis. Reliability of measures was evaluated using Intraclass Coefficient Correlation (ICC [3,k]) and percentage change in mean, shown in **Table 14**. ICC was good (0. 87- 0.90) for all physiological measures except for lingual-palatal pressure during swallowing task, which was moderate (ICC 0.58). Percentage change in mean was below 10% for all measures.

Table 14

Within session Reliability of Stroke Participant Physiological Data

	Mean +/- SD						
Outcome measures	**Trial 1**	**Trial 2**	**Trial 3**	**Estimated % change per trial (95% CI)**		**ICC (95% CI)**	**Between participants SD (95% CI)**
Sensation Posterior Tongue (mA)	2.9 +/- 1.5	2.8 +/- 1.6	2.9 +/- 1.9	Trial 2-1 Trial 3-2 Trial 3-1	-5.76 (-17.49, 7.64) 1.90 (-10.79, 16.38) -3.97 (-15.92, 9.68)	0.90 (.82, .95)	1.57 (1.19, 2.10)
Sensation Right Faucial Arch-(mA)	2.9 +/- 1.1	3.0 +/- 1.2	3.0 +/- 1.2	Trial 2-1 Trial 3-2 Trial 3-1	-0.41 (-8.39, 8.26) 1.54 (-6.59, 10.38) 1.12 (-6.98, 9.92)	0.88 (.80, .94)	1.09 (0.83, 1.46)
Sensation Left Faucial Arch (mA)	2.9 +/- 1.2	3.0 +/- 1.2	3.0 +/- 1.2	Trial 2-1 Trial 3-2 Trial 3-1	4.54 (-9.17, 20.33) -3.82 (-16.44, 10.70) 0.55 (-12.65, 15.73)	0.87 (.77, .93)	1.13 (0.86, 1.50)
Posterior Tongue Strength (mA)	20.7 +/- 10.8	21.3 +/- 12.8	21.1 +/- 10.9	Trial 2-1 Trial 3-2 Trial 3-1	-4.00 (-19.27, 14.15) 5.39 (-11.37, 25.32) 1.17 (-14.92, 20.31)	0.89 (.80, .94)	10.90 (8.26, 14.47)
Posterior Tongue Strength During Swallowing (mA)	12.7 +/- 4.7	13.7 +/- 5.8	14.4 +/- 5.6	Trial 2-1 Trial 3-2 Trial 3-1	4.57 (-11.60, 23.71) 5.09 (-11.21, 24.36) 9.89 (-7.11, 30.00)	0.58 (.33, .75)	4.17 (2.84, 5.87)

Mean and Standard Deviation of Physiological Data

Mean and Standard Deviation of Physiological Data for Healthy Participants is shown in **Table 15.**

Table 15

Mean and Standard Deviation of Physiological Data for Healthy Participants

	Men		Women	
	Young 20-59 (N=1)	**Old 60+ (N=1)**	**Young 20-59 (N=7)**	**Old 60+ (N=9)**
Posterior tongue sensation (mA)	0.65	0.8	1.31 +/- 1.38	1.46 +/- 0.78
Faucial arch sensation (mA)	1.85	2.6	1.75 +/- 0.86	2.4 +/- 1.03
Isometric posterior lingual-palatal pressure (kPa)	62.5	25.5	43.21 +/- 14.46	46.72 +/- 15.78
Posterior lingual-palatal pressure during swallowing (kPa)	38	18.5	22.07 +/- 8.03	35.72 +/- 15.36

Mean and Standard Deviation of Physiological Data for Stroke Participants is shown in **Table 16.**

Table 16

Mean and Standard Deviation of Physiological Data for Stroke Participants

	Men		Women	
	Young 20-59 (N=0)	**Old 60+ (N=18)**	**Young 20-59 (N=1)**	**Old 60+ (N=5)**
Posterior tongue sensation (mA)	N/A	3.17 (+/- 1.77)	0.75	2.29 (+/- 0.94)
Left faucial arch sensation (mA)	N/A	3.41 (+/- 0.96)	0.35	2.85 (+/- 1.09)
Right faucial arch sensation (mA)	N/A	3.22 (+/- 0.90)	1	2.4 (+/- 0.86)
Isometric posterior lingual-palatal pressure (kPa)	N/A	20.39 (+/- 11.34)	11	25.1 (+/-15.38)
Posterior lingual-palatal pressure during swallowing (kPa)	N/A	13.78 (+/- 5.60)	14.5	15 (+/-5.36)

Note: N/A represents missing data

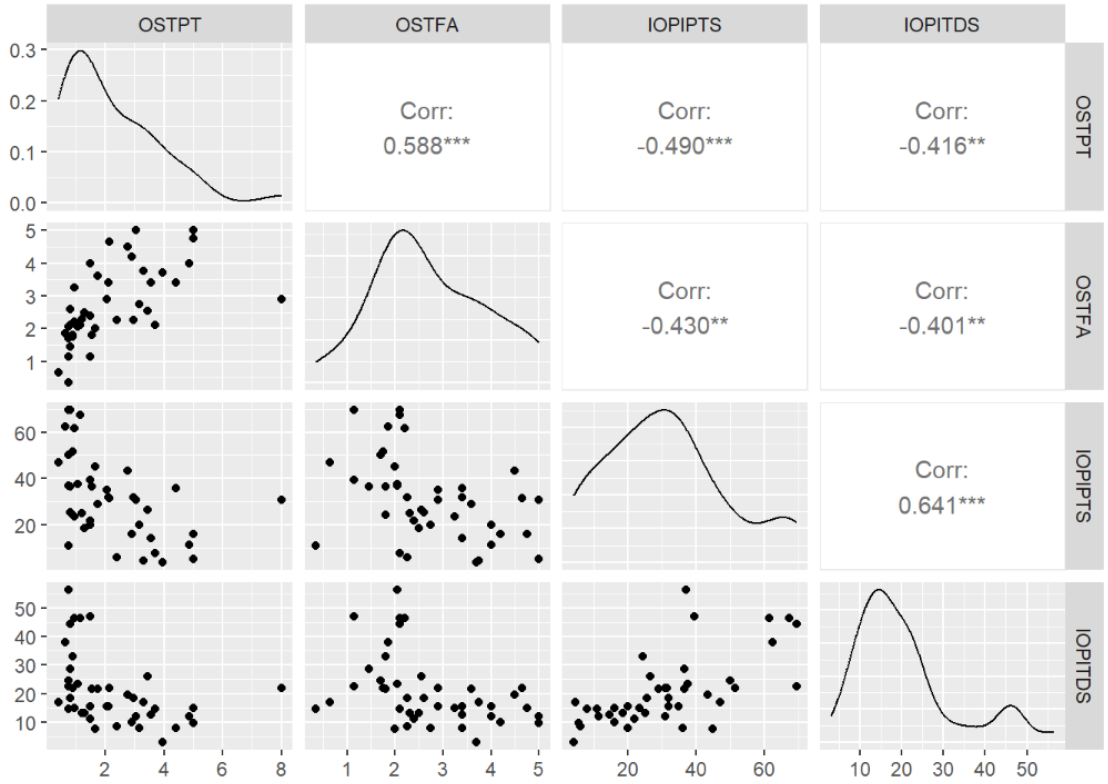
Cluster analysis

Data included in the cluster analysis relative to lingual palatal approximation included isometric posterior pressure and posterior pressure during swallowing. Sensory data included oral sensory perception thresholds at the posterior tongue and the faucial arches. Oral sensory perception measures of the lips were not included due to the poor reliability of repeated measures obtained during the normative study (Study 1). The faucial arch measures in the healthy participants differed from the stroke participants. In the healthy participants, either faucial arch was assessed randomly. In the stroke participants, both faucial arches were assessed to evaluate any significant difference between locations. A paired sample t-test was conducted in the patient data to evaluate whether there was a significant change between the left and right faucial arch sensation thresholds. No significant change was found (mean difference left to right faucial arch 0.21 [95%CI (-0.36, 0.16), p value = 0.318]), therefore the left faucial arch was randomly chosen for the patient cohort. There were three trials across each physiological measure. Due to the findings in the reliability study (Study 1) which showed a systematic difference between the first trial and the following trials, the first trial was omitted, and the remaining two trials were averaged.

Correlation plots (**Figure 9**) showed a significant moderate correlation between isometric posterior lingual-palatal pressure and posterior lingual-palatal pressure during swallowing (r = 0.64) as well as faucial arch sensation with posterior tongue sensation (r = 0.58). There were no pairs with a correlation over 0.75 therefore, no measures were removed.

Figure 9

Correlation Plots

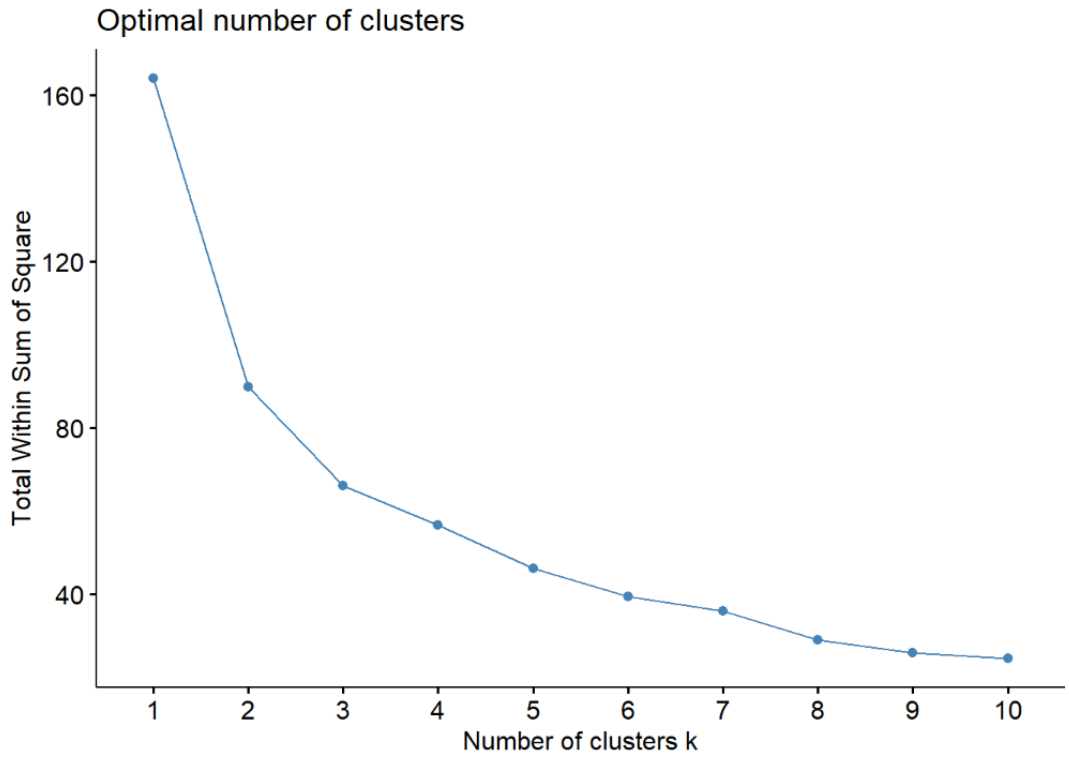


Note: Correlation plot showing collinearity between physiological variables.

To determine the optimal number of clusters, three methods were selected for inspection. First, the elbow method was used (**Figure 10**). This computes a clustering algorithm for different values of k, calculates the total within-cluster sum of square (wss), then plots the curve of wss according to the number of clusters. The location of the bend in the plot is considered the appropriate number of clusters. This method identified 3 clusters as the optimal number.

Figure 10

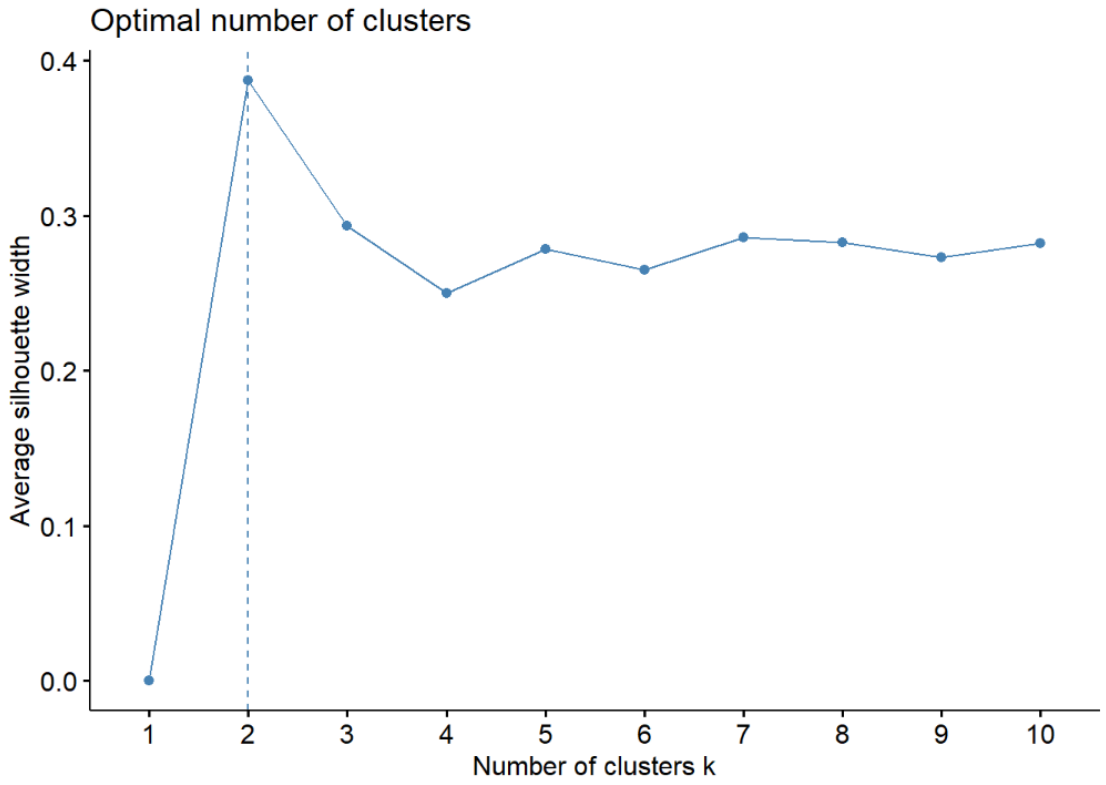
Elbow method



Then, the silhouette method (**Figure 11**) was used to evaluate how well each object lies within its cluster. A high average silhouette width indicates good clustering. This method computes the average silhouette of observations for different k values. The optimal number of clusters is shown by the k that maximizes the average silhouette over a range of the possible k values. This solution identified 2 clusters as the optimal number.

Figure 11

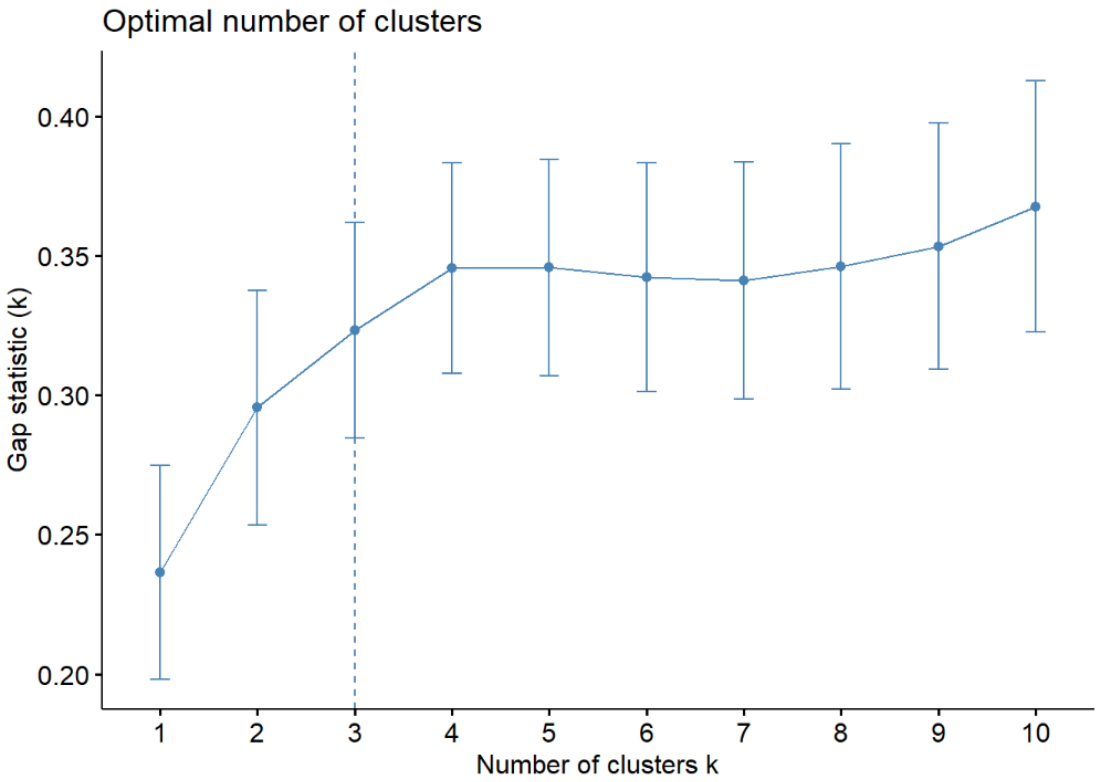
Elbow method



And finally, the gap statistic (**Figure 12**) was used to evaluate the optimum number of clusters. This compares the total variation between clusters for different k values. This solution identified three clusters as the optimum number of clusters. Since 2/3 methods identified 3 clusters as the optimum number of clusters, this was determined as the recommended number of clusters.

Figure 12

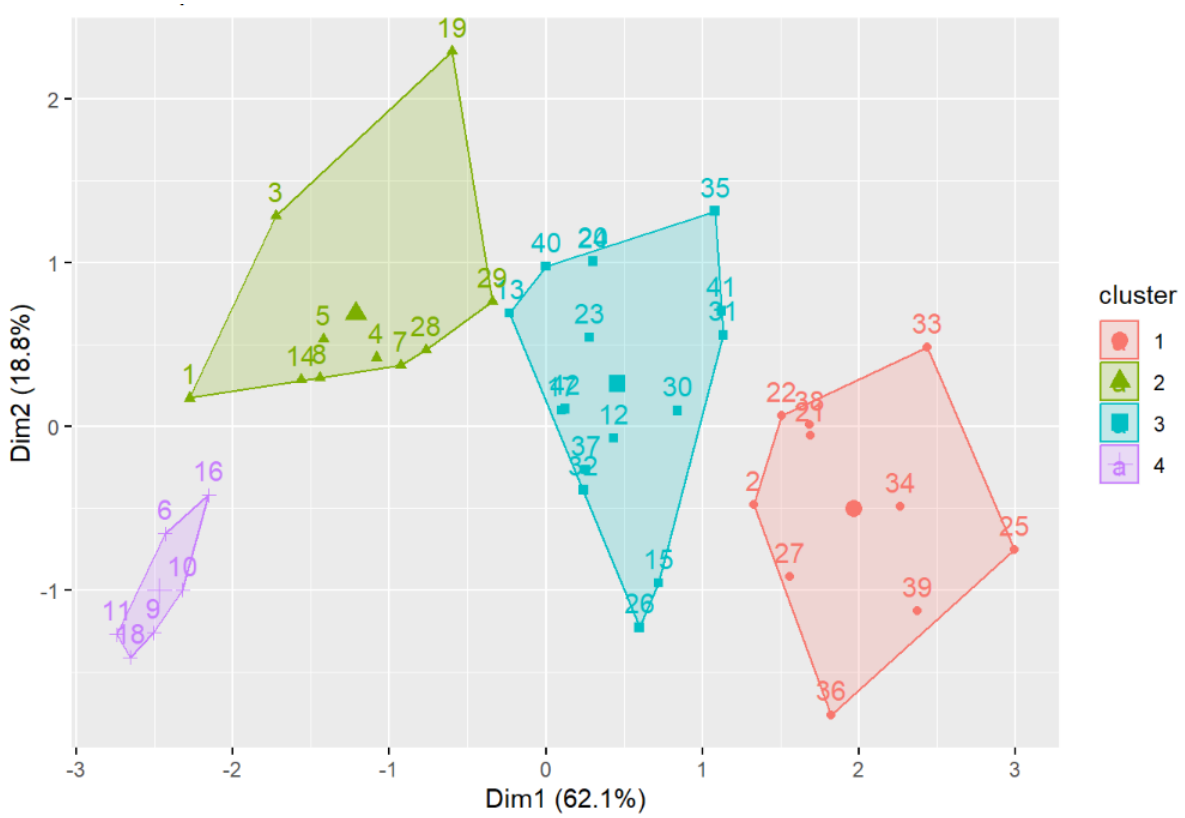
Gap statistic



Since 4 clusters were originally hypothesized, K-means was selected and computed with a predetermined number of both 3 (recommended) and 4 (hypothesized) clusters to compare the results between both clustering solutions. The representation of both clustering solutions is described below. The clustering solution with 4 clusters is illustrated in **Figure 13**.

Figure 13

Principal Components Scatterplot



Each participant is depicted within a cluster that represents values on physiological measures of strength and sensation. High values for strength and low values for sensation (low detection threshold) are considered good and vice versa.

Inspection of cluster features in 4 cluster solution

Measured variables for each cluster are depicted in **Table 17** and illustrated in **Figure 15.** The following classification can be observed from the values of these measures:

- Cluster 1 poor strength (low strength scores) and poor sensation (high sensation scores)
- Cluster 2 good strength (high strength scores) and good sensation (low sensation scores)
- Cluster 3 poor strength (low strength scores) good sensation (low sensation scores)
- Cluster 4 good strength (high strength scores) good sensation (low sensation scores)

There was no cluster that represented good strength and poor sensation. Cluster 2 and 4 represent the same classification (good strength and good sensation).

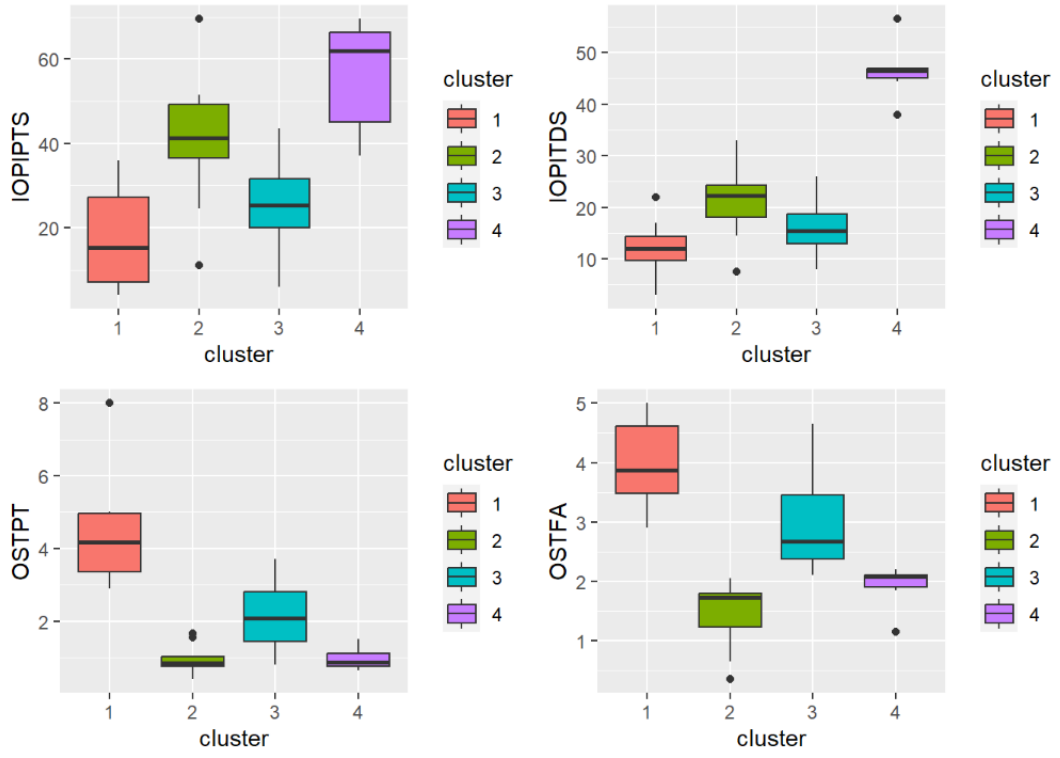
Table 17

Cluster Means for 4 Clusters

	Cluster 1 (n=10)	Cluster 2 (n=10)	Cluster 3 (n=16)	Cluster 4 (n=6)
Strength variables (mean +/- STD)				
Posterior lingual-palatal pressure (kPa)	17.00 +/- 11.78	40.90 +/- 19.92	24.88 +/- 9.50	56.25 +/- 14.28
Posterior lingual-palatal pressure during swallowing (kPa)	12.10 +/- 5.18	21.45 +/- 7.15	15.97 +/- 4.89	46.50 +/- 5.94
Sensation variables (mean +/- STD)				
Posterior tongue sensation (mA)	4.40 +/- 1.49	0.95 +/- 0.38	2.11 +/- 0.90	0.97 +/- 0.31
Faucial arch sensation (mA)	4.01 +/- 0.72	1.47 +/- 0.58	3.0 +/- 0.82	1.91 +/- 0.39

Figure 15

Box Plot of Physiological Measures for 4 Clusters



Note: Abbreviations: Posterior lingual palatal pressure (IOPIPTS). Lingual-palatal pressure during swallowing (IOPITDS). Faucial arch sensation (OSTFA). Posterior tongue sensation (OSTPT). Center lines show the median and box limits indicate the 25th and 75th percentiles. Whiskers extend 1.5 times the interquartile range

from the 25th and 75th percentiles, and outliers are represented by dots.

The representation of the clustering solution with 3 clusters is illustrated in **Figure 16**.

Figure 16

Inspection of cluster features in 3 cluster solution

Measured variables for each cluster are depicted in **Table 18**, the following classification can be observed from the values of these measures:

- Cluster 1 poor strength (low strength scores) and poor sensation (high sensation scores)
- Cluster 2 good strength (high strength scores) and good sensation (low sensation scores)
- Cluster 3 poor strength (low strength scores) good sensation (low sensation scores)

Consistent with the 4-cluster solution, there was no cluster that represented good strength and poor sensation.

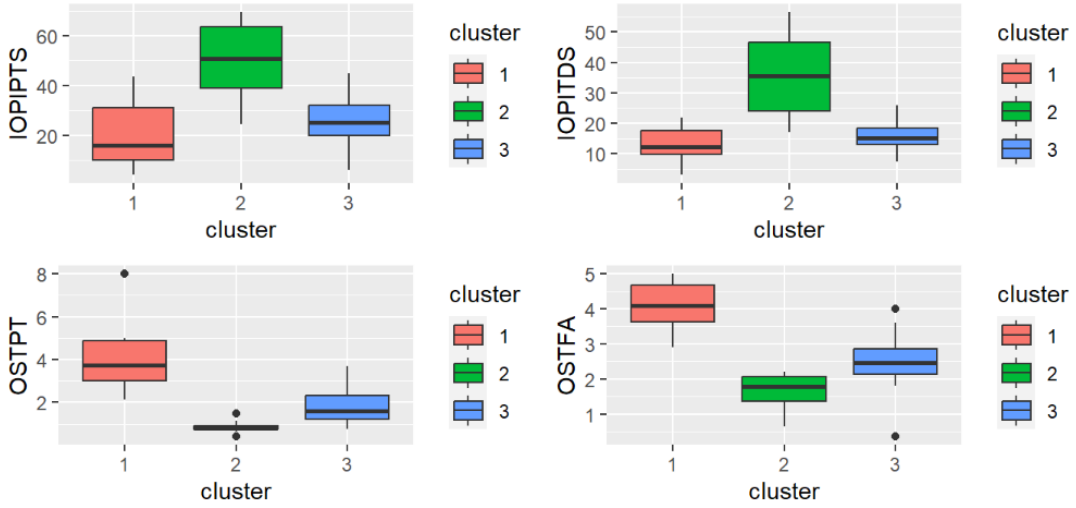
Table 18

Cluster Means for 3 Clusters

	Cluster 1 (n=12)	Cluster 2 (n=12)	Cluster 3 (n=18)
Strength variables (mean +/- STD)			
Posterior lingual-palatal pressure (kPa)	20.42 +/- 13.56	51.38 +/- 14.94	25.17 +/- 10.45
Posterior lingual-palatal pressure during swallowing (kPa)	13.54 +/- 5.79	35.54 +/- 12.69	15.61 +/- 5.25
Sensation variables (mean +/- STD)			
Posterior tongue sensation (mA)	4.08 +/- 1.56	0.86 +/- 0.27	1.88 +/- 0.91
Faucial arch sensation (mA)	4.10 +/- 0.69	1.66 +/- 0.47	2.50 +/- 0.80

Figure 17

Box Plot of Physiological Measures for 3 Clusters



Note: Abbreviations: Posterior lingual palatal pressure (IOPIPTS). Lingual-palatal pressure during swallowing (IOPITDS). Faucial arch sensation (OSTFA). Posterior tongue sensation (OSTPT). Center lines show the median and box limits indicate the 25th and 75th percentiles. Whiskers extend 1.5 times the interquartile range from the 25th and 75th percentiles, and outliers are represented by dots.

Since the 4-cluster solution contained two groups that were the same (good sensation/good strength), and one of these clusters had just 6 participants, and it is recommended for clustering solution stability to have a similar number of samples for each cluster, it was considered appropriate to proceed with 3 clusters as

recommended by the clustering solution.

Participant demographics by cluster group

Participant demographics by cluster group is shown in **Table 19**. The cluster that represented good sensation and good strength (cluster 2) only included healthy participants. There were 2 healthy participants in cluster 1, which represented a cluster that had both poor sensation and poor strength. There were 4 healthy participants in cluster 3 which represented a cluster that had good sensation and poor strength. Stroke participants were divided between cluster 1 (10) and cluster 3 (14).

Table 19

Participant Demographics by Cluster Group

		Cluster 1 (n=12)	Cluster 2 (n=12)	Cluster 3 (n=18)
Group, (%)				
	Healthy	2 (17)	12 (100)	4 (22)
	Stroke	10 (83)	0 (0)	14 (78)
Mean age (range)		71 (51-81)	62.42 (50-85)	71.56 (50-87)
Sex, n (%)				
	Males	8 (67)	1 (8)	11 (61)
	Females	4 (33)	11 (92)	7 (39)

Stroke participant demographics are shown in **Table 20**. Cluster three had more participants with pre-swallow pooling, and a greater range of stroke location and severity.

Table 20

Stroke Demographics by Cluster Group

Stroke location, n (%)	Cluster 1 (n=10)	Cluster 3 (n=14)
brainstem	3 (30)	5 (36)
cortical	7 (70)	6 (43)
subcortical	0 (0)	3 (21)
NIHSS, n (%)		
no symptoms	0 (0)	1 (7)
minor	5 (50)	5 (36)
moderate	3 (30)	7 (50)
moderate-severe	1 (10)	0 (0)

severe	1 (10)	1 (7)
Pre-swallow pooling, n (%)	4 (40)	9 (64)

Alignment of cluster analysis with speech pathologist's diagnosis of poor bolus containment and delayed pharyngeal swallowing.

A total of 84 swallows were rated by 3 speech pathologists. Each speech pathologist independently classified pre-swallow pooling as either:

1. Poor bolus containment,
2. Delayed pharyngeal swallowing,
3. Both poor bolus containment and delayed pharyngeal swallowing, or
4. Neither poor bolus containment nor delayed pharyngeal swallowing.

Percentage agreement for each swallow is shown in **Appendix 9**. Total percentage agreement was 64. Cohen's Kappa was calculated to determine reliability between rater pairs. There was slight agreement between raters 1 and 2 (k = 0.19, 95% C.I. 0.05, 0.32) and fair agreement between raters 2 and 3 (k = 0.25, 95% C.I. 0.12, 0.38) and raters 1 and 3 (k = 0.36, 95% C.I. 0.21, 0.52). Closer inspection of contingency tables (**Table 21**) identified that the most disagreement occurred with diagnoses of "delay" and "both". Following consensus, there was 100% agreement between speech pathologists and therefore no participants were excluded from the analysis.

Table 21

Contingency Tables Between Raters

	Rater 2			
Rater 1	PBC	Delay	Both	Neither
PBC	7	3	3	5
Delay	3	10	11	7
Both	7	5	6	6
Neither	1	1	0	9

Rater 3

Rater 1	PBC	Delay	Both	Neither
PBC	6	1	11	0
Delay	0	21	8	2
Both	0	10	12	2
Neither	0	3	1	7

	Rater 3			
Rater 2	PBC	Delay	Both	Neither
PBC	2	2	13	0
Delay	1	12	4	2
Both	0	8	12	0
Neither	2	13	3	9

Note: PBC = poor bolus containment

Post-hoc observation of the data identified that there was poor consistency of diagnosis across swallowing trials within each participant (k = 0.30, 95% C.I 0.12, 0.47). This was an unexpected finding. Variation of diagnoses across the six swallows for each participant as shown in **Appendix 10**. Only one participant had a consistent diagnosis across all swallows; however, the diagnosis was "neither poor bolus containment or delayed pharyngeal swallowing". There were 6 participants who had two different diagnoses across their 6 swallows, and seven participants who had three different diagnoses. No participant had all four diagnoses.

Because the diagnosis of poor bolus containment vs delay was highly variable within swallows for each participant, this could not be statistically correlated with clusters to evaluate if speech pathologists' diagnosis of poor bolus containment vs delayed pharyngeal swallowing aligned with physiological measures.

9.4. Summary

A cluster analysis approach was used to identify whether groups could be formed from the physiological measurements of oral sensation and posterior lingual-palatal pressure. Findings showed that contrary to the predicted hypothesis, 3 distinct clusters rather than 4 clusters could be established. One with both poor sensation and poor strength, one with good sensation and good strength, and one with poor strength and

good sensation. There was no cluster representing good strength and poor sensation. As predicted, the cluster that had good sensation and good strength consisted only of healthy participants. The other two clusters could not be aligned with speech pathologists' consensus diagnosis of poor bolus containment or delayed pharyngeal swallowing due to the high variability of diagnosis within each participant. All but one participant had more than one diagnosis within their 6 observed swallows, which could be interpreted that poor bolus containment and delay can both be present in a participant and therefore they must have both a sensory and a motor-based impairment. Alternatively, this may indicate that our current methods of diagnosis are inadequate to distinguish between poor bolus containment and delayed pharyngeal swallowing. Since distinct clusters were able to be established, the inconsistency suggests that our current methods may be flawed.

Chapter 10 How Does Impaired Sensation or Impaired Lingual-Palatal Pressure Align with Functional Swallowing Measures?

10.1. Introduction

Swallowing measures are commonly used to quantify dysphagia. They are also used to measure a positive change in response to dysphagia intervention, or deterioration in progressive disease. Oral transit time (OTT) is used to measure the time it takes from the bolus to move through the oral cavity (Soares et al., 2015). It was originally described by Logemann as "the time taken from the initiation of the swallow until it passes through the faucial arches" p.74 (Logemann, 1983). Oral transit time has been used in studies to measure outcomes in tongue strengthening treatments (H. D. Kim et al., 2017; Park et al., 2015; Robbins et al., 2007) and in sensory treatments (Lee, Kim, Kim, Kim, et al., 2012; Regan et al., 2010; Sdravou et al., 2012). However, there is inconsistency in measurement techniques described in the literature. Some researchers measure from the onset of lingual motion to move the bolus posteriorly until the bolus reaches the point where the base of tongue crosses the posterior ramus of the mandible (Gatto et al., 2013). Others measure from the entry of food in the mouth, thus including the oral preparatory phase (Saitoh et al., 2007).

Stage transition duration (STD) is used to measure the time between the end of the oral phase signified by the entry of the bolus in the pharynx, and the onset of the pharyngeal swallowing response as shown by the onset of hyolaryngeal excursion. There is also inconsistency in the terminology/methods for measuring STD. Some measure from the arrival of the head of the bolus in the pharynx to the onset of pharyngeal swallowing (Stephen et al., 2005). Others specify the onset as the leading edge of the bolus in the pharynx to the onset of pharyngeal swallowing (Daniels et al., 2009). Some specify the onset as the main part of the bolus, excluding any "trickle down" of the bolus that may occur prior to purposeful propulsion (Kim et al., 2005).

STD has been used to measure improvements in tongue strengthening treatments (Steele et al., 2016; Yeates et al., 2008) and in treatments designed to target delayed pharyngeal swallowing (Everton et

al., 2021; Rosenbek, Roecker, et al., 1996; Sdravou et al., 2012). The Penetration-Aspiration Scale (PAS) (Rosenbek, Robbins, et al., 1996) is regarded as the industry standard in VFSS analysis (Steele & Grace-Martin, 2017). It is used widely as a measure of improvement in many dysphagia interventions (Speyer, Cordier, et al., 2022). However, there have not been any studies that have described strength and sensory function within these measures. Therefore, this study will describe how oral sensation, and posterior tongue strength align with OTT, STD and PAS.

10.2. Methodology

Participants and Recruitment

This was a prospective observational case-control study. Data were collected from the same participants as those who participated in Study 3. Measurements of physiological assessments and the cluster analysis from Study 3 (chapter 9) were compared to measurements taken from videofluoroscopic swallowing studies (VFSS).

Procedure

The procedure for data collection and formation of clusters has been described in Study 3. Only the stroke participants were included in this study (n=24).

Outcome measures

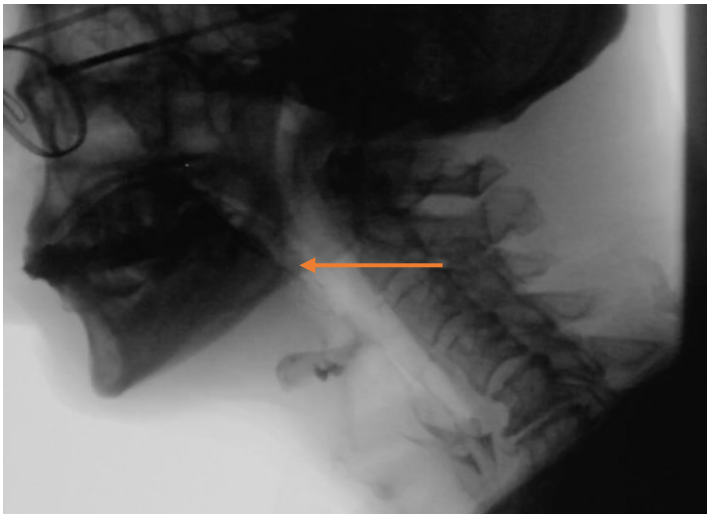
For the purposes of this study, the following definitions were applied: Oral Transit Time (OTT): Oral transit time is defined as the time between the onset of lingual movement that moves the bolus posteriorly until the head of the bolus reaches the point where the base of tongue crosses the inferior ramus of the mandible (Rademaker et al., 1994). This was measured in milliseconds.

Stage Transition Duration (STD): Stage transition duration (STD) was recorded between the time the head of the bolus reaches the point where the base of tongue crosses the inferior ramus of the mandible (**Figure 18**), to the initiation of maximal superior hyoid movement (Daniels et al., 2009) that signals the start of hyo-

laryngeal excursion, excluding any up/down movements that might occur prior. This was measured in milliseconds.

Figure 18

Cross-Section of the Base of Tongue with the Inferior Ramus of the Mandible



Due to poor interpretation of the head of the bolus, two definitions were used and measured separately as has been done in previous research (McCullough et al., 2012). STD1 (**Figure 19**) used the definition of the head of the bolus to be the leading edge/first frame where barium is seen in pharynx. STD2 (**Figure 20**) used the definition of the head of the bolus as the leading edge of the main part of the bolus as judged after oral propulsion of the bolus and excluding and part of the bolus that may have escaped prior to purposeful propulsion.

Figure 19

First Frame Where Barium Seen in Pharynx

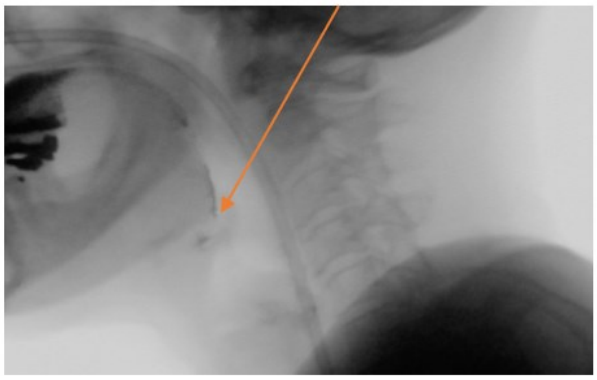
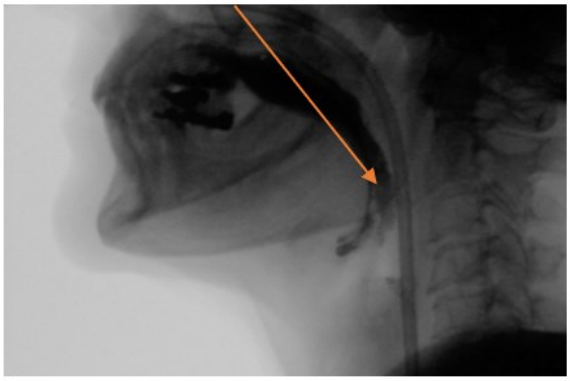


Figure 20

Leading Edge of Main Bolus



Penetration-Aspiration Scale (PAS): Penetration-aspiration scale (PAS) is an 8-point categorical scale that identifies the entry and level of depth into the laryngeal vestibule that a bolus reaches, as well as the associated response to it (Rosenbek, Robbins, et al., 1996). This includes an indication of an attempt to clear the bolus from the laryngeal vestibule or not, and whether it is successful.

Penetration-Aspiration Scale (Rosenbek, et al., 1996)

	Description
1	Material does not enter the airway
2	Material enters the airway, remains above the vocal folds, and is ejected from the airway
3	Material enters the airway, remains above the vocal folds, and is not ejected from the airway
4	Material enters the airway, contacts the vocal folds, and is ejected from the airway
5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6	Material enters the airway, passes below the vocal folds, and is ejected from the airway or larynx
7	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort
8	Material enters the airway, passes below the vocal folds, and no effort is made to eject

Statistical analysis

Descriptive data

Descriptive data was used to describe the means, standard deviation and range of oral transit time and stage transition duration, and frequency of penetration aspiration scores. Analysis of swallowing measures were then described according to cluster membership identified in study 3. Oral transit time, stage transition duration and the penetration aspiration scale were described within each cluster. Then, the swallowing

measures and clinician diagnosis of poor bolus containment, delay, both and neither with swallowing measures was examined.

Consistency of swallowing measures

Consistency of repeated measures of the swallowing measures was analysed with intraclass coefficient correlation (ICC 3, 1) and percentage change in mean.

a. *Consistency of repeated swallowing measures*

Intraclass correlation coefficients (ICC [3, 1]) were used to investigate repeatability of the results among the trials. A separate ICC was calculated for peach and fluids. ICC's were derived from mixed effects models using the lmer package (Bates et al., 2014). Wherein the model, trial was entered as a fixed effect and a by-participant intercept as a random effect. The ICC was calculated by dividing the between participant's variability by the total variability. Since the ICC depends on both measurement error and homogeneity of the sample (Bartlett & Frost, 2008), between-subject variance was reported as a measure of the sample homogeneity. A bootstrap distribution was calculated from which the 95% confidence intervals for each ICC was obtained. Residual versus fitted plots were visually inspected to identify potential deviation from homoscedasticity; and quantile-quantile plots (Q-Q plots) of the residuals were reviewed to evaluate normality. As for the reliability study with the normative participants (Study 1), interpretation of the ICC results was based on published criteria: Poor reliability (ICC < 0.50), moderate (ICC 0.50 – 0.75), good (ICC 0.75 – 0.90) and excellent reliability (ICC < 0.90) (Koo & Li, 2016).

b. *Percentage change in mean*

Percentage change in mean was completed manually as some of the values were negative. The natural logarithm function ln(x) is defined only for x>0. Therefore, percentage change in mean was calculated in excel with the formula =(new value-old value)/old value followed by changing the value to a percentage. Interpretation of change in mean between trials was considered acceptable if ≤ 10% (Hopkins, 2000).

Inter-rater reliability

A sample of 20% of the swallowing measures was taken for reliability measurement. Inter-rater reliability for oral transit time and stage transition duration measures was calculated using intra-class correlation coefficients (ICCs) derived from a linear mixed model analysis using the lmer package (Bates et al., 2014) in R (RCoreTeam, 2021). A two-way random effects model based on single measures (ICC [2,1]) was used. For inter-rater reliability, an intercept for rater and swallowing measure were included in the model as random effects and bolus was included in the model as fixed effect. Inter-rater reliability was then calculated as:

$$\text{ICC (2, 1)} = \frac{\text{between observation variance}}{\text{between rater variance + between observation variance + residual variance}}$$

For interpretation of the ICC results, criteria reported by Interpretation of reliability findings was based on published criteria: poor reliability (ICC < 0.50), moderate (ICC 0.50 – 0.75), good (ICC 0.75 - 0.90) and excellent reliability (ICC < 0.90) (Koo & Li, 2016). A 0.05 confidence interval was considered significant. Inter-rater reliability for agreement in penetration-aspiration was measured between two groups; one that represented penetration with PAS scores 1-2, and the other that represented aspiration with PAS scores 3-8. Inter-rater reliability was calculated using and Cohen's kappa coefficient (K) analysis. Interpretation of Cohen's kappa was based on published criteria, where ≤ 0; poor agreement, .01–.20; slight agreement, .21–.40; fair agreement, .41– .60; moderate agreement, .61–.80; substantial agreement, and .81–1; almost perfect agreement (Landis & Koch, 1977).

Utility of physiological measures to predict swallowing impairment

Linear regression was used to identify if any oral sensory perception thresholds (posterior tongue, left faucial arch, right faucial arch) were associated with an increased STD. An ANOVA analysis will be used to compare the means of within participants averaged STD and OTT between the clusters.

For PAS, a chi-square analysis was performed to determine the relationship between PAS scores and clusters.

10.3. Results

Descriptive data

Participant descriptive data is described in Study 3. There were 14 participants who completed VFSS analysis. There were 12 participants who completed the physiological measures in addition to the VFSS measures. Therefore, 2 participants who did not have physiological data were removed, leaving 12 participants included in the final analysis.

Consistency of swallowing measures

a. Consistency of repeated swallowing measures

ICC for repeated measures was poor for OTT, STD1 for thin fluids, and STD2 for peaches. ICC was moderate for the remaining swallowing measures. As illustrated by the dot plots (**Figures 16-19**) and reported in **Table 22,** the standard deviation between participants is large, particularly for the fruit measures. This indicates a high variability. Since the ICC is calculated by comparing the variability within a participant to the variability between participants and both are highly variable, the ICC appears higher for the fruit measures. Therefore, ICC measures of test-retest reliability for all trials can be interpreted as poor.

Table 22

Consistency of Repeated Measures

Thin fluids	**Mean +/- SD**						
Outcome measures	**Swallow 1 (s)**	**Swallow 2 (s)**	**Swallow 3 (s)**	**% of change in mean**		**ICC (95% CI)**	**Between participants SD (95% CI)**
Oral transit time	-0.22 +/- 0.89	0.35 +/- 0.78	0.28 +/- 0.89	Swallow 2-1	-59%		
				Swallow 3-2	-20%		
				Swallow 3-1	27%	0.16 (0.0, 0.54)	0.34 (0.0, 0.75)
Stage transition duration (definition 1)	0.99 +/- 0.75	0.36 +/- 0.59	0.59 +/- 0.89	Swallow 2-1	-63%		
				Swallow 3-2	65%		
				Swallow 3-1	-40%	0.42 (0.0, 0.73)	0.49 (0.18, 0.84)
				Swallow 2-1	-32%		
Stage transition duration (definition 2)	0.19 +/- 0.40	0.13 +/- 0.24	0.19 +/- 0.26	Swallow 3-2	52%		
				Swallow 3-1	3%	0.75 (0.42, 0.90)	0.27 (0.17, 0.42)
Diced peaches							
Oral transit time	-4.51 +/- 4.13	-4.47 +/- 6.53	-6.03 +/- 5.84	Swallow 2-1	-1%		
				Swallow 3-2	27%		
				Swallow 3-1	26%	0.63 (0.24, 0.86)	4.38 (2.54, 7.05)
Stage transition duration (definition 1)	4.06 +/- 3.96	5.14 +/- 5.78	6.48 +/- 5.79	Swallow 2-1	27%		
				Swallow 3-2	26%		
				Swallow 3-1	60%	0.61 (0.25, 0.83)	4.10 (2.36, 6.62)
				Swallow 2-1	4%		
Stage transition duration (definition 2)	0.39 +/- 0.72	0.40 +/- 1.01	0.82 +/- 1.35	Swallow 3-2	105%		
				Swallow 3-1	113%	0.22 (0.0, 0.59)	0.50 (0.00, 0.99)

Kappa calculation of PAS identified no agreement for thin fluids (k = .05, 95% CI -0.06, 0.17) or fruit (k = .63, 95% CI 49, 1).

Figure 21

Dot Plot OTT

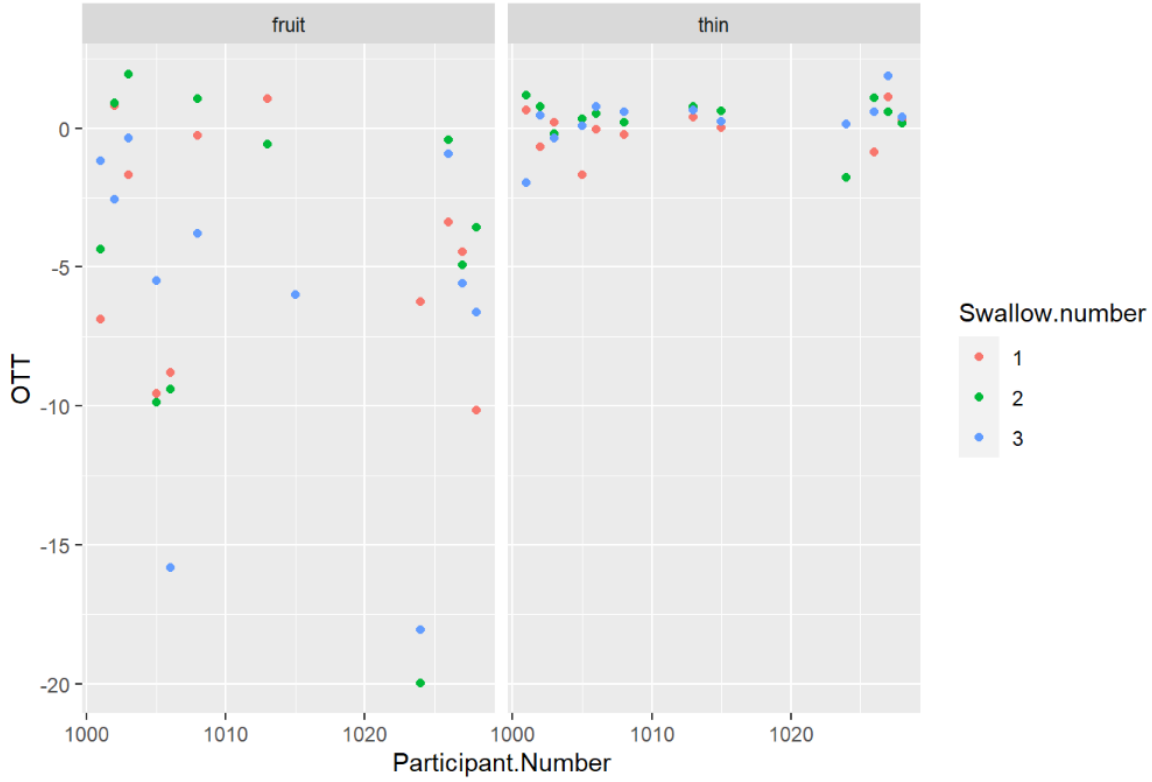


Figure 22

Dot Plot STD1

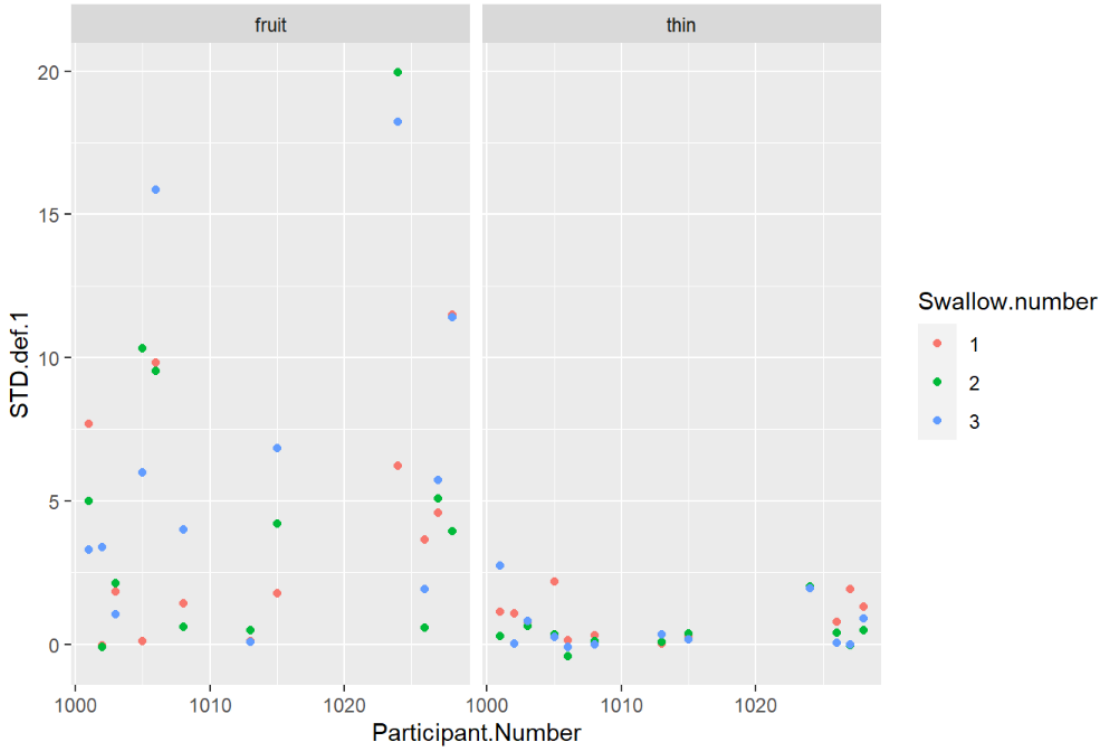


Figure 23

Dot Plot STD2

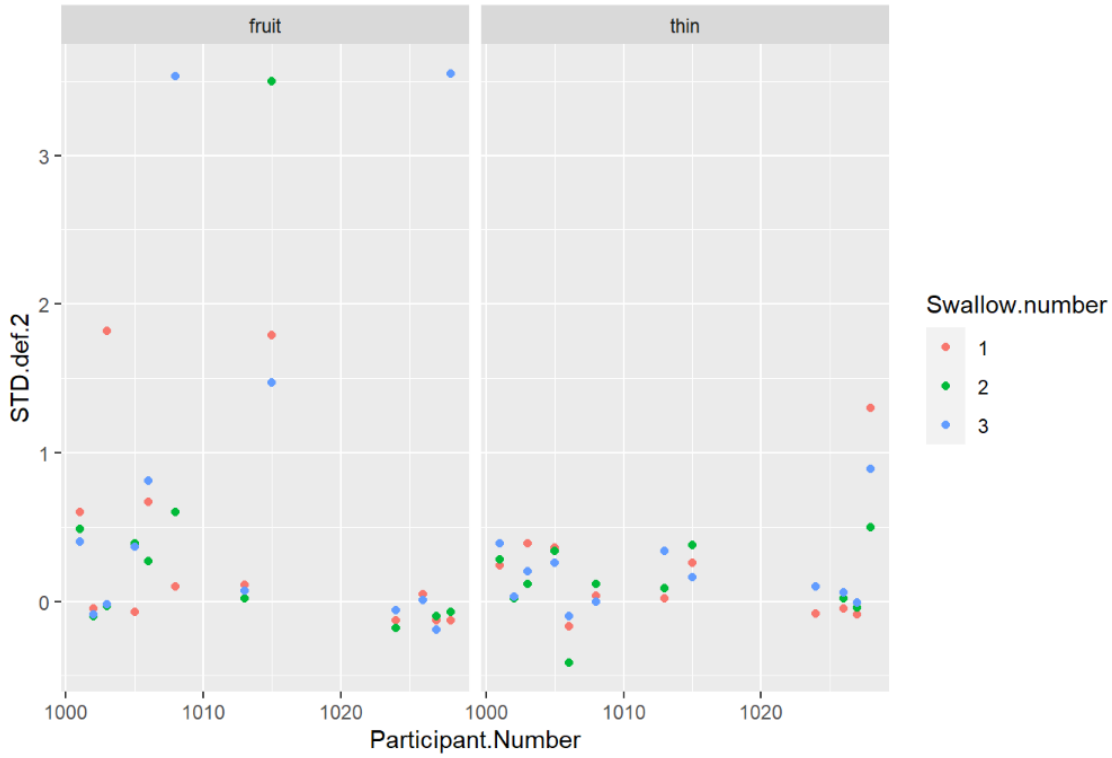
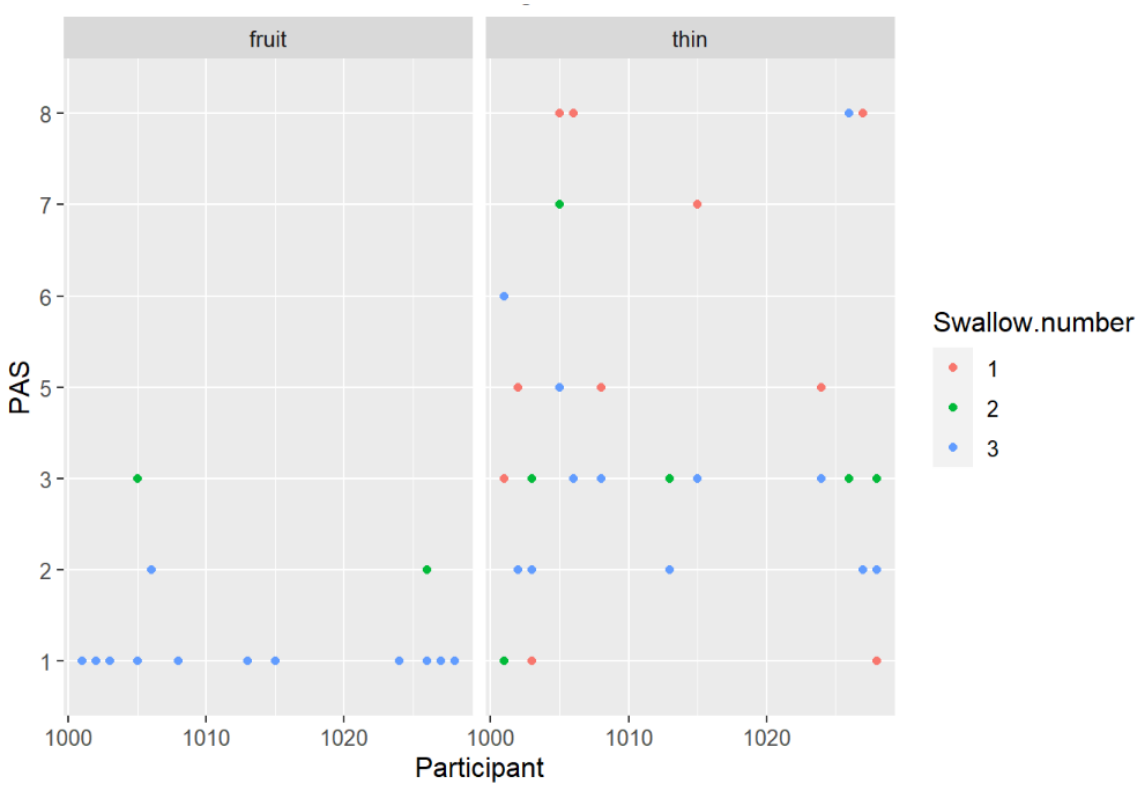


Figure 24

Dot Plot PAS



b. Percentage change in mean

Percentage change in mean was acceptable (<10%) between swallows 3 and 1 for STD2 of thin fluids and between swallows 2 and 1 for OTT and STD2 of peaches. The percentage change in mean between the remaining swallows ranged between 20 and 113%.

Inter-rater reliability measures

Inter-rater reliability of swallowing measures was completed with a sample of 18/84 swallows (21.4%). Rater 1 had 25 years' experience of VFSS scoring and interpretation. Rater 2 had 2 years' experience of VFSS scoring and interpretation, trained by rater 1.

Results of ICC are shown in **Table 23**.

Table 23

Inter-Rater Reliability of Swallowing Measures

Outcome measure	Inter-rater reliability ICC (95% CI)	Between participant SD (95% CI)
Oral transit time (OTT)	0.69 (0.36, 0.88)	5.38 (3.33, 8.06)
Stage transition duration (STD1)	0.77 (0.49, 0.90)	5.31 (3.46, 7.80)
Stage transition duration (STD2)	0.56 (0.19, 0.80)	1.70 (0.80, 2.63)

Reliability was moderate for OTT (ICC = 0.69), STD2 (ICC = 0.56), and good for STD1 (ICC = 0.77). Percentage agreement for PAS between raters was 5/7 (71%) for thin fluids and 9/11 (82%) for fruit swallows as shown in **Table 24**. Note: 1 represents PAS scores 1 and 2, and 2 represents PAS scores 3 to 8.

Table 24

Percentage Agreement of PAS

Thin Swallow	Rater 1	Rater 2	% Agreement
100202	1	1	1
100302	2	1	0
100601	2	2	1
101502	2	1	0
102701	2	2	1
102801	1	1	1
102803	1	1	1
			5/7 (71%)

Fruit Swallow	Rater 1	Rater 2	% Agreement
100103	1	1	1
100502	2	2	1
100701	1	2	0
100803	1	1	1
102203	2	2	1
102402	1	2	0

102403	1	1	1
102602	1	1	1
102603	1	1	1
102701	1	1	1
102802	1	1	1
			9/11 (82)

Inter-rater agreement of PAS classification (penetration (PAS 1 and 2) vs aspiration (PAS 3-8)) was moderate (k = 0.45, C.I -0.014, 0.90).

Mean duration of swallowing measures is presented in **Table 26**. As each participant performed three swallows of each consistency, the three measures for each consistency per participant were averaged. Since the swallowing measures for each participant were variable as shown in **Table 22**, averaging them removes this variability and needs to be considered when interpreting these results.

Table 26.

Mean Swallowing Measures

Mean (SD)	OTT	STD 1	STD 2
Thin	0.18 (0.82)	0.61 (0.73)	0.17 (0.28)
Peaches	-4.48 (5.37)	5.02 (4.91)	0.78 (1.55)

The PAS was scored on 84 swallows (14 participants, 6 swallows each). As shown in **Table 27**, there were 27/84 occasions (32.1%) of penetration not cleared, or aspiration (PAS 3-8). Of those, the majority (16/27, 59%) were PAS 3 (material enters the airway, does not contact the vocal folds, and is not ejected from the airway).

Table 27

PAS scores

PAS Score	1	2	3	4	5	6	7	8
Frequency (%)	38 (45)	18 (21)	16 (19)	0 (0)	4 (5)	1 (1)	3 (4)	4 (5)

Utility of physiological measures to predict swallowing impairment.

Due to small numbers of participants who completed both the physiological measures for the cluster analysis and the swallowing measures in VFSS (12 in total), linear regression was unable to be calculated to determine whether faucial arch sensation had a larger effect-size than all the other sensation threshold sites for stage transition duration. As there was no cluster that had good strength measures within the stroke cohort, ANOVA could not be completed to determine whether this cluster may have had lower mean OTT than other clusters. Due to low cluster numbers (3 in cluster 1 and 9 in cluster 3) it was not possible to complete an ANOVA analysis to determine whether those assigned to the cluster with good sensation measures had a lower mean STD than those assigned to a cluster with poor sensation measures. Due to the inconsistency of PAS scores across participants and the inability to average categorical data, chi-square analysis could not be performed to determine the relationship between PAS scores and clusters. Therefore, descriptive analysis is presented below for exploratory purposes.

Examination of swallowing measures within each cluster

There were 3 members of cluster 1 and 9 members of cluster 3. A complete table containing all data used for cluster analysis can be found in **Appendix 11** where mean, standard deviation and range of swallowing measures by consistency, within each cluster is illustrated. For thin fluids, cluster 3 (good sensation, poor strength) had shorter OTT but STD 1 and STD 2 were largely the same as cluster 1 (poor sensation, poor strength). As shown in **Table 28**, cluster 3 (good sensation, poor strength) had worse PAS scores for thin fluids than cluster 1 (poor sensation, poor strength). For peaches, cluster 3 (good sensation, poor strength) had a shorter OTT than cluster 1, however both were negative, indicating that the bolus reached the pharynx prior to purposeful propulsion in the mouth. Cluster 3 also had longer STD 1 and STD 2.

Table 28

Swallowing Measures by Consistency and Cluster

Oral Transit Time

	Thin		Peaches	
	Cluster 1 n=9	Cluster 3 n=27	Cluster 1 n=9	Cluster 3 n=27
Mean (SD)	0.24 (0.98)	0.10 (0.84)	-1.60 (2.85)	-5.17 (5.53)
(min, max)	(-1.98, 1.18)	(-1.79, 1.86)	(-6.87, 1.07)	(-15.83, 1.94)

Stage Transition Duration 1

	Thin		Peaches	
	Cluster 1 n=9	Cluster 3 n=27	Cluster 1 n=9	Cluster 3 n=27
Mean (SD)	0.63 (0.90)	0.65 (0.75)	2.21 (2.80)	5.22 (5.06)
(min, max)	(0.02, 2.74)	(-0.41, 2.19)	(-0.1, 7.69)	(0.1, 15.86

Stage Transition Duration 2

	Thin		Peaches	
	Cluster 1 n=9	Cluster 3 n=27	Cluster 1 n=9	Cluster 3 n=27
Mean (SD)	0.16 (0.14)	0.17 (0.34)	0.16 (0.27)	0.70 (1.03)
(min, max)	(0.02, 0.39)	(-0.41, 1.3)	(-0.09, 0.6)	(-0.07, 3.53)

Examination of PAS scores across clusters

As shown in **Table 29**, penetration/aspiration was more common in cluster 3.

Table 29

Comparison of PAS Scores Across Clusters

	Cluster 1 n=9 (%)		**Cluster 3 n=27 (%)**	
	Thin	**Fruit**	**Thin**	**Fruit**
PAS 1-2	5 (56)	9 (100)	6 (22)	26 (96)
PAS 3-8	4 (44)	0 (0)	21 (78)	1 (4)

Relationship between swallowing measures and PAS

As shown in **Table 30**, greater PAS scores were seen with thin fluids. In those who had a PAS score of 3-8, there was a negative OTT, suggesting that the bolus entered the pharynx prior to purposeful propulsion (consistent with some definitions of poor bolus containment). There was a longer STD 1 time (time between arrival of barium until hyolaryngeal excursion) but shorter STD 2 (time from arrival of head of bolus (excluding any part of the bolus which may have broken away from the main

bolus), after purposeful propulsion in the mouth, until hyolaryngeal excursion). This suggests that worse PAS scores are associated with a negative OTT and longer STD1 but not STD2.

Table 30

Comparison of Swallowing Measures Between Normal and Abnormal PAS

		PAS 1-2				PAS 3-8	
				Thin fluids			
N=11	**OTT**	**STD 1**	**STD 2**	N=25	**OTT**	**STD 1**	**STD 2**
Ave (SD)	0.58 (0.57)	0.40 (0.46)	0.31 (0.43)		-0.06 (0.91)	0.76 (0.87)	0.11 (0.21)
(min, max)	(-0.36, 1.86)	(-0.04, 1.3)	(-0.04, 1.3)		(-1.98, 1.11)	(-0.41, 2.74)	(-0.41, 0.5)
				Fruit			
N=35	**OTT**	**STD 1**	**STD 2**	N=1	**OTT**	**STD 1**	**STD 2**
Ave (SD)	-4.85 (5.48)	5.08 (5.19)	0.54 (1.05)		-9.86	10.31	0.39
(min, max)	(-19.96, 1.94)	(-0.1, 19.96)	(-0.19, 3.55)				

Relationship between swallowing measures and SP diagnosis of delay vs PBC

Mean, standard deviation and range of oral transit time and stage transition duration within each diagnosis (as reported in study 3) are described in **Table 31**. “Poor bolus containment” and “both poor bolus containment and delay”, had a negative oral transit time, suggesting that the bolus reached the second measurement (posterior ramus of the mandible) prior to the onset of the first measurement (onset of lingual movement). STD1 was the longest for “poor bolus containment” (5.99 +/- 6.4) and “both poor bolus containment and delay” (3.62 +/- 3.62). In contrast, STD2 was longest for “delay” and “both poor bolus containment and delay”, suggesting that STD1 is more sensitive to measuring poor bolus containment and STD2 is more sensitive to measuring delay.

Table 31

Swallowing Measures Within Each Diagnosis

		PBC	**Delay**	**Both**	**Neither**
OTT (s)	Mean (SD)	-5.25 (6.9)	0.14 (1.2)	-3.07 (3.56)	0.41 (0)
	Range (min, max)	(-19.96-1.94)	(-3.79-1.18)	(-10.14-0.65)	(-2.55-1.86)
STD 1 (s)	Mean (SD)	5.99 (6.4)	0.77 (1.25)	3.62 (3.62)	0.38 (1.12)

	Range (min, max)	(0.13-19.96)	(0-4.22)	(0.1-11.51)	(-0.41-3.39)
STD 2 (s)	Mean (SD)	0.07 (0.28)	0.71 (1.09)	0.43 (0.77)	-0.07 (0.13)
	Range (min, max)	(-0.19-0.81)	(0-3.53)	(-0.13-3.55)	(-0.41-0.03)

10.4 Summary

The results of this study are limited due to the very small numbers of participants. Descriptive statistics were used to describe swallowing measures within each cluster. Variability of the repeated measures was high. Inter-rater reliability of swallowing measures was acceptable. There is some evidence to suggest that poor bolus containment is associated with a negative oral transit time, and that the manner in which stage transition duration is measured may be more sensitive to determining poor bolus containment from delayed pharyngeal swallowing. This will be discussed more in the following chapter.

Chapter 11 Discussion

This research programme is the first to systematically investigate the phenomenon of pre-swallow pooling, presenting novel findings regarding this ambiguous presentation of dysphagia. While pre-swallow pooling can be identified on VFSS, its underlying cause is difficult to differentiate, in part because pathophysiology is assumed from biomechanical impairments due to the limitations of our diagnostic tools in identifying pathophysiology. A series of four studies were used to determine whether there is any physiologic evidence for distinct sensory and motor causes of pre-swallow pooling and whether our current methods of distinguishing between them are valid.

Terminology and definitions

The scoping review identified that our terminology and methods for distinguishing between sensory and motor physiological causes of pre-swallow pooling is lacking replicability and applicability. Evaluation of the literature found many terms and measurement methods used to describe pre-swallow pooling, which makes it difficult to know if researchers are studying the same thing. Delayed pharyngeal swallowing is often defined by the dwell time of the bolus in the pharynx between the offset of the oral phase and the onset of the pharyngeal phases of swallowing. However, researchers do not agree on the event which accurately reflects the end of the oral phase and that which reflects the onset of the pharyngeal phase. The end of the oral phase is indicated by passage of the bolus through the faucial arches (Eisbruch et al., 2002; Logemann, 1983), the posterior nasal spine (Kendall et al., 2003) or the posterior ramus of the mandible (Nagy et al., 2013). Adding to the inconsistency of measurement there is disagreement on when to judge the bolus entering the pharynx. Some use the first frame of barium entry into the pharynx (Newman et al., 2002; Palmer et al., 1992; Seo et al., 2011), while others disregard the first frame of bolus entry if it has segmented from the main bolus (Kim et al., 2005; B. H. Park et al., 2013), raising issues for consistency of measurement in disordered swallowing characterized by piecemeal bolus transfer.

Finally, the onset of the pharyngeal phase is also judged differently, with terms such as laryngeal elevation (Abraham & Yun, 2002; Ayala & Logemann, 2010; Bingjie et al., 2010) hyolaryngeal excursion (Daniels et al., 2007; Han et al., 2016), or hyoid bone movement used, without detailing the specific aspects of these movements that reflect the specific onset point. All these differences in measuring delayed pharyngeal swallowing means that interpretation and integration of study outcomes is difficult. For example, if delayed pharyngeal swallowing was measured using the first frame of bolus to reach the inferior ramus of the mandible until the first frame of any hyoid movement, it remains unclear whether this includes any bolus that escaped prior to purposeful propulsion, thereby disregarding the very phenomenon it aims to detect.

Inconsistencies in terminology is not unusual in dysphagia literature and can lead to difficulties interpreting research findings. For example, oral transit time (OTT) has inconsistent definitions and measurement and therefore published normative estimates range from 0.35 seconds to 1.54 seconds for liquids (Soares et al., 2015). Another example is the inconsistencies in diet modification terminology prior to IDDSI, which meant that it was difficult to compare outcomes of participants treated with thickened fluids due to the variation in consistencies. Finally, inconsistencies in the application of the Penetration-Aspiration Scale (PAS) (Rosenbek, Robbins, et al., 1996) such as when to score the penetration or aspiration, or what score to assign when there are multiple swallows per bolus with multiple possible penetration-aspiration scores have also led to difficulties in comparing research findings (Steele & Grace-Martin, 2017). Therefore, inconsistencies in the terminology and definition of terms used to describe pre-swallow pooling is not unexpected given similar issues in other terms and measurements.

Because of the limitations in identifying true pathophysiology of the symptom of pre-swallow pooling, it is not surprising that most published literature on the topic doesn't differentiate between potential motor or sensory causes. While other symptoms of dysphagia are sometimes described within the context of presumed pathophysiology, it is a common limitation in measuring

true physiology underlying swallowing in that our diagnoses rarely factor in aspects beyond the symptoms we can observe. We need to be cognisant that many differential pathophysiologic causes could underlie the symptoms we see, such as true weakness due to hypotonic muscle recruitment, but could also include weakness and restricted movement based on hypertonic muscle features, uncoordinated muscle activations or impairments in motor planning. Thus, if treatment is provided based on an inaccurate presumed cause, swallowing improvements may not occur. A good example of acknowledging differential cause is demonstrated in results reported by Steele et al., (2016). Their initial presumed cause of increased stage transition duration was the pathophysiologic feature of poor bolus containment, which they predicted would decrease following a tongue-strengthening protocol. However, a lack of improvement prompted acknowledgement that stage transition duration may have been increased due to a sensory impairment, causing delayed pharyngeal swallowing, highlighting the importance of identifying the underlying cause of impaired biomechanical movements in swallowing.

Reliability of oral sensory perception thresholds and posterior-lingual strength

The first experimental study in this research programme investigated whether physiological measurements of oral sensation and strength are feasible and reliable in a healthy population. Although measures of faucial arch sensation, and isometric posterior lingual-palatal pressure demonstrated acceptable reliability, further exploration of reliability are warranted to see if we can improve their sensitivity as an outcome measure. To our knowledge, this is the first research that has evaluated test-retest reliability of sensory input in the mouth. However, the findings of this study are consistent with test-retest findings seen in cough reflex testing. Cough reflex testing is a method of assessing the sensory integrity of the cough response mediated in the larynx by sensory fibres of the pharyngeal plexus. Wallace et al., (2019) found that cough thresholds increased in participants over time. This is in contrast to our findings which showed that sensory thresholds reduced. Since we relied on participant switch activation to signal when a sensation was felt, it is

likely that there is more reliance on perception than that required for cough reflex testing and thus orientation to the sensation from the prior session may have led to a faster reaction time. Reaction time is a known feature amongst methods of limits threshold testing. It can be explained by a faster reaction time on the second and third trials due to participant orientation to the task. Once accustomed to the sensation, the reaction time is quicker. This elevated first response can lead to overestimation of sensory thresholds (Chong & Cros, 2004) and may change with repeated measures or with experience of the stimulus. This is also known as a carryover effect: when responses are influenced by repeated attempts at the measurement (Salkind, 2010). To allow for this variability, the first trial could be discarded, or practice trials could be used to increase familiarisation, which may reduce the effects of learning (Hopkins, 2000). It has been suggested that abbreviated methods that use fewer trials may reduce this sensory adaptation, subject fatigue (and thus reduced concentration) and criterion shift (Snyder et al., 2006). While this might offer a way of making sensory testing more accurate, further research needs to link functional response with these measurements to determine if the initial, or the subsequent reduced responses are more reflective of true sensory responses. When doing multiple trials to establish a threshold, it may be appropriate to start subsequent stimulation closer to the previous trial threshold to reduce the time taken to achieve the threshold and thus reduce the potential for this variation. Future studies controlling for sensory adaptation and subject fatigue could quantify the variation in measurement of lip sensation. A further consideration is that the lips are highly sensate (Capra, 1995). This was evident in our study, with thresholds for both the upper and lower lip being the lowest of all the oral sensory perception sites. Therefore, it is possible that small changes to the placement of the electrodes between sessions may have caused inconsistent results. The instability of measurements of the lips, therefore, may prohibit useful information regarding sensory perception within the oral cavity. The lips were included in the oral sensory measures because of research indicating that sensory information is required from multiple areas in the oral cavity in order for the NTS in order to initiate

a pharyngeal motor response (Doty, 1951). However, research has also shown that the most sensitive sites to inform sensation related to pre-swallow pooling are those innervated by the glossopharyngeal nerve (posterior tongue and faucial arch) (Pommerenke, 1928), although reliability data has not been established. The assumptions for the posterior tongue sensory measure were violated for homoscedasticity and therefore could not reliably be interpreted, most likely due to inadequate statistical power. Further research with a larger sample size would be necessary to establish whether this site may serve as a reliable measure of oral sensation. Faucial arch sensation demonstrated good within-session reliability, meaning it was the only measure that was able to be reliably interpreted for assessing the sensory responses. As this measure, and the isometric posterior lingual-palatal pressure measures had acceptable reliability, the normative data collected for these measures may be useful for comparison in further studies. However, due to inadequate participants, normative data collection was incomplete.

Between session reliability of maximum isometric posterior lingual-palatal pressure was worse than prior research (Adams et al., 2013, 2014). Adams et al., (2013) using a similar methodology whereby participants were tested twice, one week apart found a higher ICC (0.81 – 0.93) (Adams et al., 2013). Their later study reported ICCs that were more like the current study, although with an older cohort. ICC was reported between 0.77 – 0.84 however between trial variability (ICC) was not reported and the ICC methodology was not described. Furthermore, they did not report whether statistical assumptions were met for calculations. Consideration of statistical analysis are crucial when deciphering the cause of such different results. ICC methodology is important to state, as different ICC models can lead to different results and interpretation (Koo & Li, 2016). Considerations such as whether the model is a one-way or two-way model; whether the calculations should be based on averaged values by multiple raters or by one rater, and whether the selected coders are randomly selected from a larger population can change the results and influence interpretation (Hallgren, 2012). Therefore, the absence of details about the ICC model used by

Adams et al. (2013; 2014) and the absence of reporting on statistical assumptions makes it difficult to decipher the cause of differences in results between the current studies and their previous reliability estimates. Since within trial variability was also not addressed, it is unknown whether variation in repeated trials within each session may have influenced the between session reliability interpretation. Reporting the subject variability is a crucial step for comparison across studies. Since the ICC is calculated by comparing the variability within a participant to the variability between participants, if both are highly variable, the ICC can appear higher between sessions. Therefore, it is important to understand both within and between subject variability. While between session reliability was less than prior research, this study adds more accurate estimates due to the inclusion of within trial variability.

The same ICC model used in the current study has been used to evaluate reliability for electrical perception threshold in the spinal cord (Ellaway & Catley, 2013), with similar timeframes to evaluate test-retest reliability. Assessors received 2-3 days training and achieved reliable results in training prior to the study. ICCs were reported between 0.67 to 0.81, achieving higher reliability than the current findings of 0.42 to 0.76. This suggests that training could be a potential factor that could improve the results of ICC. There may be some evidence for this in study 3, where ICCs were moderate to good with participants with dysphagia following stroke. Based on the findings from Ellaway and Catley, a most likely explanation for the difference between the reliability results in study 1 and study 3 is operator familiarity with the assessment because the same rater had completed all procedures for study 1 before completing study 3. However, the results could also have been influenced by a younger and presumably healthier cohort of participants in study 1, therefore reducing the between subject variability.

Intra- and inter-rater reliability of speech pathologists' (SPs) diagnoses

The next step in this research program evaluated whether the current clinical methods for differentiating poor bolus containment from delayed pharyngeal swallowing have acceptable

agreement. The minimal agreement achieved between SP ratings indicate that current methods for distinguishing poor bolus containment from delayed pharyngeal swallowing are unreliable. This concurs with two prior research studies that found minimal agreement for concepts reflecting delayed pharyngeal swallowing and poor bolus containment (Kim et al., 2012; Stoeckli et al., 2003). Neither of these studies provided definitions to guide interpretation of dysphagic symptoms. The results of this current study showed that the addition of definitions for distinguishing between the two diagnoses did not improve reliability, reinforcing the inadequacy of our current methods.

The finding that ratings were more reliable when the same speech pathologist re-rated videos compared with results across different speech pathologists suggests that clinicians apply consistent rules to interpreting the measures individually, but that these rules are different across clinicians. Speech pathologists may have been taught different methodologies or theories behind the distinction between these physiologic observations and may be using this prior learning to a greater extent than the provided definitions to diagnose the physiologic abnormality. It is possible that training in interpretation and application of definitions would increase reliability. Prior research shows that inter-rater reliability in judging dysphagic symptoms on VFSS measures is poor unless pre-training and consensus on definitions is achieved (McCullough et al., 2001; Stoeckli et al., 2003). Training was not delivered in the current study because the aim of the study was to investigate intra- and inter-rater reliability based on current practices. However, further investigation could evaluate reliability of these measures following training to determine whether reliability is poor due to poor knowledge and interpretation of the measures or whether the measures themselves are too subjective and unable to differentiate one from the other.

The finding that speech pathologists had difficulty distinguishing “delayed pharyngeal swallowing” from “neither poor bolus containment or delay”, suggests that clinical identification of delayed pharyngeal swallowing may not offer a sensitive method of measuring swallowing impairment. This is evident in other work that shows that delayed pharyngeal swallowing (according

to the definition used in this research) has been reported as a normal variation of swallowing (Martin-Harris et al., 2007), as well as the wide range of norms for stage transition duration which is used to measure the length of delayed pharyngeal swallowing. Normal stage transition duration for thin fluids has a range of between 0.35-0.50 seconds in both young and older adults (Byeon & Koh, 2016) and 1.09 seconds in a young cohort (Steele et al., 2019). As the stage transition duration (definition 2) measures for these participants (as measured in study 4) fall within the norms, it can be assumed that none had prolonged stage transition duration and thus one could interpret, no delayed pharyngeal swallowing. Thus, delayed pharyngeal swallowing may not be a useful measure of swallowing impairment.

Since speech pathologists often agreed on the absence of poor bolus containment and delayed pharyngeal swallowing, it's likely that the absence of pre-swallow pooling is easier to detect than differentiating between two causes of pre-swallow pooling. However, it's also possible that speech pathologists ignore pre-swallow pooling if they are aware of research that indicates that it's normal, (Martin-Harris et al., 2007). Future research could use video examples of pre-swallow pooling that might all be considered abnormal to control for these influences when exploring differential judgement of poor bolus containment and delayed pharyngeal swallowing.

The relationship between strength and sensation to clinical diagnosis

A cluster analysis approach was utilised to evaluate relationships between clinical diagnosis of poor bolus containment and delayed pharyngeal swallowing to physiological findings of oral sensation and lingual-palatal pressure. To our knowledge this approach has not previously been taken. The three distinct clusters of participants established from physiological measures of sensation and strength negated our hypothesis that four clusters would emerge. Knowledge of how the clusters aligned with speech pathologists' diagnosis of poor bolus containment or delayed pharyngeal swallowing was not gained, due to each participant having multiple different diagnoses of poor bolus containment and delayed pharyngeal swallowing over repeated swallows. This was

unanticipated because it was assumed that a diagnosis of poor bolus containment or delayed pharyngeal swallow would be stable across swallows for each person. This suggests that either speech pathologists' diagnoses of these physiologic abnormalities are not reliable, or that the functional presentation of swallowing pathophysiology is highly variable for people with dysphagia following acute stroke. It's also possible that these two presumed distinct physiologic features are highly related, making co-occurrence of them common. Kappa analysis revealed minimal agreement between speech pathologists' ratings. Therefore, it is likely that the high variability of diagnoses for each participant is at least someway explained by poor diagnostic methods of determining poor bolus containment from delayed pharyngeal swallowing. This supports the results of Study 2, reinforcing that our methods for distinguishing between poor bolus containment and delayed pharyngeal swallowing are flawed or that two distinct causes of pre-swallow pooling do not exist. Better methods for determining a potential sensory or motor cause of pre-swallow pooling are needed.

Since cluster analysis was able to distinguish a group who had both poor sensation and poor strength, a group who had good sensation and poor strength, and a group who had good strength and good sensation, there is evidence that there is at least a physiologic distinction between those who have a sensory impairment and those who do not. Both clusters had poor strength values, suggesting that lingual weakness may be a common feature in dysphagia post stroke. Indeed, in comparison to reported normative data, both cluster 1 and 3 had posterior lingual strength values below the cut off of 40kPa for healthy participants (Clark & Solomon, 2012; Fei et al., 2013). Furthermore, since there was no cluster that represented good strength and poor sensation, it appears that the stroke participants sampled have impaired strength, irrespective of whether they have pre-swallow pooling. Therefore, reduced posterior lingual strength may occur in people who have had an acute stroke irrespective of a diagnosis of dysphagia. The absence of a cluster representing good strength and poor sensation may be explained by Ding et al.'s, (2003) suggestion

that adequate sensation is required to enable the NTS to send a signal to the NA resulting in a strong swallow. If sensation is reduced, then an inadequate signal to the NTS may result in the NA initiating a weak swallow. Therefore, sensation impairments may always influence presentation of weakness. Reduced sensation of these bolus characteristics may lead to reduced glossopalatal approximation and subsequent loss of the bolus into the pharynx prior to purposeful propulsion of the bolus in the mouth. Similarly, strength may be reduced in the physiologic deficit of delayed pharyngeal swallowing. While the bolus may be perceived in the mouth with an appropriate motor command sent to the NA to initiate a response, peripheral weakness fails to adequately perform a timely pharyngeal motor swallow. Alternatively, since both strength and sensation are important for timely and efficient swallowing, the possibility that both strength and sensation are equally important and can both be impaired in poor bolus containment and delayed pharyngeal swallowing must be considered. Further research is required to determine whether these physiologic impairments can both exist in isolation of each other.

In addition, it is well-reported that cognition plays a significant role in dysphagia (Dehaghani et al., 2021; Falsetti et al., 2009; Moon et al., 2012; Mourão et al., 2019). Saito et al., (2016) argue that 'swallowing hesitation' is due to a lesion in the pre-frontal cortex which is responsible for attention and self-awareness as well as executive control of the working memory. Jo et al., (2017) found that premature bolus loss was significantly correlated with executive function and visual attention. Therefore, attention, motor planning and other cognitive functions may be more important than strength or sensation and warrants further investigation in relation to poor bolus containment and delayed pharyngeal swallowing.

The relationship of strength and sensation to swallowing measures

The final study investigated the relationship between the clusters formed from the physiological measures of strength and sensation against swallowing measures from VFSS, and the diagnoses of poor bolus containment and delayed pharyngeal swallowing from speech pathologists.

It is well-known that within-subject variability in swallowing is considerable, and that the swallowing features of healthy subjects within the same age and sex range are also highly variable (Lof & Robbins, 1990; Molfenter & Steele, 2012). To control for this, 3 boluses of each consistency were completed. Despite this, reliability of repeated swallowing measures was poor with a large variability between the measures of oral transit time, stage transition duration and the penetration-aspiration scale. This variation may have been because bolus size was not controlled, which was decided to allow participants' natural bolus size to be utilized. In addition to this, the physiological measures had small participant numbers due to restrictions imposed as a result of covid-19, and thus some had poor ICC results, likely as a result of an underpowered study. Future research controlling for bolus size and with greater participant numbers may increase the reliability of repeated measures.

Inter-rater reliability between speech pathologists was better for the swallowing measures in this study compared to inter-rater reliability for the diagnosis of poor bolus containment or delay seen in study two. It is likely that the use of the quantitative timing measures and anatomical landmarks provide more consistent results than interpretations of the clinical definitions. Previous inter-rater reliability research in videofluoroscopy studies concur with this finding, with studies using quantitative measurements (Leonard & Kendall, 2019) having higher agreement than those using more qualitative descriptive measurements (Kendall, 2017; Kim et al., 2012; Stoeckli et al., 2003). Kerrison et al., (2023) compared reliability between quantitative measures and speech pathologists' subjective clinical measures. They found that the quantitative measures had substantial agreement between raters compared with fair agreement between raters when using a binary choice of impairment. However, there is no quantitative measure that can distinguish the two causes of poor bolus containment and delayed pharyngeal swallowing. Leonard & Kendall (2019) measure "lingual-palatal valving" by instructing the subject to swallow on command. It is understood that a cue to swallow alters the swallow initiation location (Daniels et al., 2007) and may act as a compensatory strategy to compensate for pre-swallow pooling (Daniels et al., 2019) and by instructing the subject

to swallow, this symptom of dysphagia may be missed. Using the Leonard & Kendall (2019) method, delayed pharyngeal swallowing is measured from B1 (the first movement of the bolus past the nasal spine) to H1 (the first movement of the hyoid for the pharyngeal swallow) (Leonard & McKenzie, 2006). However, this would capture the symptom of pre-swallow pooling, but not distinguish between poor bolus containment and delayed pharyngeal swallowing, thus not a useful measure for distinction of physiology. However, with some considered interpretation, these measures may be useful. The negative values in oral transit time measures were due to the definition used, which was from the initial movement of the tongue to propel the bolus in the mouth until the bolus reached the point where the posterior ramus of the mandible crossed the base of tongue. If parts of the bolus broke away and entered the pharynx prior to the purposeful propulsion of the tongue (consistent with our definition of poor bolus containment), a negative value would occur. Therefore, using this definition of oral transit time and obtaining a negative oral transit time could distinguish poor bolus containment. If poor bolus containment does not exist, then a positive oral transit time would occur.

Stage transition duration could also be used to distinguish between the two causes of pre-swallow pooling. Two measures of stage transition duration were used to reflect the fact that one might be biased towards identifying delayed pharyngeal swallowing and the other might be biased towards identifying poor bolus containment. The definition of stage transition duration (definition 2) was the difference between the arrival of the head of the bolus at the intersection of the base of tongue and inferior ramus of the mandible and the onset of anterior hyoid movement that signals the start of the pharyngeal motor response. As seen with some of the oral transit time measures, some of the values for stage transition duration (definition 2) were negative for both the liquid and solid boluses. Using this definition ignores any part of the bolus that may break away from the main part of the bolus prior to or during oral transit and, thus, may be considered a measure that may capture delayed pharyngeal swallowing only, rather than poor bolus containment. This was

confirmed in this study since stage transition duration (definition 2) was greatest in the participants who were diagnosed with delay, followed by those with both poor bolus containment and delayed pharyngeal swallowing. It was the least in the group with the diagnosis of neither, with a negative value, followed by those diagnosed with poor bolus containment, supporting the idea that it may have biased observations towards delayed pharyngeal swallowing. On the other hand, stage transition duration (definition 1) was defined as the difference between the arrival of the first sign of barium arriving at the intersection of the base of tongue and inferior ramus of the mandible and the onset of anterior hyoid movement that signals the start of the pharyngeal motor response. Thus, it would capture both poor bolus containment and delayed pharyngeal swallowing.

The results of the study found that the greatest value for stage transition duration (definition 1) was for those who were diagnosed with poor bolus containment, followed by those who were diagnosed with both. Those who had the lowest scores for stage transition duration (definition 1) were those diagnosed with neither, followed by those diagnosed with delayed pharyngeal swallowing. Penetration-aspiration scale scores were worse when there was a negative oral transit time and a longer stage transition duration (definition 1) time. If both are considered markers of poor bolus containment as described above, then worse penetration-aspiration scores are seen in those with poor bolus containment. Longer stage transition duration (definition 2) was not associated with worse PAS scores. If stage transition duration (definition 2) is considered a measure of delayed pharyngeal swallowing as described above, then delayed pharyngeal swallowing is not associated with increased penetration-aspiration scale scores. This further supports the idea that since delayed pharyngeal swallowing may not be an abnormal feature of swallowing, it may not be a useful measure to use in dysphagia analysis. Thus, the results of this study support the idea that stage transition duration (definition 1) may be more sensitive in detection of poor bolus containment, and stage transition duration (definition 2) may offer increased sensitivity to delayed pharyngeal swallowing. Using these two definitions of stage transition duration may assist clinicians

to differentiate between poor bolus containment and delayed pharyngeal swallowing in clinical practice and may be a better indicator of poor bolus containment and delayed pharyngeal swallowing since inter-rater reliability was better between speech pathologists for the swallowing measures than the diagnosis of poor bolus containment or delayed pharyngeal swallowing.

Participants with dysphagia, alongside healthy participants who do not have poor bolus containment will have the same measure for both stage transition duration (definition 1 and 2). This explains why such little attention has been given to differentiating between the two causes of pre-swallow pooling: since poor bolus containment is only seen in those with dysphagia, normative studies have not described this feature as a cause of pre-swallow pooling. It is not until we see swallowing symptoms in people with dysphagia that we realise that there are two mechanisms behind the symptom of pre-swallow pooling. However, we still don't know if one represents a sensory disorder, and one represents a motor disorder.

Limitations

There were several limitations in this research program. Firstly, due to covid, the target of 120 participants for the healthy study was not achieved. Only half of the sample size was obtained, with a greater number of women and fewer participants in the older age group. This was not enough participants to make conclusions regarding norms within each age bracket and between males and females. Therefore, the normative data obtained are unlikely to be representative of the population. Additionally, also due to covid, only 24 stroke participants were included in the final analyses for study 3. This was matched with 18 participants from the healthy study. Of the 24 stroke participants, only 13 had pre-swallow pooling, the feature being investigated. Therefore, the results need to be interpreted with this in mind. Future research could replicate these studies with improved sample sizes. Whilst acute stroke was believed to be an ideal population to investigate pre-swallow pooling due to the high frequency of this reported phenomenon in stroke (Veis & Logemann, 1985), other

populations or chronic stroke participants may have been a better cohort to examine. Chronic stroke participants would exclude those who had spontaneously improved in the acute period as well as those who had difficulty performing the physiological measures due to acute cognitive impairments. Other conditions such as Parkinsons disease could also be considered as pre-swallow pooling has been reported in this population (Kwon & Lee, 2019; Nascimento et al., 2020).

Study 1 was originally designed as a normative study with a reliability element. Therefore, an a priori 20% sample was selected for reliability analysis. However, given the poor reliability results, it perhaps poses the need to establish reliability as the first step. Therefore, the sample size for reliability should have been calculated statistically, rather than based on 20% of the normative participants. Based on Bonett (2002), who describe methods to obtain a sample size with a 95% confidence interval for two or more raters with any confidence interval, the sample size should have been at least 40. Since the sample size was 24 and thus underpowered, the results may not be applicable. Repeating the reliability study with an appropriately powered sample size would determine whether reliability was limited in this study by an inadequate sample size.

Another factor that may have influenced the results of the test-retest study was that the order of physiological assessment tasks was not randomised. Thus, for the lingual-palatal pressure tasks, the maximum isometric lingual-palatal pressure task was always completed prior to the lingual-palatal pressure during swallowing task by default. This could bias the data because the maximum isometric lingual-palatal pressure task may have acted as an exercise or warm-up task and thus yield greater lingual-palatal pressure during swallowing results. Future research should randomise the order of tasks.

Our equipment was not able to deliver alternating frequencies of 5Hz, 250Hz and 2000Hz that is used in other electrical stimulation current perception threshold protocols (Ogawa et al., 2017; Ogura et al., 2007). However, frequencies above 50Hz may be more uncomfortable at higher amplitudes. Furthermore, high frequencies elicit a sensation of pressure in some nerve fibres, which

may be difficult to determine from the pressure applied by the hand. The frequency (Hz) chosen to stimulate the oral structures was set at 10Hz to target the superficial, fast-adapting nerve fibres in the mouth without causing discomfort. This also controls for the sensation of pressure applied by the finger to the skin as the participant is oriented to detect the sensation of vibration rather than pressure. A lower frequency of 5Hz may have been sufficient for targeting all aδ-, AB-, and C fibres (Felix et al., 2009), but it is unknown whether this would increase reliability measures. Further research to determine the optimum frequency of stimulation for perception threshold in the mouth is recommended.

The method of detecting sensitivity thresholds may have also influenced reliability findings. A variation of the method of limits known as the staircase method was used. This was selected because it is a quicker and simpler variation of the method of limits, and therefore better for those who may have cognitive or communication difficulties. However, reaction time can influence the results. Therefore, the methods of levels is commonly regarded as a superior approach for determining thresholds. However, there is poor comparative data for either method to establish sensory thresholds in the mouth. Sunnergren et al., (2010), compared the two methods in assessment of thermal sensory thresholds in the mouth. They tested sensation at the lips (as a control site) and soft palate with an intra-oral thermode. They found that mean thresholds were lower for the method of levels, but the test-retest reliability for the soft palatal was better for the method of limits. They also reported that the method of limits was faster, which may be an important consideration for clinical use with those who have difficulties concentrating for longer periods of time (Sunnergren et al., 2010). This supports the use of the method of limits and suggests that variation may be due to other factors such as participant cognition or operator variability. It is possible that two participants in study 3 (participants with dysphagia following stroke) could not complete the oral sensory threshold test due to impaired cognition or motor planning. Both participants had sustained a left MCA stroke and presented with aphasia and apraxia of speech. It

was difficult to tell whether they were unable to follow directions to be able to complete the test, or whether a motor planning deficit prevented them from engaging the handheld “stop” device to indicate that they had detected a sensation in the mouth. The switch was either engaged prior to starting the stimulation, not engaged at all, or a combination of both. This is an important consideration for future research involving oral sensory perception assessment using this method. Alternatively, the use of a finger to deliver the sensory stimuli to the oral structures may have affected reliability. Pressure applied by the finger is difficult to control. To mitigate this factor, the finger was kept in place for all three trials. Furthermore, the use of a low frequency stimulus was selected so as not to mimic a sensation of pressure, therefore directing the participant to the electrical sensation instead. The participants were oriented to the sensation of electrical stimulation on the arm prior to placement of the electrode in the mouth. Nonetheless, it is difficult to determine whether this may have influenced sensory perception. Similarly, the placement of the IOPI bulb may have been an influencing factor. Placement of the bulb in the posterior position is more difficult to keep in place as unlike in the anterior position where the bulb is held in place against the alveolar ridge, there are no anterior or posterior structures to keep it in place in the posterior position. Therefore, despite holding it in place, it is difficult to know whether the bulb may have slipped laterally from the tongue.

Operator familiarity may also have influenced the results and may explain for more consistent results in study 3 compared with study 1. It is therefore recommended that operators are experienced with the equipment and provided with ample practice of testing methodology prior to performing further research or in clinical practice.

Due to the poor within and between session reliability for the lips in study 1, these measures were omitted and the first trial of each other repeated measure was discarded for study 3. However, study 3 found that the repeated trials for each measure were more consistent, and thus including the lips and the first trial of each measure may have been appropriate and may have influenced the

results. Assumptions for ICC calculation were not met for the model for oral sensory threshold of the posterior tongue. However, it was not discarded in order to keep the number of variables consistent across the healthy and stroke participant groups, and even between strength and sensation. Therefore, the inclusion of this measure in the cluster analysis may not yield reliable results. This needs to be considered in the evaluation of the cluster analysis results.

In study 3 and 4, the participant numbers were very small due to limitations imposed by covid. This, along with low numbers for the test-retest study with healthy participants meant that in study 3, age and sex was not well matched between healthy and stroke participants. There was a higher proportion of females and younger participants in the healthy cohort and a higher proportion of males and older participants in the stroke cohort. This could have been explored further by adding age and gender in the cluster analysis to investigate how this may have altered the results. Also due to lower participants numbers, standard deviations were wide for the swallowing measures in study 4. This reduces the ability to interpret estimated values with certainty. Researchers recommend completion of at least three trials during VFSS analysis (Lof & Robbins, 1990) to account for within subject variation. Averaging the data removes this variation and may misrepresent the differences within and between participants. The results of the ICC show that despite obvious greater variability within subjects for the fruit trial when compared to the thin fluid trial (visually inspected), the ICC for the fruit trials was smaller than for the fluid one. This is due to the much larger between participant variability of the fruit trial when compared to the fluid one. For this reason, comparison of ICCs on the same measurements between studies should always be done under the lenses of the different variabilities. Reporting the between subjects' variability is a crucial step for comparison across studies.

Due to the reduced participant numbers and the high variability of the repeated measures, we were unable to run the planned statistical measures for study 4. This was unexpected and may have been due to not controlling bolus size. A descriptive analysis was performed to explore the data

and therefore the repeated measures for oral transit time and stage transition duration were averaged. This reduces the variability inherent of swallowing measures, and therefore may make the data less meaningful. Design of future studies will need to consider these issues a priori.

There were a few limitations for study 2. Interpretation of the onset of swallowing movements can be highly subjective if definitions are not clear. Definitions in this study could have been clearer regarding when to judge entry of the bolus in the pharynx and when to judge onset of hyolaryngeal excursion. This may have increased intra-rater reliability in the group who were provided definitions which may in turn have indicated that reliability is poor due to poor adherence to the definitions rather than the measures themselves.

Two groups were used to investigate the impact of providing definitions to increasing agreement in study 2. On reflection, it would have been interesting to use the same group to complete the survey twice under both conditions: first without the definitions, and then with the definitions. This would have reduced a potential source of variation seen due to coder differences and offers an alternative design for future research.

Another design flaw was the intra-rater reliability component which was evaluated by repeating 5 videos within the one survey. This does not allow time between ratings, and thus does not control for rater memory, which could artificially increase reliability. However, as the kappa was low and had minimal change within raters, it is unlikely that memory positively influenced the results. Nonetheless, future research should allow at least one week for intra-rater reliability evaluation (Dunn, 2004).

There was no pre-training included prior to evaluating reliability. Studies show that pre-training increases reliability (Silbergleit et al., 2018). Pre-training could be included prior to reliability studies to reduce this influencing variable; however, this would not enable an understanding of usual clinical practice. Should training have been included as part of the study, reliability may have

increased. If poor reliability persisted after training, it would be clear that the results are due to the inadequacy of the measures themselves.

Another limitation for the reliability study is that the experience levels of the speech pathologists was not collected. It is therefore unknown whether years or frequency of experience may have contributed to the results. In the same manner, proof of competency was also not collected. Speech Pathologists self-determined the acquisition of competency.

Finally, the use of an online questionnaire platform by which to view and score the swallows may have influenced the ability of the speech pathologists' to accurately diagnose the disorder as frame-by-frame analysis was difficult to monitor due to the online and remote nature of the questionnaire. However, prior research reports poor reliability despite the use of frame-by-frame analysis (McCullough et al., 2001) and therefore this may not have influenced the results.

Future Directions

The first step in furthering this research, requires consistent terminology and definitions of the terms used for pre-swallow pooling. To address these issues, a Delphi study could be completed using experts in the field of dysphagia to reach consensus on terminology and definitions for pre-swallow pooling. This could inform international VFSS guidelines and training could be offered to ensure that clinicians undertaking VFSS use consistent terminology and measurement techniques. Once this is achieved, reliability studies should be repeated before normative and patient data is taken.

As the sample size for the test-retest and normative study was not adequately powered, it remains unclear whether the oral sensory perception threshold test using electrical stimulation is reliable. Adequate participant numbers were also not achieved to understand normative values in the community. Therefore, repeating the test-retest reliability and normative studies would be able to inform future use of this novel approach to assessing oral sensation. In repeating this study, considerations for improved methodology include randomisation of the physiological tasks and

ensuring adequate training of the examiner prior to collecting data. Consideration should also be given to how repeated measures will be considered, for example averaged, omitting the first trial, or taking the best performance. Electrical stimulation could also be refined by comparing 5Hz with 10Hz to determine the optimum frequency.

The reliability study for speech pathology diagnosis of poor bolus containment vs delayed pharyngeal swallowing could be redone using one group instead of two groups with a break of one week between data collection. Recording of speech pathologists' years of experience in VFSS and type of training may also offer insights into reliability findings. In addition to the definitions of poor bolus containment and delayed pharyngeal swallowing, further definitions of the onset and offsets of swallowing events and bolus characteristics could increase reliability. Reliability may also be improved by delivering training prior to the collection of data and allowing real-time evaluation rather than online to enable better frame by frame analysis. This would further delineate the difference between the usefulness of the measurement methods themselves and the reliability of the measures.

The patient studies require replication with improved sample size. An alternative patient group could also be considered. Chronic, instead of acute stroke, would remove those who may spontaneously recover, allowing those with persistent dysphagia to be evaluated. Patients with Parkinsons disease also present with pre-swallow pooling and could be ideal candidates to evaluate as they are commonly presumed to have both sensory and motor dysphagia signs.

Chapter 12 Conclusion

This research program presents an initial investigation into the use of oral electrical stimulation and posterior lingual-palate pressure to support differential diagnosis of pre-swallow pooling using quantitative physiological evidence. Since findings identified that there is a need for consistent terminology and measurement techniques, speech pathologists should be cautious when critically reviewing research findings that use terms to describe pre-swallow pooling. As there are many different terms and measurement techniques used in dysphagia literature, there may be inconsistent reports of the effectiveness of treatment studies. Closer examination of methods of measurement will be required to understand how researchers are measuring pre-swallow pooling. Comparison across studies will not be possible until consensus has been achieved.

Since our current clinical methods using observations of biomechanical movements and bolus flow on VFSS cannot differentiate poor bolus containment and delayed pharyngeal swallowing nor align with physiological measures of reduced sensation and strength, speech pathologists should be cautious about assigning a diagnosis of poor bolus containment or delayed pharyngeal swallowing based on biomechanical observations on VFSS or limiting dysphagia intervention to either sensory or motor interventions. Replicable measurement techniques and methods for determining poor bolus containment from delayed pharyngeal swallowing will be required to ensure that variation reflects true physiologic variation, rather than inconsistencies in measurements and definitions. There was some evidence that speech pathologists' clinical diagnosis of poor bolus containment and delayed pharyngeal swallowing align with oral transit time and stage transition duration. A negative oral transit time and a longer stage transition duration (definition 1) may suggest poor bolus containment, whereas a positive oral transit time and equal measures for stage transition duration (definition 1 and 2) may indicate delayed pharyngeal swallowing. Therefore, speech pathologists

may consider using this approach to differentiate between poor bolus containment and delayed pharyngeal swallowing. However, since the physiological measures were unable to provide evidence that one is a sensory and one is a motor disorder, their identification does not clarify the underlying physiology. The finding that reduced strength is present in all clusters of pre-swallow pooling raise the consideration that weakness may underlie this biomechanical symptom in all instances. However, it is also possible that sensory processing underlies all presentations of pre-swallow spill through its role in feedback of bolus location, size, and consistency. Therefore, attempts to differentiate between them may be impossible, suggesting that sensory and motor components are co-dependent in swallowing biomechanics and pathophysiology. Until research can validate more sensitive measures of physiology, and these symptoms can reliably be categorised as impaired strength or impaired sensation, speech pathologists should address both in swallowing rehabilitation. When we can better understand the pathophysiology underlying pre-swallow pooling, swallowing outcomes for those with dysphagia following stroke are likely to improve.

Part C: References

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Part D: Appendices

Appendix 1.

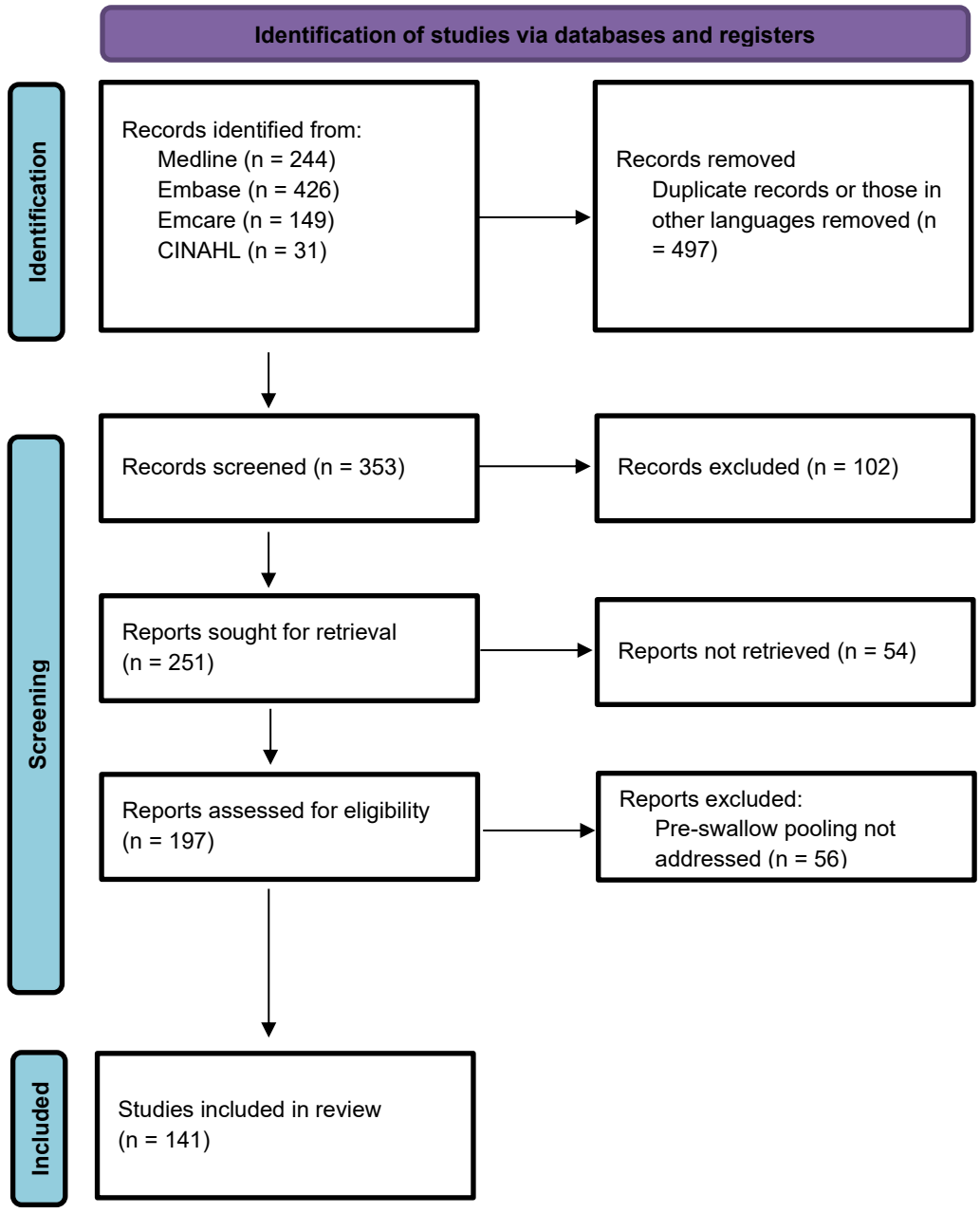
Scoping Review Search terms

1. Deglutition or dysphagia
2. Videofluoroscopy or Modified barium swallow
3. Temporal or timing or duration (Delayed pharyngeal swallow* or pre-swallow pooling or pre-swallow spill* or premature spill* or delayed laryngeal closure or delayed airway closure or (increased) stage transition duration or (delayed) pharyngeal response or pharyngeal delay time or pharyngeal response time or delayed trigger* of the pharyngeal response or delayed initiation or glossopalatal approximation or glossopalatal seal or pre-swallow aspiration or poor bolus containment.)

Medline search terms

1. Dysphagia
2. swallowing/
3. ((swallow$ or deglutit$ or dysphag$) adj3 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.
4. exp pharynx/
5. ((pharyn$ or oropharyn$) adj3 (disturbance$ or disorder$ or difficult$ or dysfunction$ or impair$ or condition$ or abnormal$ or damage$ or injur$)).tw.
6. 1 or 2 or 3 or 4 or 5
7. Videofluoroscop*.mp. or Modified barium.tw. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
8. (delay* or pooling or spill*).mp.
9. 6 and 7 and 8

Appendix 2.
PRISMA 2020 flow diagram



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix 3

Scoping Review Extracted Data

Paper	Population	Instrumentation used to detect PSS	Terminology	Definition or measurements of terminology	Is it used as an outcome measurement?	Measurement method provided?	Cued to swallow?	Acknowledgement of differentiation between	Reliability established
Abraham, S. S., & Yun, P. T. (2002)	neuro (MS)	VFSS	Pharyngeal delay time	The time interval in seconds from the bolus head reaching the point where the ramus of the mandible crosses the tongue base to the onset (first frame) of laryngeal elevation.	yes	yes	not specified	no	no
Ayala, K. J., & Logemann, J. A. (2010)	healthy	VFSS	Pharyngeal delay time	The time required to trigger the pharyngeal swallow. PDT was calculated as the difference between the onset of laryngeal elevation and the point when the bolus head passes the cross-point between the inferior edge of the mandible and tongue base.	Yes	yes	not specified	no	no
Bazemore, P. H., Tonkonogy, J., & Ananth, R. (1991)	other (psychiatric patients)	VFSS	Delay in initiation of swallow reflex	n/a	yes	no	not specified	no	no
Bingjie, L., Tong, Z., Xinting, S., Jianmin, X., & Guijun, J. (2010)	neuro (stroke)	VFSS	Pharyngeal delay time	From the time bolus head passing ramus of the mandible to the beginning of laryngeal elevation	yes	yes	not specified	no	no
Bird, M. R., Woodward, M. C., Gibson, E. M., Phyland, D. J., & Fonda, D. (1994)	neuro (PD)	VFSS	Delay in initiation of swallow	Delay results in bolus pooling in the vallecular space and pyriform fossa Place of bolus at initiation of swallow: Anterior to velum / Posterior velum to vallecular/ Sub-epiglottic. Degree of vallecular pooling: None/ Mild/ Severe	yes	no	not specified	no	no
Bisch, E. M., Logemann, J. A., Rademaker, A. W., Kahrilas, P. J., & Lazarus, C. L. (1994)	neuro (stroke)	VFSS	Pharyngeal delay time	The period from the head of the bolus passing the point where the ramus of the mandible crosses the tongue (end of the oral stage) to the onset of laryngeal elevation (beginning of the pharyngeal stage)	yes	yes	not specified	no	no
Byeon, H., & Koh, H. W. (2016)	healthy	VFSS	Delayed stage transition duration	The time from the moment food boluses passed the ramus of the mandible until the start of upward movement of the hyoid	yes	yes	not specified	no	no
Cantarella, G., Neglia, C. B., Civelli, E., Roncoroni, L., & Radice, F. (2001)	head and neck	FEES	Latency of the swallowing reflex	n/a	no	no	not specified	no	no

Clark, H. M., Stierwalt, J. A. G., Tosakulwong, N., Botha, H., Ali, F., Whitwell, J. L., & Josephs, K. A. (2019)	neuro	VFSS	Delayed onset/initiation of the pharyngeal swallow/Posterior spillage	Used MBSIMP which describes different locations that the bolus reaches before hyoid elevation is initiated	yes	no	not specified	yes	yes
Coelho, C. A., & Ferrante, R. (1988)	neuro (post-polio)	VFSS	Delayed swallowing reflex	The swallowing reflex should be triggered when the bolus passes the back of the tongue	yes	no	not specified	no	no
Cook, I. J., Dodds, W. J., Dantas, R. O., Kern, M. K., Massey, B. T., Shaker, R., & Hogan, W. J. (1989)	healthy	VFSS	Premature spillage of barium into the pharynx	n/a	no	no	not specified	no	no
Daniels, S. K., & Foundas, A. L. (1999)	neuro (stroke)	VFSS	Delayed pharyngeal swallow/Premature posterior spillage	n/a	yes	no	not specified	no	no
Daniels, S. K., Foundas, A. L., Iglesia, G. C., & Sullivan, M. A. (1996)	neuro (stroke)	VFSS	Delayed pharyngeal swallow	Entry of the bolus head into the pharynx without initiation of laryngeal elevation	Yes	yes	not specified	no	no
Daniels, S. K., Schroeder, M. F., DeGeorge, P. C., Corey, D. M., & Rosenbek, J. C. (2007)	healthy	VFSS	Delayed swallow	The leading edge of the bolus should not be inferior to the ramus of the mandible at onset of maximum hyolaryngeal excursion in evocation of the pharyngeal swallow. If it is distal to this region, the swallow may be considered as "delayed"	yes	yes	yes	no	yes
Daniels, S. K., Schroeder, M. F., DeGeorge, P. C., Corey, D. M., Foundas, A. L., & Rosenbek, J. C. (2009)	neuro (stroke)	VFSS	Delayed stage transition duration	Onset for STD was identified as the arrival of the leading edge of the bolus at the posterior angle of the ramus of the mandible, and offset was identified by initiation of maximum superior movement of the hyoid bone	yes	yes	yes	no	yes
Denk, D. M., Swoboda, H., Schima, W., & Eibenberger, K. (1997)	head and neck	VFSS	Delayed triggering of the swallowing reflex/ Pharyngeal delay time/Leaking	Leaking: material falls into the pharynx before the swallowing reflex is triggered (via FEES); pharyngeal delay time (via VFSS): according to Logemann (ref provided)	yes	no	not specified	no	no
DeVita, M. A., & Spierer-Rundback, L. (1990)	other (trache/ICU)	VFSS	Delayed (and inconsistent) triggering of the swallow response	n/a	yes	no	not specified	no	no
Dietsch, A. M., Dorris, H. D., Pearson, W. G., Jr., Dietrich-Burns, K. E., & Solomon, N. P. (2019)	other (trache/ICU)	VFSS	Delayed onset of the pharyngeal swallow response	The onset of the pharyngeal response was considered delayed if the leading edge of the (liquid) bolus had advanced beyond the valleculae at the initiation of hyoid movement.	yes	yes	no	no	yes
Eisbruch, A., Lyden, T., Bradford, C. R., Dawson, L. A., Haxer, M. J., Miller, A. E., . . . Wolf, G. T. (2002)	head and neck	VFSS	Swallow reflex delay	The bolus was beyond the anterior faucial arches before the swallow reflex was initiated	yes	no	not specified	no	no
Fattori, B., Giusti, P., Mancini, V., Grosso, M., Barillari, M. R., Bastiani, L., . . . Nacci, A. (2016)	dysphagia	VFSS + FEES	Premature spillage	n/a	yes	no	not specified	no	no

Feinberg, M. J., & Ekberg, O. (1990)	dysphagia	VFSS	Delayed initiation/Bolus leakage/Premature entry (of the bolus in the pharynx)	n/a	yes	no	not specified	yes	no
Ford, L. C., & Cruz, R. M. (2004)	neuro	VFSS	Delayed initiation of swallowing	n/a	yes	no	not specified	no	no
Fuh, J. L., Lee, R. C., Wang, S. J., Lin, C. H., Wang, P. N., Chiang, J. H., & Liu, H. C. (1997)	neuro (PD)	VFSS	Delayed swallowing reflex	n/a	no	no	not specified	no	no
Furuya, J., Hara, A., Nomura, T., & Kondo, H. (2014)	healthy	VFSS	Delayed pharyngeal swallowing/Spillage	Duration from STII onset to swallow onset: swallow onset was defined as the rapid elevation of the hyoid bone in an anterosuperior direction. STII onset was defined as the time at which the bolus was first clearly detected between the soft palate and the pharyngeal surface of the tongue; Duration from STII onset to swallow onset: swallow onset was defined as the rapid elevation of the hyoid bone in an anterosuperior direction	yes	yes	not specified	no	no
Gaeckle, M., Domahs, F., Kartmann, A., Tomandl, B., & Frank, U. (2019)	neuro (PD)	VFSS	Delayed initiation of the swallowing reflex (pharyngeal swallow)	No initiation of the pharyngeal swallow or very delayed initiation >3 seconds after bolus fills the valleculae and sinus pyriform or delayed initiation <3 seconds after bolus fills valleculae and sinus pyriform	yes	no	yes	no	no
Gullung, J. L., Hill, E. G., Castell, D. O., & Martin-Harris, B. (2012)	dysphagia	VFSS	Delay in initiation of the pharyngeal swallow	MBSImp definition (location at swallow onset)	yes	yes	not specified	no	no
Han, D. S., Chang, Y. C., Lu, C. H., & Wang, T. G. (2005)	neuro (stroke)	VFSS	Impaired swallowing reflex/Delayed initiation of pharyngeal reflex/Premature leakage	Premature leakage: non-intended leakage of barium into valleculae or below before swallowing trigger. Delayed swallowing trigger: time interval between arrival of bolus at valleculae and swallowing motion longer than 1 s	yes	yes	not specified	yes	no
Han, H., Shin, G., Jun, A., Park, T., Ko, D., Choi, E., & Kim, Y. (2016)	neuro (stroke)	VFSS	Delayed initiation of the swallow	When the bolus reaches the vallecula but hyolaryngeal elevation is not triggered	yes	yes	Not specified	no	no
Han, T. R., Paik, N. J., & Park, J. W. (2001)	neuro (stroke)	VFSS	Delay in the swallowing reflex/Delayed triggering of pharyngeal swallow/Premature bolus loss	Premature bolus loss, which pertains to bolus drop into the pharynx from the oral cavity before the swallowing reflex. Triggering of pharyngeal swallow not defined	yes	no	not specified	no	yes
Helfrich-Miller, K. R., Rector, K. L., & Straka, J. A. (1986)	neuro (CP)	VFSS	Delayed swallow reflex	n/a	no	no	not specified	no	no
Hirai, H., Omura, K., Harada, H., & Tohara, H. (2010)	head and neck	VFSS + FEES	Pharyngeal delay time	n/a	yes	no	yes	no	no
Hsiao, H. T., Leu, Y. S., Chang, S. H., & Lee, J. T. (2003)	head and neck	VFSS	Premature spillage	n/a	yes	no	yes	no	no

Huggins, P. S., Tuomi, S. K., & Young, C. (1999)	healthy	VFSS	Delayed initiation of the pharyngeal response/Premature leakage	Duration of stage transition (DST) was measured from the moment the bolus head passed the mandibular ramus until maximal hyoid excursion was initiated.	yes	yes	yes	no	yes
Humbert, I. A., Fitzgerald, M. E., McLaren, D. G., Johnson, S., Porcaro, E., Kosmatka, K., . . . Robbins, J. (2009)	healthy	VFSS	Delayed onset of the pharyngeal swallow response	Stage transition duration used to measure delay	yes	yes	yes - but some were cued some not cued	no	no
Iida, Y., Katsumata, A., & Fujishita, M. (2011)	healthy	VFSS	Spillage into the pharynx	We defined spillage as having occurred when a drop of material on the base of the tongue was observed on VFSS images before initiation of swallowing	yes	no	yes	no	no
Jung, S. J., Kim, D. Y., & Joo, S. Y. (2011)	head and neck	VFSS	Delayed swallowing reflex	n/a	yes	no	not specified	no	no
Kahrilas, P. J., Lin, S., Rademaker, A. W., & Logemann, J. A. (1997)	neuro	VFSS	Delayed initiation	n/a	no	yes	not specified	no	no
Kang, S. H., Kim, D. K., Seo, K. M., & Seo, J. H. (2011)	neuro	VFSS	Pharyngeal delay time/Premature bolus loss/Posterior spillage (of liquid prematurely)	n/a	yes	no	not specified	yes	no
Kang, S. H., Kim, D. K., Seo, K. M., Lee, S. Y., Park, S. W., & Kim, Y. B. (2016)	other (spinal surgery)	VFSS	Pharyngeal delay time	PDT is defined as the time elapsed since oral transit time ends (head of the bolus reach to lower edge of mandibular ramus) until laryngeal elevation begins.	yes	yes	not specified	no	no
Karnell, M. P., & Rogus, N. M. (2005)	dysphagia	VFSS	Delayed pharyngeal swallow onset	Delayed response is defined as the presence of the leading edge of the bolus beyond the lower edge of the mandibular ramus before anterior movement of the hyoid associated with the swallow.	yes	yes	yes	no	yes
Keage, M., Baum, S., Pointon, L., Lau, J., Berndt, J., Hopkins, J., . . . Vogel, A. P. (2020)	neuro (HD)	VFSS	Delayed pharyngeal swallow initiation	n/a	yes	no	not specified	no	no
Keeling, W. B., Hernandez, J. M., Lewis, V., Czapla, M., Zhu, W., Garrett, J. R., & Sommers, K. E. (2010)	other (thoracotomy)	VFSS	Delay in pharyngeal onset of swallow/Premature spillage	n/a	yes	no	not specified	no	no
Kim, D. H., Choi, K. H., Kim, H. M., Koo, J. H., Kim, B. R., Kim, T. W., . . . Yang, H. S. (2012)	dysphagia	VFSS	Delayed triggering of pharyngeal swallowing/Delayed swallowing reflex/Premature bolus loss	n/a	yes	no	not specified	no	yes

Kim, H. R., Lee, S. A., Kim, K., Leigh, J. H., Han, T. R., & Oh, B. M. (2015)	neuro (stroke)	VFSS	Delayed swallowing onset/Premature bolus loss	Premature bolus loss, which pertains to bolus drop into the pharynx from the oral cavity before the swallowing reflex. Triggering of pharyngeal swallow not defined	yes	no	yes	yes	no
Kim, J. H., & Kim, M. S. (2012)	neuro (stroke)	VFSS	Pharyngeal delay time/Delayed triggering of pharyngeal swallowing	Pharyngeal delay time (PDT): from the time the bolus head passed the ramus of the mandible to the beginning of laryngeal elevation.	yes	yes	yes	no	no
Kim, J. W., Choi, H., Jung, J., & Kim, H. J. (2020)	dysphagia	VFSS	Pharyngeal delay time	n/a	yes	no	not specified	no	no
Kim, S. J., Cheon, H. J., Lee, H. N., & Hwang, J. H. (2016)	other (esophagectomy)	VFSS	Pharyngeal delay time/Delayed pharyngeal (swallowing) reflex	Pharyngeal delay time (PDT) was measured for the delay of pharyngeal swallowing reflex which was defined as the time (sec) elapsed from the bolus passing to the posterior tongue base to the beginning of the hyoid motion.	yes	yes	not specified	no	no
Kim, S. J., Han, T. R., & Kwon, T. K. (2010)	other (pneumonectomy)	VFSS	Pharyngeal delay time/Delayed pharyngeal swallowing reflex	Pharyngeal delay time (PDT) was defined as the time taken to laryngeal elevation commencement after the bolus head reached the point where the lower edge of the mandible crossed the tongue base.	yes	yes	not specified	no	no
Kim, S. Y., Kim, T. U., Hyun, J. K., & Lee, S. J. (2014)	neuro (stroke)	VFSS	Pharyngeal transit time/Delay in the triggering of pharyngeal swallowing	PTT was measured from arrival of the bolus at the lower edge of the mandible until pharyngeal swallow was triggered	yes	yes	not specified	no	no
Kim, Y. H., Han, T. R., Nam, H. S., Seo, H. G., & Oh, B. M. (2019)	neuro (stroke)	VFSS	Delayed swallow/Pharyngeal delay time/Premature bolus loss	n/a	yes	no	not specified	yes	no
Kim, Y. H., Oh, B. M., Jung, I. Y., Lee, J. C., Lee, G. J., & Han, T. R. (2014)	neuro (PD)	VFSS	Pharyngeal delay time/Premature bolus loss	Pharyngeal delay time (PDT) was defined as the time taken to laryngeal elevation commencement after the bolus head reached the point where the lower edge of the mandible crossed the tongue base. Premature bolus loss not defined.	yes	no	not specified	yes	yes
Kim, Y., & McCullough, G. H. (2007)	neuro (stroke) and healthy	VFSS	Delayed initiation of the pharyngeal phase/Transition delay/Delayed onset of the pharyngeal phase/Swallowing delay	n/a	yes	yes	no	no	yes

Kim, Y., McCullough, G. H., & Asp, C. W. (2005)	healthy	VFSS	Pharyngeal Delay Time/Delayed pharyngeal swallow/Delayed transition	1) Pharyngeal Delay Time (PDT): The time from bolus head passing the posterior edge of the ramus of the mandible until the initial observation of laryngeal elevation. Initial laryngeal elevation time was recorded by observing the most superior-anterior edge of the thyroid cartilage. Typically, some calcification helps in the localization of this area. The first superior movement of the thyroid cartilage that actually results in a swallow was recorded. Any up and down movements of the larynx before the onset of the swallow were ignored. (2) Delayed Pharyngeal Swallow (DPS): The time from the head of the bolus reaching the valleculae to the initiation of laryngeal movement. Perlman et al. did not specifically define how they rated the bolus entering the valleculae. For this study we used the methodology used with the other measures for the head of the bolus movement. Trickle down barium was not counted in this measure. Rather, the tongue must have been actively pushing the barium into the pharynx for the first part of this measure to be counted. The bolus head was considered to have reached the valleculae when it passed below and anterior to the tip of the upright epiglottis. Thus, if you drew a straight line from the tip of the epiglottis at rest back to the base of tongue, you would mark the top of the valleculae for this measure. Initiation of laryngeal movement was defined exactly as it was for PDT.	yes	yes	not specified	yes	no
Kiyohara, H., Adachi, K., Kikuchi, Y., Uchi, R., Sawatsubashi, M., & Nakagawa, T. (2018)	dysphagia	VFSS	Delayed initiation of the swallowing reflex/Pharyngeal delay time	PDT was defined as the time the bolus head passed at the lower rim of the mandible until the onset of laryngeal elevation, similar to the swallowing response time.	yes	yes	not specified	yes	yes
Kocdor, P., Siegel, E. R., Giese, R., & Tulunay-Ugur, O. E. (2015)	dysphagia	VFSS + FEES	Delayed swallow initiation/Preswallow pooling	n/a	yes	no	not specified	no	no
Kreuzer, S. H., Schima, W., Schober, E., Pokieser, P., Kofler, G., Lechner, G., & Denk, D. M. (2000)	head and neck	VFSS	Delayed/absent triggering of the pharyngeal swallowing phase	n/a	yes	no	not specified	yes	no
Kumai, Y., Miyamoto, T., Matsubara, K., Samejima, Y., Yoshida, N., Baba, H., & Orita, Y. (2019)	other (esophogectomy)	VFSS + FEES	Delayed initiation	Delayed initiation assessed by whiteout timing	yes	no	not specified	no	yes

Kunieda, K., Hayashi, Y., Yamada, M., Waza, M., Yaguchi, T., Fujishima, I., & Shimohata, T. (2020)	neuro (CJD)	VFSS	Delayed swallowing reflex	n/a	yes	no	not specified	no	no
Kweon, S., Koo, B. S., & Jee, S. (2016)	head and neck	VFSS	Pharyngeal delay time	The pharyngeal delay time (PDT) is a component of the PTT, defined as the time from the bolus head arrival at the point where the shadow of the lower edge of the mandible crosses the tongue base until the pharyngeal swallow is triggered.	yes	yes	not specified	no	no
Langdon, P. C., Mulcahy, K., Shepherd, K. L., Low, V. H., & Mastaglia, F. L. (2012)	neuro (IBM)	VFSS	Delayed swallow initiation	K. M. Brookes, Sir Charles Gairdner Hospital Videofluoroscopy Rating Scale, ‘‘unpublished data’’.	yes	no	not specified	no	yes
Lazarus, C. L., Logemann, J. A., Rademaker, A. W., Kahrilas, P. J., Pajak, T., Lazar, R., & Halper, A. (1993)	neuro (stroke) and healthy	VFSS	Pharyngeal delay time/Delay in triggering pharyngeal swallow	Pharyngeal delay time (interval from the time the bolus head reached the point at which the ramus of the mandible crossed the base of the tongue until onset of laryngeal elevation indicating the beginning of the pharyngeal swallow:	yes	yes	not specified	no	yes
Lee, J. T., Park, E., Hwang, J. M., Jung, T. D., & Park, D. (2020)	neuro and healthy	VFSS	Delayed (response time) of the swallowing reflex	The starting point of a pharyngeal swallowing reflex is defined as the first video frame in which the head of the bolus reaches the lower edge of the mandibular ramus. The end point of the swallowing reflex is defined as the last video frame in which the head of the bolus reaches the vallecular sinus, until the first time of hyoid bone elevation is triggered by a pharyngeal swallow	yes	yes	not specified	no	yes
Lee, K. L., Kim, D. Y., Kim, W. H., Kim, E. J., Lee, W. S., Hahn, S. J., . . . Ahn, S. Y. (2012)	neuro	VFSS	Pharyngeal delay time	From the bolus head arrival at the point where the lower rim of the mandible crosses the tongue base until the first onset of the laryngeal elevation.	yes	yes	no	no	no
Lee, K. L., Kim, W. H., Kim, E. J., & Lee, J. K. (2012)	dysphagia	VFSS	Pharyngeal delay time/Premature bolus loss	The pharyngeal delay time was measured from the arrival of the main bolus head at the intersection of the tongue and mandibular ramus to the onset of the elevation of the hyoid bone or larynx, that is, the onset of the pharyngeal swallow.	yes	yes	no	yes	no
Lee, S. I., Yoo, J. Y., Kim, M., & Ryu, J. S. (2013)	dysphagia	VFSS	Delayed pharyngeal phase	n/a	yes	yes	yes	no	no
Lee, T. H., Lee, J. S., Park, J. W., Cho, S. J., Hong, S. J., Jeon, S. R., . . . Kim, J. O. (2014)	dysphagia	VFSS	Pharyngeal delay time	PDT was defined as the time elapsed from the time the bolus head passed the ramus of the mandible to the beginning of laryngeal elevation.	yes	yes	not specified	no	yes

Leonard, R., & McKenzie, S. (2006)	healthy	VFSS	Pharyngeal swallow delay/Delayed response/Delayed swallow initiation/Delayed onset of the pharyngeal swallow	Bolus transit times subtracted included B1 (first posterior movement of the bolus past the posterior nasal spine that leads to a swallow), Bmand (head of the bolus passes the base of tongue at the angle of the mandible), BV1 (head of the bolus enters the valleculae), BV2 (head of the bolus exits or passes the valleculae), and BP1 (head of the bolus enters the UES).	yes	yes	Yes	no	no
Lewis, C., Keage, M., Watanabe, M., Schubiger, D., Velakoulis, D., Walterfang, M., & Vogel, A. P. (2020)	neuro (NPC)	VFSS	Delayed swallowing reflex	The Bethlehem Swallowing Scale (BAS) was used to quantify VFSS data. The BAS characterizes swallow function in ten domains across oral, pharyngeal phases using a 4-point scale (where scores increase with severity of impairment)	yes	yes	not specified	no	yes
Linden, P., Tippett, D., Johnston, J., Siebens, A., & French, J. (1989)	healthy	VFSS	Delayed swallowing reflex/response	When the swallow reflex is not triggered when the bolus passes the back of the tongue at the anterior faucial arch	yes	yes	not specified	no	no
Logemann, J. A. (1985)	head and neck	VFSS	Delayed triggering of the pharyngeal swallow	The swallowing reflex triggering was indicated by the elevation and retraction of the soft palate, elevation and closure of the larynx, pharyngeal peristalsis and cricopharyngeal relaxation. If any two of those functions occurred, the reflex was said to have triggered	no	yes	yes	yes	no
Logemann, J. A., Pauloski, B. R., Colangelo, L., Lazarus, C., Fujiu, M., & Kahrilas, P. J. (1995)	neuro	VFSS	Delay in triggering the pharyngeal swallow/Pharyngeal delay time	PDT - bolus head arrival at the point where the lower rim of the mandible crosses the tongue base until first laryngeal elevation;	yes	yes	yes	no	yes
Logemann, J. A., Pauloski, B. R., Rademaker, A. W., Lazarus, C. L., Gaziano, J., Stachowiak, L., . . . Mittal, B. (2008)	head and neck	VFSS	Delayed pharyngeal swallow	Reference to Logemann: when bolus reaches ramus of mandible to onset of laryngeal elevation	yes	no	not specified	no	no
Logemann, J. A., Rademaker, A. W., Pauloski, B. R., Lazarus, C. L., Mittal, B. B., Brockstein, B., . . . Liu, D. (2006)	head and neck	VFSS	Delay in triggering the pharyngeal swallow/Pharyngeal delay	Time from the bolus head reaching the point where the lower edge of the mandible crosses the tongue base until the first laryngeal elevation in the swallow is seen. Up to 30 seconds	yes	yes	not specified	no	no
Lundy, D. S., Smith, C., Colangelo, L., Sullivan, P. A., Logemann, J. A., Lazarus, C. L., . . . Gaziano, J. (1999)	dysphagia	VFSS	Delayed triggering of pharyngeal swallow(stage)/Pharyngeal delay/Delayed pharyngeal swallow time	n/a	no	no	not specified	no	no
Mann, G., Hankey, G. J., & Cameron, D. (1999)	neuro (stroke)	VFSS	Delayed swallowing reflex	n/a	yes	no	not specified	no	no

Martin-Harris, B., Brodsky, M. B., Michel, Y., Lee, F. S., & Walters, B. (2007)	healthy	VFSS	Delayed onset/Delayed initiation (of the pharyngeal swallow)/Pharyngeal delay	Stage transition duration to denote the time interval between the point when the bolus first passes the ramus of the mandible and the onset of hyoid excursion. Any difference between these temporal points implicated a delay in initiation of the pharyngeal swallow.	no	no	no	no	no
Martin-Harris, B., Michel, Y., & Castell, D. O. (2005)	healthy	VFSS	Pharyngeal swallow delay time	Time between bolus head arrival at the posterior angle of the mandible and the onset of the brisk, angular movement of the hyoid.	no	yes	no	no	no
Maruo, T., Fujimoto, Y., Ozawa, K., Hiramatsu, M., Suzuki, A., Nishio, N., & Nakashima, T. (2014)	head and neck	VFSS	Pharyngeal delay time/Delayed pharyngeal swallowing	PDT was measured from when the leading edge of a food bolus reached the lower border of the mandible until the greatest elevation of hyoid bone movement.	yes	yes	not specified	no	no
McConnel, F. M. S., Pauloski, B. R., Logemann, J. A., Rademaker, A. W., Colangelo, L., Shedd, D., . . . Johnson, J. (1998)	head and neck	VFSS	Pharyngeal delay time	The time required to initiate a pharyngeal swallow, measured from the time the head of the bolus passes the ramus of the mandible until the onset of laryngeal elevation.	yes	yes	not specified	no	no
Mendell, D. A., & Logemann, J. A. (2007)	healthy	VFSS	Pharyngeal (swallow) delay/Delay in triggering the pharyngeal swallow	n/a	no	no	yes	no	yes
Meng, N. H., Wang, T. G., & Lien, I. N. (2000)	neuro (stroke)	VFSS	Delay (or absence) of the swallowing reflex	n/a	yes	no	not specified	no	no
Min, Y., Kim, W. S., Kang, S. S., Choi, J. M., Yeom, J. S., & Paik, N. J. (2013)	other (spinal surgery)	VFSS	Pharyngeal delay time	n/a	yes	no	not specified	no	no
Miyaji, H., Umezaki, T., Adachi, K., Sawatsubashi, M., Kiyohara, H., Inoguchi, T., . . . Komune, S. (2012)	neuro (stroke) and healthy	VFSS	Delayed triggering of pharyngeal stage/Pharyngeal stage delay/Pharyngeal delay time/Spillage	PDT was defined as the time from arrival of the bolus head at the point where the lower rim of the mandible crosses the tongue base until the first laryngeal elevation. Spillage, defined as the head of the bolus entering the bottom of either side of the pyriform sinus for more than 1 second	yes	yes	not specified	no	no
Mok, P., Woo, P., & Schaefer-Mojica, J. (2003)	neuro (vagus nerve injuries)	VFSS +/- FEES	Delayed onset	n/a	no	no	not specified	no	no
Moon, H. I., Kim, G. S., & Lee, E. (2019)	neuro (stroke)	VFSS	delayed swallowing response time/Early spillage	Swallowing response time was the interval between the arrival of the bolus at the ramus of the mandible and the first frame showing upward excursion of the larynx	yes	yes	not specified	yes	no
Moon, H. I., Pyun, S. B., & Kwon, H. K. (2012)	neuro (stroke)	VFSS	Delay in pharyngeal triggering time/Premature loss of food material	Pharyngeal triggering time, determined to be the time until the swallowing reflex appearance, a time of less than 0.4 seconds was considered normal	yes	yes	not specified	yes	no

Morton, R. E., Bonas, R., Minford, J., Kerr, A., & Ellis, R. E. (1997)	neuro (Rett syndrome)	VFSS	Delayed pharyngeal swallow/Premature spillover (of fluids)	For spill over: liquids escaped freely from the mouth into the pharynx without control. Delay not defined.	yes	no	not specified	yes	no
Munchau, A., Good, C. D., McGowan, S., Quinn, N. P., Palmer, J. D., & Bhatia, K. P. (2001)	neuro (dystonia)	VFSS	Delayed initiation of the swallow reflex	INITIATION OF SWALLOW 0=Swallow is triggered as the head of the bolus crosses the ramus of the mandible; 2=slight delay in initiation of swallow as the bolus passes tongue base and passes ramus of mandible; 2=swallow delayed to the valleculae; 3=swallow initiated when bolus head passes laryngeal vestibule or enters pyriform sinuses; 4=no swallow is initiated.	yes	yes	not specified	no	yes
Nagy, A., Leigh, C., Hori, S. F., Molfenter, S. M., Shariff, T., & Steele, C. M. (2013)	healthy	VFSS	Delayed swallow onset/Delayed pharyngeal swallow/Premature spillage	Stage transition duration, i.e., the time interval between the passing of the bolus head across the radiological shadow of the mandibular ramus and the onset of anterosuperior hyoid motion. A negative value for stage transition duration reflects onset of hyolaryngeal excursion prior to bolus entry into the pharynx and is thought to represent optimum safety in swallow onset timing with liquids.	yes	yes	no	yes	yes
Nakamori, M., Hosomi, N., Imamura, E., Matsushima, H., Maetani, Y., Yoshida, M., . . . Maruyama, H. (2020)	neuro (stroke)	VFSS	Swallowing reflex delay	Defined as liquid remaining in the pyriform sinuses for more than 0.1 s (three frames) before swallowing	yes	yes	not specified	no	no
Nativ-Zeltzer, N., Logemann, J. A., & Kahrilas, P. J. (2014)	dysphagia	VFSS	Delayed pharyngeal response	Time from bolus passing valleculae until onset of laryngeal superior movement.	yes	yes	not specified	no	no
Nayak, V. K., Bhattacharyya, N., Kotz, T., & Shapiro, J. (2002)	neuro (vocal fold palsy)	VFSS	Swallow delay	n/a	yes	no	not specified	no	no
Newman, L. A., Thomas Robbins, K., Logemann, J. A., Rademaker, A. W., Lazarus, C. L., Hamner, A., . . . Huang, C. F. (2002)	head and neck	VFSS	Pharyngeal delay time/Delayed pharyngeal swallow	Pharyngeal delay time -the time required to trigger the pharyngeal swallow -Head (leading edge) of the bolus passes the point where the ramus of the mandible crosses the tongue base to start of hyoid movement	yes	yes	yes	no	yes
Oh, E., Jee, S., Kim, B. K., Lee, J. S., Cho, K., & Ahn, S. (2020)	neuro (PD)	VFSS	Pharyngeal delay time/Premature bolus loss	The pharyngeal delay time (PDT) is defined as the time from the bolus head arriving at the lower edge of the mandibular ramus to triggering of the pharyngeal swallow. Premature bolus loss not defined	yes	yes	not specified	yes	no
Ohashi, N., Iwai, T., Tohara, H., Chiba, Y., Oguri, S., Koizumi, T., . . . Tohnai, I. (2019)	head and neck	VFSS	Pharyngeal delay time/Delayed pharyngeal swallow/Delayed swallowing reflex,	The bolus head reaching the point where the lower border of the mandible crosses the tongue base, until laryngeal elevation in the pharyngeal stage of swallowing	yes	yes	yes	no	yes
Ohki, M., & Kikuchi, S. (2018)	neuro (amyloidosis)	VFSS	Delayed onset	n/a	no	no	not specified	no	no

Oommen, E. R., Kim, Y., & McCullough, G. (2011)	neuro (stroke)	VFSS	Delayed response of pharyngeal musculature/Delayed initiation of pharyngeal swallowing/Delayed swallow	STD: represents the transition between the oral and pharyngeal stages of swallowing and the timely initiation of the pharyngeal swallow/refers to the time between bolus head passing the ramus of the mandible and the onset of maximum hyoid excursion	yes	yes	yes	no	yes
Palmer, J. B., Rudin, N. J., Lara, G., & Crompton, A. W. (1992)	healthy	VFSS	Delayed initiation of pharyngeal swallowing/Premature entry of food into the pharynx	The onset of swallowing was defined as the start of sudden, rapid superior and anterior motion of the hyoid bone. This event was chosen because it consistently differentiated the swallow from mastication and other actions. Swallow ending was defined as the moment the hyoid completed its return phase, having moved anteriorly and superiorly and reversed direction. Bolus progression was noted by recording the time contrast medium passed the inferior border of the mandible and reached the floor of the valleculae. Entry of contrast medium into the oropharynx was defined as contrast medium reaching the inferior border of the mandible.	yes	yes	not specified	yes	yes
Park, B. H., Seo, J. H., Ko, M. H., & Park, S. H. (2013)	neuro	VFSS	Pharyngeal delay time/Premature bolus loss	Premature bolus loss was not considered, and only the main bolus was the object of the measurement. Pharyngeal delay time was measured from the moment when the main bolus arrived at the lower part of the ramus of the mandible to the moment when the larynx began to rise.	yes	yes	not specified	yes	no
Park, J. W., Oh, J. C., Lee, J. W., Yeo, J. S., & Ryu, K. H. (2013)	neuro (stroke)	VFSS	Delayed triggering of pharyngeal swallowing/Delayed swallowing reflex/Premature bolus loss	n/a	yes	no	not specified	yes	no
Park, J. W., Sim, G. J., Yang, D. C., Lee, K. H., Chang, J. H., Nam, K. Y., . . . Kwon, B. S. (2016)	neuro (stroke)	VFSS	Pharyngeal delay time/Delayed pharyngeal swallowing (response)/Premature bolus loss	Delayed pharyngeal swallowing occurs when the head of the bolus enters the pharynx and the pharyngeal swallow is not triggered within 0.4-0.5 seconds, commonly indicated by laryngeal elevation when being discussed in the context of the rest of the pharyngeal swallow	yes	yes	not specified	yes	no
Parreira, L. C., Salgado-Junior, W., & Dantas, R. O. (2020).	other (obese)	VFSS	Premature posterior spillage	Premature spillage to pharynx (part of the bolus leave the oral cavity during the oral preparation, before the onset of the oral transit),	yes	yes	not specified	no	no

Pauloski, B. R., & Nasir, S. M. (2016)	dysphagia	VFSS	Pharyngeal (swallow) delay/Pharyngeal delay time	The time in seconds (s) until the pharyngeal swallow triggers, measured from the time the head of the bolus passes the ramus of the mandible until the onset of laryngeal elevation.	yes	yes	not specified	no	no
Pauloski, B. R., Logemann, J. A., Rademaker, A. W., McConnel, F. M. S., Stein, D., Beery, Q., . . . Baker, T. (1994)	head and neck	VFSS	Pharyngeal delay time/Loss of bolus (from the oral cavity)	n/a	yes	no	not specified	no	yes
Perez, I., Smithard, D. G., Davies, H., Kalra, L. (1998)	neuro (stroke)	VFSS	delayed triggering of swallow(reflex)/Swallow delay/Pooling	Swallow delay (length of time taken for the swallow to trigger following the presentation of the bolus to the pharynx),	yes	yes	not specified	no	no
Perlman, A.L., Booth, B.M., Grayhack, J.P. (1994)	dysphagia	VFSS	Delayed initiation of the pharyngeal stage of the swallow	The swallow was considered delayed when the first swallow of a bolus did not trigger within a minimum of 1 sec after barium entered the valleculae. Severity of the delay was rated on a scale of 1-3 where 1 represented mild delay (>1 but <2 sec) and 3 represented a severe delay (>5 sec)	yes	yes	not specified	no	yes
Perlman, A. L., Booth, B. M., & Grayhack, J. P. (1994)	dysphagia	VFSS	Delayed initiation of the pharyngeal stage of swallow	The swallow was considered delayed when the first swallow of a bolus did not trigger within a minimum of 1 sec after barium entered the valleculae. Severity of the delay was rated on a scale of 1-3 where 1 represented mild delay (>1 but <2 sec) and 3 represented a severe delay (>5 sec)	yes	no	not specified	no	yes
Regan, J., Walshe, M., Tobin, W.O. (2010)	neuro (PD)	VFSS	Pharyngeal delay time/Pharyngeal reflex delay	Pharyngeal reflex delay was defined as the time taken from bolus head arrival at the point where the shadow of the lower edge of the mandible crosses the tongue base until laryngeal elevation indicating the onset of the pharyngeal swallow	yes	yes	not specified	no	yes
Rhie, S. H., Choi, J. W., Jeon, S. J., Kang, S. D., Joo, M. C., & Kim, M. S. (2016)	neuro (SAH)	VFSS	Premature bolus loss	n/a	yes	no	not specified	yes	no
Riski, J. E., Horner, J., & Nashold, B. S., Jr. (1990)	neuro (torticollis)	VFSS	Delayed swallowing reflex initiation	Reflex initiation = Swallow reflex initiated beyond the delay base of the tongue/faucial pillars	yes	no	not specified	no	no
Saconato, M., Chiari, B. M., Lederman, H. M., & Goncalves, M. I. R. (2016)	neuro	VFSS	Delayed swallowing trigger	The triggering or onset of pharyngeal swallowing is considered normal below 0.24s. It is delayed whenever laryngeal elevation and closure of the laryngeal aditus occur after the bolus transit through the region between the oral cavity and the oral portion of the pharynx.	yes	no	not specified	no	no
Saito, T., Hayashi, K., Nakazawa, H., & Ota, T. (2016)	neuro (stroke)	VFSS	Delayed swallowing/Swallowing hesitation	n/a	yes	no	Yes	no	no

Santos, R. R., Sales, A. V., Cola, P. C., Ribeiro, P. W., Jorge, A. G., Peres, F. M., . . . Silva, R. G. (2014)	neuro (stroke)	VFSS	Posterior oral spillage/Oral posterior escape	The occurrence of premature food escape to the hypopharynx, surpassing the region in which pharyngeal response should take place (ramus of mandible and base of tongue), was described as posterior oral spillage.	yes	yes	not specified	yes	no
Sdravou, K., Walshe, M., & Dagdilelis, L. (2012)	neuro	VFSS	Delayed pharyngeal response (swallow)/pharyngeal delay	n/a	yes	yes	no	no	Yes
Sellars, C., Campbell, A. M., Stott, D. J., Stewart, M., & Wilson, J. A. (1999)	neuro (stroke)	FEES	Delay in the initiation/trigger of the swallow/Pre-swallow pooling/Pre-swallow spillage	Seen as a significant increase in the time from the command to swallow to the onset of epiglottic tilt (delay)	yes	yes	yes	no	no
Seo, H. G., Oh, B. M., & Han, T. R. (2011)	neuro (stroke)	VFSS	Delayed swallowing triggering/Pharyngeal delay time/Premature bolus loss	Don't define what constitutes a delay. VDS used for premature bolus loss. latency to the initiation of hyoid motion in this study is the same as stage transition duration (STD), which was defined as the time from when barium first passes the ramus of the mandible to the beginning of maximum hyoid excursion	yes	no	not specified	no	yes
Shaw, G. Y., Sechtem, P. R., Searl, J., Keller, K., Rawi, T. A., & Dowdy, E. (2007)	dysphagia	VFSS	Swallowing delay	n/a	yes	no	not specified	no	no
Steele, C. M., Bailey, G. L., Polacco, R. E. C., Hori, S. F., Molfenter, S. M., Oshalla, M., & Yeates, E. M. (2013)	neuro (ABI)	VFSS	Delayed pharyngeal swallow/Premature spillage	n/a	no	no	Yes	yes	yes
Steele, C. M., Bayley, M. T., Peladeau-Pigeon, M., Nagy, A., Namasivayam, A. M., Stokely, S. L., & Wolkin, T. (2016)	neuro (stroke)	VFSS	Delay in the initiation of the pharyngeal phase of the swallow/Premature spillage	The first video frame where the head of the bolus was positioned below the shadow of the ramus of the mandible, and the first video frame of the hyoid burst movement associated with a swallow. STD: a measure of the duration of bolus presence in the pharynx prior to swallow initiation/time interval between the bolus passing the shadow of the ramus of mandible and the onset of hyolaryngeal excursion for a swallow	yes	yes	not specified	yes	yes
Steinhagen, V., Grossmann, A., Benecke, R., & Walter, U. (2009)	neuro (stroke)	FEES	Delayed or absent pharyngeal swallow	n/a	yes	no	Yes	no	no

Stephen, J. R., Taves, D. H., Smith, R. C., & Martin, R. E. (2005)	healthy	VFSS	Delayed pharyngeal swallow/Delayed stage transition	The pharyngeal swallow is triggered when the bolus head passes the anterior faucial pillars. Individuals in whom the bolus advanced past this critical oropharyngeal location by swallow onset were thought to have a delay of the pharyngeal swallow	yes	no	not specified	no	no
Su, H. K., Khorsandi, A., Silberzweig, J., Kobren, A. J., Urken, M. L., Amin, M. R., . . . Lazarus, C. L. (2015)	healthy	VFSS	Pharyngeal delay time	PDT—bolus head arrival at the point where the lower rim of the mandible crosses the tongue base until first laryngeal elevation	yes	yes	yes	no	yes
Suh, M. K., Kim, H., & Na, D. L. (2009)	neuro (dementia)	VFSS	Delayed swallow reflex	n/a	yes	no	not specified	no	no
Sulica, L., Hembree, A., & Blitzer, A. (2002)	healthy	FEES	Premature spillage	Present or absent	yes	no	not specified	no	no
Tabaee, A., Johnson, P. E., Gartner, C. J., Kalwerisky, K., Desloge, R. B., & Stewart, M. G. (2006)	dysphagia	VFSS	Spillage	Spillage was defined as the premature passage of the food bolus from the oropharynx to the hypopharynx before the initiation of swallow	yes	no	not specified	no	no
Takeda, C., Yoshida, M., Nakamori, M., Hosomi, N., Nagasaki, T., Yoshikawa, M., . . . Tsuga, K. (2020)	neuro (stroke)	VFSS	Swallowing reflex delay	The presence or absence of swallowing reflex delay, defined as liquid remaining in the pyriform sinus for more than 0.1 seconds (3 frames) before swallowing.	yes	no	not specified	no	no
Terre, R., & Mearin, F. (2006)	neuro (stroke)	VFSS	Pharyngeal delay time/Reduced palatoglossal closure	Reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex). Pharyngeal delay time, defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex. reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex); PDT defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex.	yes	yes	not specified	yes	no

Terré, R., & Mearin, F. (2009)	neuro (TBI)	VFSS	Pharyngeal delay time/Delay in triggering swallowing reflex/Delay in swallowing response/Reduced palatoglossal closure	Reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex). Pharyngeal delay time, defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex. PDT: time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex (considered to be normal below 0.24 s)	yes	yes	not specified	yes	no
Terre, R., & Mearin, F. (2009)	neuro (stroke)	VFSS	Pharyngeal delay time/Delayed triggering of swallow/Reduced palatoglossal closure	Reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex). Pharyngeal delay time, defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex. pharyngeal delay time (PDT): defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex (considered to be normal below 0.24 s), reduced palatoglossal closure defined when all or part of the bolus falls into the pharynx prematurely (before activation of the swallowing reflex)	yes	yes	not specified	yes	no

Terre, R., & Mearin, F. (2012)	neuro (ABI)	VFSS	Pharyngeal delay time/Reduced palatoglossal closure	Reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex). Pharyngeal delay time, defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex. PDT: time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex (considered to be normal below 0.24 s).	yes	yes	not specified	yes	no
Terré, R., Panadés, A., & Mearin, F. (2013)	neuro (stroke)	VFSS	Pharyngeal delay time/Delay in triggering swallowing reflex/Reduced palatoglossal closure	Reduced palatoglossal closure: defined when part or all the bolus falls into the pharynx prematurely (before activation of the swallowing reflex). Pharyngeal delay time, defined as time from bolus head arrival at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow is defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex. pharyngeal delay: Pharyngeal swallowing response was defined as the time the bolus head arrives at the point where the shadow of the longer edge of the mandible crosses the tongue base until pharyngeal swallow is triggered. Triggering or onset of pharyngeal swallow was defined as the first video frame showing laryngeal elevation as part of the pharyngeal swallowing complex (considered to be normal below 0.24 s), therefore, values above this were considered abnormal: presence of pharyngeal swallow delay time (PDT)	yes	yes	not specified	yes	no

Triadafilopoulos, G., Hallstone, A., Nelson-Abbott, H., & Bedinger, K. (1992)	other (oesophageal dysphagia)	VFSS	Delayed or absent swallowing reflex	Vallecular stasis and hesitation of material in the valleculae prior to initiation of the swallowing reflex. An absent swallowing reflex was defined if bolus material hesitated in the valleculae for 30 sec or longer without triggering the reflex.	yes	no	not specified	no	no
Veis, S. L., & Logemann, J. A. (1985)	neuro (stroke)	VFSS	Delayed (triggering) of the swallowing reflex	n/a	yes	no	not specified	no	no
Vogel, A. P., Rommel, N., Oettinger, A., Stoll, L. H., Kraus, E. M., Gagnon, C., . . . Synofzik, M. (2018)	neuro (ARSACS)	VFSS	Delayed initiation of the swallowing reflex	n/a	yes	no	not specified	no	no
Warabi, T., Ito, T., Kato, M., Takei, H., Kobayashi, N., & Chiba, S. (2008)	neuro (stroke)	VFSS	Pharyngeal delay time	Pharyngeal delay time (PDT), from the time the bolus head reached the posterior margin of the mandibular ramus to the time of hyoid elevation;	yes	yes	yes	no	no
Wintzen, A. R., Badrising, U. A., Roos, R. A., Vielvoye, J., Liauw, L., & Pauwels, E. K. (1994)	neuro (PD)	VFSS	Delayed swallowing reflex	n/a	yes	no	not specified	no	no
Wu, C. H., Hsiao, T. Y., Chen, J. C., Chang, Y. C., & Lee, S. Y. (1997)	dysphagia	VFSS + FEES	Premature oral leakage to the pharynx	n/a	yes	no	no	yes	no
Yamamoto, H., Furuya, J., Tamada, Y., & Kondo, H. (2013)	other (edentulous)	VFSS	Delayed swallowing reflex	n/a	yes	yes	not specified	no	no
Yoshida, M., Endo, Y., Nishimura, R., Masuda, S., Amano, J., & Tsuga, K. (2019)	dysphagia	VFSS	Pharyngeal delay time	PDT was defined as the time from when the head of the bolus reaches the point where the lower edge of the mandible crosses the tongue base to the start of laryngeal elevation in the context of completion of swallowing.	yes	yes	not specified	no	no
Zhang, J., Zhou, Y., Wei, N., Yang, B., Wang, A., Zhou, H., . . . Groher, M. (2016)	neuro (stroke)	VFSS	Delayed pharyngeal phase(swallowing)/Latency of the pharyngeal phase	Latency of the pharyngeal phase: This was defined as the delay between the onset of pharyngeal phase of swallowing and the elevation of laryngeal. The onset of pharyngeal phase was defined when the barium head reached the intersection between the lower edge of the mandibular ramus and tongue base.	yes	yes	not specified	no	yes

Appendix 4

Intra-Rater Reliability of Individual Raters

Control Group		Experimental Group	
Rater 1	0.29 (-0.36, 0.94)	Rater 1	0.64 (0.19, 1.08)
Rater 2	0.71 (0.23, 1.19)	Rater 2	0.33 (-0.30, 0.96
Rater 3	1	Rater 3	1
Rater 4	0.72 (0.29, 1.15)	Rater 4	0.69 (0.16, 1.22)
Rater 5	0.47 (0.09, 0.85)	Rater 5	1
Rater 6	0.58 (-0.06, 1.22)	Rater 6	0.44 (-0.13, 1.01)

Appendix 5

Intra-rater comparison

Control Group			Experimental Group		
	rating 1	rating 2		rating 1	rating 2
101503_1	4	4	101503_1	4	4
101503_2	4	4	101503_2	4	4
101503_3	4	4	101503_3	4	4
101503_4	4	4	101503_4	4	4
101503_5	4	4	101503_5	2	2
101503_6	2	2	101503_6	1	4
102703_1	4	4	102703_1	4	4
102703_2	4	4	102703_2	4	4
102703_3	4	4	102703_3	4	4
102703_4	4	4	102703_4	4	4
102703_5	4	4	102703_5	4	4
102703_6	4	2	102703_6	4	4
102602_1	1	4	102602_1	4	4
102602_2	1	1	102602_2	4	1
102602_3	1	1	102602_3	1	1
102602_4	1	1	102602_4	1	1
102602_5	1	3	102602_5	1	1
102602_6	2	2	102602_6	1	1
102803_1	2	2	102803_1	3	3
102803_2	3	3	102803_2	3	3
102803_3	2	2	102803_3	2	2
102803_4	3	2	102803_4	2	2
102803_5	3	3	102803_5	3	3
102803_6	1	1	102803_6	3	3
100102_1	4	2	100102_1	2	3
100102_2	4	2	100102_2	2	4
100102_3	4	4	100102_3	2	2
100102_4	2	2	100102_4	2	4
100102_5	1	2	100102_5	2	2

100102_6	2	2	100102_6	4	2

Appendix 6

Cohen's Kappa by Pairs

Control Group		Experimental Group	
1+2	0.41 (0.21, .61)	1+2	0.25 (0.04, 0.46)
1+3	0.55 (0.33, 0.77)	1+3	0.35 (0.14, 0.56)
1+4	0.4 (0.18, 0.62)	1+4	0.14 (-0.05, 0.33)
1+5	0.34 (0.14,0.54)	1+5	0.25 (0.05, 0.45)
1+6	0.07 (-0.1, 0.24)	1+6	0.33 (0.10, 0.56)
2+3	0.47 (0.25, 0.69)	2+3	0.27 (0.08, 0.46)
2+4	0.52 (0.32, 0.72)	2+4	0.49 (0.29, 0.69)
2+5	0.39 (0.2, 0.58)	2+5	0.44 (0.24, 0.64)
2+6	0.02 (-0.11, 0.15)	2+6	0.41 (0.20, 0.62)
3+4	0.43 (0.22, 0.64)	3+4	0.35 (0.17, 0.53)
3+5	0.22 (0.03, 0.41)	3+5	0.45 (0.23, 0.67)
3+6	0.02 (-0.13, 0.17)	3+6	0.38 (0.16, 0.60)
4+5	0.35 (0.14, 0.56)	4+5	0.17 (0.02, 0.32)
4+6	0.01 (-0.15, 0.17)	4+6	0.29 (0.09, 0.49)
5+6	0.18 (-0.04, 0.4)	5+6	0.40 (0.19, 0.61)

Appendix 7

4x4 Contingency Comparison Between Pairs

	Group 1						Group 2				
		R2						R2			
		Both	Delay	Neither	PBC			Both	Delay	Neither	PBC
R1	Both	1	0	0	1	R1	Both	2	1	2	1
	Delay	3	2	2	2		Delay	0	3	3	2
	Neither	0	0	14	3		Neither	0	0	10	2
	PBC	2	0	1	4		PBC	3	4	1	1
		R3						R3			
		Both	Delay	Neither	PBC			Both	Delay	Neither	PBC
R1	Both	0	1	0	1	R1	Both	2	4	0	0
	Delay	1	4	3	1		Delay	1	5	0	2
	Neither	0	1	15	1		Neither	0	2	7	3
	PBC	0	0	1	6		PBC	2	2	1	4

		R4			
		Both	Delay	Neither	PBC
R1	Both	2	0	0	0
	Delay	3	3	1	2
	Neither	0	4	11	2
	PBC	2	0	1	4

		R4			
		Both	Delay	Neither	PBC
R1	Both	0	2	2	2
	Delay	0	1	5	2
	Neither	0	0	9	3
	PBC	0	2	3	4

		R5			
		Both	Delay	Neither	PBC
R1	Both	0	0	0	2
	Delay	2	5	0	2
	Neither	2	4	9	2
	PBC	2	1	0	4

		R5			
		Both	Delay	Neither	PBC
R1	Both	3	3	0	0
	Delay	1	5	0	2
	Neither	0	3	6	3
	PBC	4	4	0	1

		R6			
		Both	Delay	Neither	PBC
R1	Both	0	0	0	2
	Delay	1	3	0	5
	Neither	2	11	3	1
	PBC	1	2	0	4

		R6			
		Both	Delay	Neither	PBC
R1	Both	3	2	0	1
	Delay	0	3	3	2
	Neither	0	0	8	4
	PBC	1	3	1	4

		R3			
		Both	Delay	Neither	PBC
R2	Both	1	3	1	1
	Delay	0	1	1	0
	Neither	0	2	14	1
	PBC	0	0	3	7

		R3			
		Both	Delay	Neither	PBC
R2	Both	0	2	0	3
	Delay	2	5	0	1
	Neither	0	6	8	2
	PBC	3	0	0	3

		R4			
		Both	Delay	Neither	PBC
R2	Both	4	1	0	1
	Delay	1	1	0	0
	Neither	0	4	12	1
	PBC	2	1	1	6

		R4			
		Both	Delay	Neither	PBC
R2	Both	0	3	0	2
	Delay	0	2	4	2
	Neither	0	0	15	1
	PBC	0	0	0	6

		R5			
		Both	Delay	Neither	PBC
R2	Both	2	2	0	2
	Delay	0	2	0	0
	Neither	0	6	9	2
	PBC	4	0	0	6

		R5			
		Both	Delay	Neither	PBC
R2	Both	4	1	0	0
	Delay	2	6	0	0
	Neither	0	8	6	2
	PBC	2	0	0	4

		R6			
		Both	Delay	Neither	PBC
R2	Both	0	0	0	6
	Delay	0	1	0	1
	Neither	2	10	3	2
	PBC	2	5	0	3

		R6			
		Both	Delay	Neither	PBC
R2	Both	2	1	0	2
	Delay	0	4	1	3
	Neither	0	2	11	3
	PBC	2	1	0	3

		R4			
		Both	Delay	Neither	PBC
R3	Both	1	0	0	0
	Delay	3	3	0	0
	Neither	0	4	12	3
	PBC	3	0	1	5

		R4			
		Both	Delay	Neither	PBC
R3	Both	0	1	0	4
	Delay	0	3	10	0
	Neither	0	0	8	0
	PBC	0	1	1	7

		R5			
R3		Both	Delay	Neither	PBC
	Both	0	1	0	0
	Delay	2	2	1	1
	Neither	1	6	8	4
	PBC	3	1	0	5

		R5			
R3		Both	Delay	Neither	PBC
	Both	2	1	0	2
	Delay	2	10	1	0
	Neither	0	3	5	0
	PBC	4	1	0	4

		R6			
R3		Both	Delay	Neither	PBC
	Both	0	0	0	1
	Delay	1	1	0	4
	Neither	2	11	3	3
	PBC	1	4	0	4

		R6			
R3		Both	Delay	Neither	PBC
	Both	2	1	0	2
	Delay	2	4	5	2
	Neither	0	0	7	1
	PBC	0	3	0	6

		R5			
R4		Both	Delay	Neither	PBC
	Both	1	3	0	3
	Delay	2	3	1	1
	Neither	1	4	8	0
	PBC	2	0	0	6

		R5			
R4		Both	Delay	Neither	PBC
	Both	0	0	0	0
	Delay	4	1	0	0
	Neither	0	12	6	1
	PBC	4	2	0	5

		R6			
		Both	Delay	Neither	PBC
R4	Both	0	0	0	7
	Delay	2	3	0	2
	Neither	0	9	3	1
	PBC	2	4	0	2

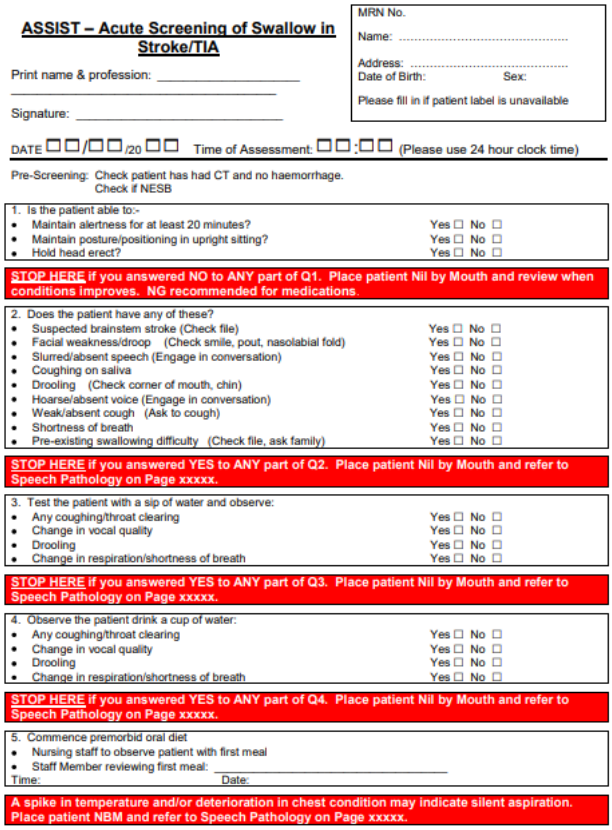
		R6			
		Both	Delay	Neither	PBC
R4	Both	0	0	0	0
	Delay	2	1	1	1
	Neither	0	4	11	4
	PBC	2	3	0	6

R5		R6 Both	Delay	Neither	PBC
	Both	1	2	0	3
	Delay	1	5	0	4
	Neither	1	5	3	0
	PBC	1	4	0	5

R5		R6 Both	Delay	Neither	PBC
	Both	3	3	0	2
	Delay	0	5	6	4
	Neither	0	0	6	0
	PBC	1	0	0	5

Appendix 8

ASSIST swallow screening tool



ASSIST – Acute Screening of Swallow in Stroke/TIA

Print name & profession: _____

Signature: _____

MRN No.
Name: .....
Address: .....
Date of Birth: Sex:
Please fill in if patient label is unavailable

DATE ☐☐/☐☐/20☐☐ Time of Assessment: ☐☐:☐☐ (Please use 24 hour clock time)

Pre-Screening: Check patient has had CT and no haemorrhage.
Check if NESB

1. Is the patient able to:-
- Maintain alertness for at least 20 minutes? Yes ☐ No ☐
- Maintain posture/positioning in upright sitting? Yes ☐ No ☐
- Hold head erect? Yes ☐ No ☐

STOP HERE if you answered NO to ANY part of Q1. Place patient Nil by Mouth and review when conditions improves. NG recommended for medications.

2. Does the patient have any of these?
- Suspected brainstem stroke (Check file) Yes ☐ No ☐
- Facial weakness/droop (Check smile, pout, nasolabial fold) Yes ☐ No ☐
- Slurred/absent speech (Engage in conversation) Yes ☐ No ☐
- Coughing on saliva Yes ☐ No ☐
- Drooling (Check corner of mouth, chin) Yes ☐ No ☐
- Hoarse/absent voice (Engage in conversation) Yes ☐ No ☐
- Weak/absent cough (Ask to cough) Yes ☐ No ☐
- Shortness of breath Yes ☐ No ☐
- Pre-existing swallowing difficulty (Check file, ask family) Yes ☐ No ☐

STOP HERE if you answered YES to ANY part of Q2. Place patient Nil by Mouth and refer to Speech Pathology on Page xxxxx.

3. Test the patient with a sip of water and observe:
- Any coughing/throat clearing Yes ☐ No ☐
- Change in vocal quality Yes ☐ No ☐
- Drooling Yes ☐ No ☐
- Change in respiration/shortness of breath Yes ☐ No ☐

STOP HERE if you answered YES to ANY part of Q3. Place patient Nil by Mouth and refer to Speech Pathology on Page xxxxx.

4. Observe the patient drink a cup of water:
- Any coughing/throat clearing Yes ☐ No ☐
- Change in vocal quality Yes ☐ No ☐
- Drooling Yes ☐ No ☐
- Change in respiration/shortness of breath Yes ☐ No ☐

STOP HERE if you answered YES to ANY part of Q4. Place patient Nil by Mouth and refer to Speech Pathology on Page xxxxx.

5. Commence premorbid oral diet
- Nursing staff to observe patient with first meal
- Staff Member reviewing first meal: _____

Time: Date:

A spike in temperature and/or deterioration in chest condition may indicate silent aspiration. Place patient NBM and refer to Speech Pathology on Page xxxxx.

Appendix 9

Percentage Agreement of Speech Pathologist Diagnosis

Bolus	Rater 1	Rater 2	Rater 3	% Agreement
10011	2	3	3	2/3
10012	2	2	2	3/3
10013	3	3	3	3/3
10014	3	1	2	0/3
10015	3	1	3	2/3
10016	3	1	3	2/3
10021	3	2	4	0/3
10022	4	4	4	3/3
10023	2	4	4	2/3
10024	4	4	4	3/3
10025	4	4	4	3/3
10026	4	4	4	3/3
10031	2	3	2	2/3
10032	3	3	3	3/3
10033	3	3	3	3/3
10034	2	4	2	2/3
10035	2	1	3	0/3
10036	4	1	3	0/3
10051	3	1	3	2/3
10052	2	2	3	2/3
10053	2	4	2	2/3
10054	3	4	2	0/3
10055	3	4	2	0/3
10056	3	4	2	0/3
10061	1	1	3	2/3
10062	4	4	2	2/3
10063	4	4	4	3/3
10064	3	1	2	2/3
10065	3	1	3	2/3
10066	3	1	3	2/3
10071	1	1	1	3/3
10072	2	1	3	0/3
10073	2	3	3	2/3
10074	3	4	2	0/3
10075	3	4	4	2/3
10076	2	4	2	2/3
10081	1	1	3	2/3
10082	2	3	2	2/3

10083	4	4	2	2/3
10084	2	4	2	2/3
10085	2	4	2	2/3
10086	2	2	2	3/3
10131	2	3	2	2/3
10132	2	3	2	2/3
10133	2	3	3	2/3
10134	2	2	4	2/3
10135	2	3	2	2/3
10136	2	2	2	3/3
10151	2	3	2	2/3
10152	2	3	2	2/3
10153	2	3	2	2/3
10154	2	1	3	0/3
10155	2	2	3	2/3
10156	3	4	3	2/3
10221	2	2	2	3/3
10222	2	2	2	3/3
10223	2	2	2	3/3
10224	3	3	3	3/3
10225	3	3	3	3/3
10226	3	3	3	3/3
10241	1	3	3	2/3
10242	1	3	3	2/3
10243	1	3	3	2/3
10244	1	2	3	0/3
10245	1	4	3	0/3
10246	1	4	3	0/3
10261	1	1	1	3/3
10262	1	1	1	3/3
10263	4	2	2	2/3
10264	1	4	1	2/3
10265	1	2	1	2/3
10266	1	4	1	2/3
10271	1	2	3	0/3
10272	4	4	4	3/3
10273	4	4	4	3/3
10274	1	4	2	0/3
10275	1	1	3	2/3
10276	1	1	3	2/3
10281	3	2	2	2/3
10282	2	2	2	3/3
10283	3	2	2	2/3

10284	2	4	2	2/3
10285	3	2	2	2/3
10286	3	2	2	2/3
				161/252 (64%)

Appendix 10

Diagnosis of Poor Bolus Containment vs Delayed Pharyngeal Swallowing

Participant Number	Trial	Consistency	Diagnosis
1001	1	thin	3
	2	thin	2
	3	thin	3
	1	fruit	1
	2	fruit	3
	3	fruit	3
1002	1	thin	4
	2	thin	4
	3	thin	4
	1	fruit	4
	2	fruit	4
	3	fruit	4
1003	1	thin	3
	2	thin	3
	3	thin	3
	1	fruit	2
	2	fruit	1
	3	fruit	1
1005	1	thin	3
	2	thin	2
	3	thin	2
	1	fruit	3
	2	fruit	3
	3	fruit	1
1006	1	thin	1
	2	thin	4
	3	thin	4
	1	fruit	3
	2	fruit	1
	3	fruit	1
1007	1	thin	1
	2	thin	1
	3	thin	2

	1	fruit	1
	2	fruit	1
	3	fruit	4
1008	1	thin	3
	2	thin	2
	3	thin	2
	1	fruit	3
	2	fruit	2
	3	fruit	2
1013	1	thin	2
	2	thin	2
	3	thin	2
	1	fruit	2
	2	fruit	3
	3	fruit	2
1015	1	thin	2
	2	thin	2
	3	thin	2
	1	fruit	2
	2	fruit	2
	3	fruit	3
1022	1	thin	2
	2	thin	2
	3	thin	2
	1	fruit	3
	2	fruit	3
	3	fruit	3
1024	1	thin	3
	2	thin	3
	3	thin	3
	1	fruit	1
	2	fruit	1
	3	fruit	1
1026	1	thin	1
	2	thin	1
	3	thin	2
	1	fruit	1
	2	fruit	1
	3	fruit	1
1027	1	thin	1
	2	thin	4
	3	thin	4
	1	fruit	3
	2	fruit	3
	3	fruit	1

1028	1	thin	3
	2	thin	2
	3	thin	3
	1	fruit	3
	2	fruit	3
	3	fruit	3

Note: 1 = Poor bolus containment; 2 = Delay; 3 = Both; 4 = Neither

Appendix 11

Cluster Membership

Participant Number	Age	Gender	Consistency	Swallow number	PAS	OTT	STD def 1	STD def 2	Posterior isometric lingual-palatal pressure	Posterior isometric lingual-palatal pressure during swallowing	Posterior tongue sensation	Right FA sensation	Left FA sensation	Cluster group
1001	70	f	thin	1	3	0.65	1.12	0.24	43.5	19.5	2.75	2.9	4.5	1
				2	1	1.18	0.28	0.28						
				3	6	-1.98	2.74	0.39						
			fruit	1	1	-6.87	7.69	0.6						
				2	1	-4.37	5	0.49						
				3	1	-1.17	3.31	0.4						
1002	77	m	thin	1	5	-0.68	1.07	0.03	11.5	12	4.85	4.85	4	1
				2	2	0.76	0.02	0.02						
				3	2	0.45	0.03	0.03						
			fruit	1	1	0.8	-0.05	-0.05						
				2	1	0.9	-0.1	-0.1						
				3	1	-2.55	3.39	-0.09						
1003	71	f	thin	1	1	0.22	0.77	0.39	36.5	21.5	1.55	2.2	1.8	3
				2	3	-0.21	0.64	0.12						
				3	2	-0.36	0.8	0.2						
			fruit	1	1	-1.69	1.82	1.82						
				2	1	1.94	2.13	-0.03						
				3	1	-0.36	1.05	-0.02						
1005	74	m	thin	1	8	-1.68	2.19	0.36	20	8	3.15	2.6	2.75	3
				2	7	0.32	0.34	0.34						
				3	5	0.08	0.26	0.26						
			fruit	1	1	-9.56	0.1	-0.07						
				2	3	-9.86	10.31	0.39						

				3	1	-5.48	5.98	0.37						
1006	66	m	thin	1	8	-0.06	0.13	-0.17	22	11	1.5	4.25	2.4	3
				2	3	0.51	-0.41	-0.41						
				3	3	0.76	-0.1	-0.1						
			fruit	1	2	-8.79	9.82	0.67						
				2	2	-9.38	9.52	0.27						
				3	2	-15.83	15.86	0.81						
1008	79	f	thin	1	5	-0.23	0.3	0.04	6	8.5	2.4	2.75	2.25	3
				2	3	0.2	0.12	0.12						
				3	3	0.57	0	0						
			fruit	1	1	-0.28	1.43	0.1						
				2	1	1.04	0.6	0.6						
				3	1	-3.79	4.01	3.53						
1013	63	f	thin	1	2	0.39	0.02	0.02	14.5	12.5	3.55	3.15	3.4	1
				2	3	0.78	0.09	0.09						
				3	2	0.64	0.34	0.34						
			fruit	1	1	1.07	0.11	0.11						
				2	1	-0.57	0.49	0.02						
				3	1	missing	0.07	0.07						
1015	80	m	thin	1	7	0.03	0.26	0.26	29	21.5	1.75	2.85	3.6	3
				2	3	0.62	0.38	0.38						
				3	3	0.25	0.16	0.16						
			fruit	1	1	missing	1.79	1.79						
				2	1	missing	4.22	3.5						
				3	1	-5.98	6.84	1.47						
1024	83	m	thin	1	5	-1.79	1.96	-0.08	8	14.5	3.7	3.1	2.1	3
				2	3	-1.79	2	0.1						
				3	3	0.14	1.96	0.1						
			fruit	1	1	-6.26	6.23	-0.13						
				2	1	-19.96	19.96	-0.18						
				3	1	-18.06	18.23	-0.06						
1026	82	f	thin	1	3	-0.85	0.77	-0.05	25	13	1.2	1	2.3	3

				2	3	1.09	0.41	0.02					
				3	8	0.58	0.06	0.06					
			fruit	1	1	-3.38	3.66	0.05					
				2	2	-0.41	0.57	0.01					
				3	1	-0.93	1.93	0.01					
1027	87	m	thin	1	8	1.11	1.93	-0.09	35	15.5	2.05	2.5	2.9	3
				2	2	0.57	-0.04	-0.04					
				3	2	1.86	-0.01	-0.01					
			fruit	1	1	-4.46	4.6	-0.13					
				2	1	-4.93	5.08	-0.1					
				3	1	-5.6	5.73	-0.19					
1028	63	m	thin	1	1	0.27	1.3	1.3	23.5	15	0.95	1.55	3.25	3
				2	3	0.18	0.5	0.5					
				3	2	0.39	0.89	0.89					
			fruit	1	1	-10.14	11.51	-0.13					
				2	1	-3.58	3.95	-0.07					
				3	1	-6.61	11.42	3.55					

Appendix 12

Participant Information Sheets

THE UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
ROSE CENTRE
FOR STROKE RECOVERY & RESEARCH
Te Puna Whakaora Rehu Ohotata
AT ST. GEORGE'S MEDICAL CENTRE
Ki te Whare Hauora o St.George

NSW GOVERNMENT Health
Northern Sydney
Local Health District

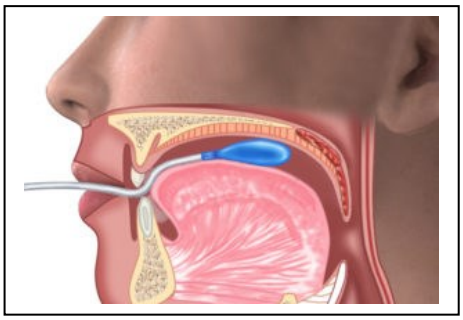
ROYAL NORTH SHORE HOSPITAL

RESEARCH PARTICIPANTS WANTED

We are looking for healthy participants to investigate tongue strength and oral sensation in healthy adults.

This research project will take approximately 45 minutes of your time, carried out on one occasion. You will be asked to perform three tasks designed to identify normal function of the tongue and normal oral sensation.

The first task will involve placing an electrode, which is attached to a gloved hand into your mouth (Picture 1). A small, painless electrical current will be applied to your mouth through these electrodes and you will be asked to indicate when any sensation is felt. The second and third task will involve using your tongue to squeeze an air-filled bulb as hard as you can and during swallowing (Picture 2).



2

You will receive a parking voucher to allow you to park in the hospital car park during the study. If you do agree to take part in this study, you are free to withdraw at any time, without having to give a reason.

If you are over 20 years of age, have no history of swallowing impairment or neurological disorder, and are interested in participating, contact:

Dijana Dragicevich
Royal North Shore Hospital
94631622

The study is being conducted by Dijana Dragicevich, Senior Speech Pathologist at Royal North Shore Hospital and PhD student, under the supervision of Professor Maggie-Lee Huckabee at the Rose Centre for Stroke Recovery and Research at the University of Canterbury, Christchurch, New Zealand and Professor Ng, Neurologist at Royal North Shore Hospital. This study has been approved by the Northern Sydney Local Health District Human Research Ethics Committee, ref: 2019/ETH00413.

ROYAL NORTH SHORE HOSPITAL
PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL RESEARCH STUDY

What is Normal Oral Sensation and Tongue Strength in a Healthy Population of Community Dwelling Adults?

Invitation
You are invited to participate in a research study that will measure oral sensation and tongue strength in healthy individuals.

The study is being conducted by Dijana Dragicevich, Senior Speech Pathologist at Royal North Shore Hospital and PhD student, under the supervision of Professor Maggie-Lee Huckabee from the Rose Centre for Stroke Recovery and Research at the University of Canterbury, Christchurch, New Zealand and Professor Karl Ng, Neurologist at Royal North Shore Hospital.

Before you decide if you wish to participate in this study, it is important to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

'What is the purpose of this study?'
The purpose of this study is to establish normal values for oral sensation and tongue strength, which will be used as a comparison in further study as a measure to compare impaired oral sensation and tongue strength and patients who have had a stroke. Understanding how oral sensation and tongue strength are impaired in those who have swallowing difficulties following a stroke will improve the diagnosis of swallowing difficulties and better guide swallowing rehabilitation techniques.

'Why have I been invited to participate in this study?'
You are eligible to participate in this study because

- You are healthy with no open wounds, abrasions or dental work in your mouth within the 3 months prior to the study,
- You do not have any pre-existing neurological disorder including numbness in the tongue, impaired sensitivity, poor circulation or inability to keep the tongue in one position for a period of time,
- You are not pregnant
- You have not used any substances that may affect perception including alcohol, drugs or caffeine in the 12-hour period prior to the study.

'What if I don't want to take part in this study or if I want to withdraw later?'
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. Your participation in the study will involve 1 visit. You are also invited to participate in a repeat study of the tests by another clinician on the same day and then again one week later by the original clinician. This will be evaluating the reliability of the tests.

If you agree to be involved in this study, you will be asked to participate in two assessments:

1. Assessment of tongue strength: You will be asked to squeeze a small air-filled bulb in the mouth against the roof of your mouth with your tongue.
2. Assessment of oral sensation: A small, safe electrode will be placed in various parts of your mouth. You will be required to indicate when you can feel a sensation, which will feel like a vibration.

Both of these assessments will be done in the outpatients department on level 3 of the Royal North Shore Hospital by an experienced speech pathologist.

'How is this study being paid for?'
The study is being sponsored by Northern Sydney Local Health District.

'Are there risks to me in taking part in this study?'
All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study involve the assessment of sensation. This assessment uses electrical stimulation. Electrical stimulation can be associated with skin irritation. However, as the amount of stimulation in this case is very low, so as only to detect a sensation, this is unlikely to occur.

'What happens if I suffer injury or complications as a result of the study?'
If you suffer any injuries or complications as a result of this study, you should contact the primary investigator as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

'Will I benefit from the study?'
This study aims to further medical knowledge and may improve future treatment of swallowing difficulties. However, the study will not directly benefit you.

'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. You will be provided with a parking voucher to cover your costs of parking on site at Royal North Shore Hospital.

'How will my confidentiality be protected?'
Of the people treating you, only those named above will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above and members of the Research Office at Northern Sydney Local Health District i.e. the Human Research Ethics Committee (HREC) for monitoring purposes will have access to your details and results that will be held securely at the Royal North Shore Hospital. Only non-identifiable information will be sent off site. This will only occur when necessary and the provisions of Australian privacy law will be complied with. Non-identifiable data will be sent to researchers at the University of Canterbury in New Zealand for analysis using a secure NSW Health online sharing platform called ShareFile.

'What happens with the results?'
If you give us your permission by signing the consent document, we plan to discuss/publish the results as part of a PhD thesis, in peer-reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

'What should I do if I want to discuss this study further before I decide?'
When you have read this information, the researcher Dijana Dragicevich will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 9463-1622. You may also contact Maggie-Lee Huckabee via email maggie-lee.huckabee@canterbury.ac.nz who is the academic supervisor of the study or Professor Karl Ng who is a local supervisor on 9463-1831.

'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference number 2019/ETH00413.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

ROYAL NORTH SHORE HOSPITAL
CLINICAL RESEARCH STUDY

WHAT IS NORMAL ORAL SENSATION AND TONGUE STRENGTH IN A HEALTHY POPULATION OF COMMUNITY DWELLING ADULTS?

I,.....
of.....
agree to participate as a subject in the study described in the Participant Information Sheet set attached to this form.

I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators or my treatment at Royal North Shore Hospital.

I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

I understand that if I have any questions relating to my participation in this research, I may contact Dijana Dragicevich 9463-1622 who will be happy to answer them.

I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065 Phone 02 9926 4590
Email: NSLHD-research@health.nsw.gov.au

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____
Signature of investigator	**Please PRINT name**	**Date**

ROYAL NORTH SHORE HOSPITAL
CLINICAL RESEARCH STUDY

WHAT IS NORMAL ORAL SENSATION AND TONGUE STRENGTH IN A HEALTHY POPULATION OF COMMUNITY DWELLING ADULTS?

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Royal North Shore Hospital or my medical attendants.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Dijana Dragicevich
Senior Speech Pathologist
Royal North Shore Hospital
Reserve Road
St Leonards
NSW 2065

THE UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
ROSE CENTRE
FOR STROKE RECOVERY & RESEARCH
Te Puna Whakaora Rehu Ohotata
AT ST. GEORGE'S MEDICAL CENTRE
Ki te Whare Hauora o St.George

NSW GOVERNMENT Health
Northern Sydney
Local Health District

ROYAL NORTH SHORE HOSPITAL
PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL RESEARCH STUDY

THE CONTRIBUTION OF SENSORY LOSS AND WEAKNESS TO DYSPHAGIA IN ACUTE STROKE

Invitation

You are invited to participate in a research study into how sensation and weakness in the mouth contribute to swallowing difficulties after a new stroke.

The study is being conducted by Dijana Dragicevich, Senior Speech Pathologist at Royal North Shore Hospital and PhD student, under the supervision of Professor Maggie-Lee Huckabee from the Rose Centre for Stroke Recovery and Research at the University of Canterbury, Christchurch, New Zealand and Professor Karl Ng, Neurologist at Royal North Shore Hospital.

Before you decide if you wish to participate in this study, it is important to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

'What is the purpose of this study?'

The purpose of this study is to investigate whether Speech Pathologists' diagnosis of swallowing disorders match results of sensation and strength tests. Understanding how oral sensation and tongue strength are impaired in those who have swallowing difficulties following a stroke will improve the diagnosis of swallowing difficulties and better guide swallowing rehabilitation techniques.

'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you have had a stroke and have swallowing difficulties.

'What if I don't want to take part in this study or if I want to withdraw later?'
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

'What does this study involve?'
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. Your involvement in the study will involve 2-3 visits over a weeklong period during your stay in hospital. Most of the assessments will occur on the same day. All of the assessments are usual practice except for the test of oral sensation, which is additional to standard care.

If you agree to participate in this trial, you will receive an assessment of swallowing known as a Fibreoptic Endoscopic Evaluation of Swallowing (FEES). This will occur at your bedside whilst you are in hospital. A small camera is inserted into the nose by a Speech Pathologist who is trained and competent to perform these examinations. This test is commonly used for assessment of swallowing. It is a little uncomfortable but not usually painful and will let us evaluate how you manage the food in your throat.

You will then be asked to participate in two more assessments:

1. Assessment of tongue strength: You will be asked to squeeze a small air-filled bulb in the mouth against the roof of your mouth with your tongue. This will also be done at your bedside by an experienced speech pathologist. This test is a common test to evaluate tongue strength for those who have speech and swallowing difficulties.
2. Assessment of oral sensation: A small, safe electrode will be placed in various parts of your mouth. You will be required to indicate when you can feel a sensation,

which will feel like a vibration. This will be done in the outpatients department on level 3 of the Royal North Shore Hospital by an experienced speech pathologist.

Depending on the results, you may be asked to participate in one further assessment of swallowing known as a “modified barium swallow” or “videofluoroscopic swallowing study”. This assessment will be done in the radiology department by a team of speech pathologists and radiographers. You will be asked to swallow 3 sips of water and 3 spoons of diced fruit. Both of these have barium mixed into them so that they can be seen on the x-ray equipment. This assessment is a shortened version of usual practice.

In addition, the researchers would like to have access to your medical record to obtain information relevant to the study. The information collected will include demographic details, medical history details, medical imaging tests and results, and details regarding your stroke and how it has affected you.

‘How is this study being paid for?’

The study is being sponsored by Northern Sydney Local Health District.

‘Are there risks to me in taking part in this study?’

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

- Fibreoptic Endoscopic Evaluation of Swallowing (FEES): There is minor discomfort and a very small risk of nose bleeding that stops easily. This is not common, affecting 6 in 100 stroke patients.
- Videofluoroscopic Swallowing Study (VFSS): There is exposure to radiation associated with the procedure; however, this is a very small amount. As with all exposure to radiation, the risk is associated with the amount or duration of exposure. Duration will be kept as short as possible to reduce this risk. The

amount of radiation you will receive from the VFSS is less than half of the radiation exposure on a long-haul flight.

- Assessment of sensation: This assessment uses electrical stimulation. Electrical stimulation can be associated with skin irritation. However, as the amount of stimulation in this case is very low, so as only to detect a sensation, this is unlikely to occur.

'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the primary investigator as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

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This study aims to further medical knowledge and may improve future treatment of swallowing difficulties. You will have information regarding your swallowing diagnosis obtained from the assessments, which may benefit your swallowing treatment planning; however, the study may not directly benefit you.

'Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything. All the tests will be done while you are a patient in the hospital. You will not be paid for your participation in the study.

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'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results as part of a PhD thesis, in peer-reviewed journals, presentation at conferences or other professional forums.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher Dijana Dragicevich will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 9463-1622. You may also contact Maggie-Lee Huckabee via email maggie-lee.huckabee@canterbury.ac.nz who is the

academic supervisor of the study or Professor Karl Ng who is a local supervisor on 9463-1831.

'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference number 2019/ETH00413.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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NSW GOVERNMENT Health
Northern Sydney
Local Health District

ROYAL NORTH SHORE HOSPITAL
CLINICAL RESEARCH STUDY

THE CONTRIBUTION OF SENSORY LOSS AND WEAKNESS TO DYSPHAGIA IN ACUTE STROKE

(How sensation and weakness in the mouth contributes to swallowing difficulties after a new stroke)

I,.....
of.....
agree to participate as a subject in the study described in the Participant Information Sheet set attached to this form.

I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation, and I have received satisfactory answers.

I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators or my treatment at Royal North Shore Hospital.

I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

I understand that if I have any questions relating to my participation in this research, I may contact Dijana Dragicevich 9463-1622 who will be happy to answer them.

I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065 Phone 02 9926 4590
Email: NSLHD-research@health.nsw.gov.au

Signature of participant	**Please PRINT name**	**Date**
_____		
Signature of witness	**Please PRINT name**	**Date**

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NSW GOVERNMENT Health
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Signature of investigator **Please PRINT name** **Date**

ROYAL NORTH SHORE HOSPITAL
CLINICAL RESEARCH STUDY

THE CONTRIBUTION OF SENSORY LOSS AND WEAKNESS TO DYSPHAGIA IN ACUTE STROKE

(How sensation and weakness in the mouth contributes to swallowing difficulties after a new stroke)

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Royal North Shore Hospital or my medical attendants.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Dijana Dragicevich
Senior Speech Pathologist
Royal North Shore Hospital
Reserve Road
St. Leonards, NSW 2065

ROYAL NORTH SHORE HOSPITAL
PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL RESEARCH STUDY

THE CONTRIBUTION OF SENSORY LOSS AND WEAKNESS TO DYSPHAGIA IN ACUTE STROKE

Invitation
The person you are responsible for (the participant) has been invited to participate in a research study into how sensation and weakness in the mouth contribute to swallowing difficulties after a new stroke.

The study is being conducted by Dijana Dragicevich, Senior Speech Pathologist at Royal North Shore Hospital and PhD student, under the supervision of Professor Maggie-Lee Huckabee from the Rose Centre for Stroke Recovery and Research at the University of Canterbury, Christchurch, New Zealand and Professor Karl Ng, Neurologist at Royal North Shore Hospital.

Before you and the participant decide to participate in this study, it is important to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with the participant and others if you wish.

'What is the purpose of this study?'
The purpose of this study is to investigate whether Speech Pathologists' diagnosis of swallowing disorders match results of sensation and strength tests. Understanding how oral sensation and tongue strength are impaired in those who have swallowing difficulties following a stroke will improve the diagnosis of swallowing difficulties and better guide swallowing rehabilitation techniques.

'Why has the participant been invited to participate in this study?'
The participant is eligible to participate in this study because they have had a stroke and have swallowing difficulties.

'What if I don't want the participant to take part in this study or if I want them to withdraw later?'
Participation in this study is voluntary. It is completely up to you and the participant to decide whether or not they participate. If you decide not to participate, it will not affect the treatment the participant receives now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for the participant. If you wish the participant to withdraw from the study once it has started, you can do so at any time without having to give a reason.

‘What does this study involve?’
If you and the participant agree to participate in this study, you will be asked to sign the Participant Consent Form. The participant’s involvement in the study will involve 2-3 visits over a weeklong period during their stay in hospital. Most of the assessments will occur on the same day. All of the assessments are usual practice except for the test of oral sensation, which is additional to standard care.

If you agree to the participant’s participation in this trial, they will receive an assessment of swallowing known as a Fibreoptic Endoscopic Evaluation of Swallowing (FEES). This will occur at their bedside whilst they are in hospital. A small camera is inserted into the nose by a Speech Pathologist who is trained and competent to perform these examinations. This test is commonly used for assessment of swallowing. It is a little uncomfortable but not usually painful and will let us evaluate how the participant manages the food in their throat.

The participant will then be asked to participate in two more assessments:
1. Assessment of tongue strength: The participant will be asked to squeeze a small air-filled bulb in the mouth against the roof of their mouth with their tongue. This will also be done at the bedside by an experienced speech pathologist. This test is a common test to evaluate tongue strength for those who have speech and swallowing difficulties.
2. Assessment of oral sensation: A small, safe electrode will be placed in various parts of the participant’s mouth. They will be required to indicate when they can feel a sensation, which will feel like a vibration. This will be done in the outpatients department on level 3 of the Royal North Shore Hospital by an experienced speech pathologist.

Depending on the results, the participant may be asked to participate in one further assessment of swallowing known as a “modified barium swallow” or “videofluoroscopic swallowing study”. This assessment will be done in the radiology department by a team of speech pathologists and radiographers. The participant will be asked to swallow 3 sips of water and 3 spoons of diced fruit. Both of these have barium mixed into them so that they can be seen on the x-ray equipment. This assessment is a shortened version of usual practice.

In addition, the researchers would like to have access to the participant’s medical record to obtain information relevant to the study. The information collected will include demographic details, medical history details, medical imaging tests and results, and details regarding the participant’s stroke and how it has affected them.

‘How is this study being paid for?’
The study is being sponsored by Northern Sydney Local Health District.

‘Are there risks to the participant in taking part in this study?’
All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all

reasonable precautions, the participant might develop medical complications from participating in this study. The known risks of this study are:

- Fibreoptic Endoscopic Evaluation of Swallowing (FEES): There is minor discomfort and a very small risk of nose bleeding that stops easily. This is not common, affecting 6 in 100 stroke patients.
- Videofluoroscopic Swallowing Study (VFSS): There is exposure to radiation associated with the procedure; however, this is a very small amount. As with all exposure to radiation, the risk is associated with the amount or duration of exposure. Duration will be kept as short as possible to reduce this risk. The amount of radiation the participant will receive from the VFSS is less than half of the radiation exposure on a long haul flight.
- Assessment of sensation: This assessment uses electrical stimulation. Electrical stimulation can be associated with skin irritation. However, as the amount of stimulation in this case is very low, so as only to detect a sensation, this is unlikely to occur.
- Additionally, if the participant has a cognitive impairment, it may be more difficult to know if they are suffering discomfort. However, as the lead researcher is a Speech Pathologist with over 20 years of experience, their ability to facilitate communication should make this easier. A visual pain scale will also be used to assess if pain is experienced during the oral sensation task.

'What happens if the participant suffers injury or complications as a result of the study?'

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Signature of responsible person	**Please PRINT name**	**Date**
_____		
Signature of witness	**Please PRINT name**	**Date**

Signature of investigator	Please PRINT name	Date

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