New Directions in the Diagnostic Assessment of Swallowing Disorders in Children

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Submitted for the Degree of Master of Science
February 2011

To Tim

& Amelie

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ASCII	The American Standard Code for Information Interchange
AP	Aspiration – Penetration Score
BR	Bolus Residue Score
CLD	Chronic Lung Disease
cm	centimetre
CP	Cerebral Palsy
DDS	Dysphagia Disorders Survey
DMSS	Dysphagia Management Staging Scale
ENT	Ear, Nose and Throat
FEES	Fibreoptic Endoscopic Evaluation of Swallowing
FTT	Failure To Thrive
fMRI	functional Magnetic Resonance Imaging
HRM	High Resolution Manometry
LOS	Lower Oesophageal Sphincter
LRTI	Lower Respiratory Tract Infection
MATLAB®	Matrix Laboratory (Mathworks Inc.)
MII	Multi-channel Intraluminal Impedance
mm	millimetre
mmHg	millimetre mercury
Ω	Ohms
OSAS	Obstructive Sleep Apnoea Syndrome
TOF	Tracheo-Oesophageal Fistula
VFSS	Videofluoroscopic Swallowing Study
WCH	Women's and Children's Hospital

SUMMARY AND DECLARATION

Assessment and management of swallowing disorders is one of the key areas focused on by speech pathologists working with children in an acute setting. Swallowing is an extremely complex process of bolus passage from the oral cavity through to the oesophagus. Numerous muscles and nerves work together to produce contractions of the tongue and pharynx, initiate laryngeal elevation, and together with the passage of the bolus create pressure changes to move the food or liquid toward the oesophagus. Swallowing difficulties are disruptive to quality of life, impact nutrition and chest health, and at their worst can significantly reduce lung function and ultimately result in reduced life span and death. The age and range of children experiencing dysphagia varies widely, but the group experiencing most swallowing difficulties is that of children with neurological conditions. Feeding difficulties affect over half of children with neurological impairment (such as cerebral palsy), and swallowing disorders are present in up to 76% of children with severe brain injury (Morgan, Mageandran, & Mei, 2009; Morgan, Ward, Murdoch, Kennedy, & Murison, 2003; Sullivan et al., 2000). Pharyngeal stage swallowing difficulties are common within this group (Rogers, Arvedson, Buck, Smart, & Msall, 1994; Sullivan, et al., 2000) and the degree of disability correlates with the severity of dysphagia (Sullivan, et al., 2000).

The aim of this body of work was to contribute knowledge regarding the assessment of paediatric swallowing disorders, with the long-term goal of impacting therapy and management. Currently the most common assessment of dysphagia in this group, the videofluoroscopic swallow study (VFSS), utilises radiology. For children in particular, the issue of radiation exposure must be considered, especially if the child is to have repeat studies throughout childhood (Weir et al., 2007). Alternative methods of determining pharyngeal dysphagia and risk of aspiration and, therefore, also its impact on health and wellbeing, would be extremely beneficial for this group.

This study proposes the use of impedance, or combined manometry and impedance to objectively assess swallowing disorders in children. While these methods were combined with radiology for validation purposes in this study, there is the potential for the technique to be developed to a level where information regarding the swallow can be derived without the need for radiology.

The *Flow Interval*, an objective method utilising impedance during assessment of bolus flow through the pharynx, was derived during the study. A longer Flow Interval was identified in those children who were at increased risk of aspiration. The further development of this technique will serve to enable more precise objective definition of the mechanisms of swallow dysfunction, and therefore, also the possibility of developing novel therapy options for these children with significant swallowing disorders.

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

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Larissa Kate Noll, 28th February 2011

ACKNOWLEDGMENTS

To all the patients and their families who participated in this study or discussions about it – thank you. Your time and interest has been greatly appreciated and has contributed towards assisting others who experience dysphagia in the future. Thank you to Professor Dr Nathalie Rommel for her support, her encouragement of me in taking on the project, hosting me at her workplace in Leuven, Belgium, and offering her advice and expertise on assessment and management of children with dysphagia. Thank you to Dr Taher Omari for all his knowledge and work on the manometry and impedance systems, and for teaching me and encouraging the development of my research and analytical skills. To my supervisors at Flinders University, Dr Ingrid Scholten for her review of many drafts and Professor Andy Butcher for his support with draft reviews and insight into the balance of fitting life around a Master's degree. My appreciation also goes to the staff of the Women's and Children's Hospital, particularly Lisa McCall and staff of the Gastroenterology and Radiology departments for all their assistance during the assessments, my colleagues in Speech Pathology and to those who assisted in data analysis.

A special thanks to my family and friends … my parents for always encouraging me in my education, my parents in-law for their understanding and all the baby-sitting support during hours of write up …to my best friend Anita for making such a difference with her words of wisdom, her constant support and care, the many laughs and time out from study to keep things in balance. To my dear little daughter Amelie for teaching me so many other things along the way, for the hugs and cuddles and for putting up with all of "mummy's work"… and to my husband Tim for all his love, the many meals cooked, and for being my travel companion and loyal supporter over the years this study took. I couldn't have completed it without all your love and support. I'm incredibly thankful.

PUBLICATIONS

Noll, L., Rommel, N., Davidson, G. P. & Omari, T. I. (2011). Pharyngeal flow interval: a novel impedance-based parameter correlating with aspiration. *Neurogastroenterology and Motility*, *23*(6), 551-e206.

1 INTRODUCTION

Swallowing disorders (dysphagia) can result from structural, infectious, metabolic, myopathic, neurological and iatrogenic causes (Burklow, Phelps, Schultz, McConnell, & Rudolph, 1998; Cook & Kahrilas, 1999; Rommel, De Meyer, Feenstra, & Veereman-Wauters, 2003). Swallowing difficulties in children are related to, but not limited to disruptions to respiratory systems, for example laryngomalacia or tracheomalacia (floppy larynx or trachea); cardiorespiratory problems, such as diseases that interrupt the coordination of sucking, swallowing and breathing; structural abnormalities, such as oesophageal strictures, cleft palate, vocal fold palsy etc.; behavioural issues; metabolic disorders and neurological conditions (Burklow, et al., 1998). Attempts to classify feeding disorders into a dichotomy of organic versus non-organic have not been possible as such disorders in children are often a combination of both organic and non-organic factors (Burklow, et al., 1998). Dysphagia as a result of prematurity, neurological insult or acute medical conditions has become a more frequent occurrence due to the increasing survival rate of these infants (Newman, Keckley, Peterson, & Hamner, 2001; Rommel, et al., 2003). Sequelae, such as poor nutrition, aspiration pneumonia and choking during feeds often necessitate alternative feeding methods by nasogastric or gastrostomy tube and generally also negatively impact the development of oromotor and oral feeding skills in these young children (Burklow, et al., 1998; Rommel, et al., 2003; Starr, 2006; Wolf & Glass, 1992). Prolonged failure to feed orally due to a swallowing disorder can result in aversion and lack of interest in feeding once it is deemed safe to do so (Burklow, et al., 1998; Rommel, et al., 2003; Wolf & Glass, 1992). Effective assessment of these difficulties is necessary in order to safely provide intervention to maintain and develop oral skills.

The role of speech pathology in assessment and management in the area of dysphagia has increased and become more widely identified since its beginning in the 1930s (Miller & Groher, 1993). Speech pathologists initially became involved in dysphagia assessments due to the combined presentation of speech and swallowing disorders in clients receiving therapy. These early assessments not only described the disorder, but aimed at finding the clients' strengths in order to rehabilitate function (Miller & Groher, 1993).

While there has been extensive research into normal and disordered swallowing in the adult population, there currently exists little objective information about the mechanics of the normal paediatric swallow (DeMatteo, Matovich, & Hjartarson, 2005), and therefore, knowledge regarding what is occurring when swallowing fails is also limited. Children are not merely "little adults", and therefore, the results of research in adults cannot be directly applied to assessment and therapy with children (DeMatteo, et al., 2005; Newman, et al., 2001). In the following chapter, a discussion of anatomy and physiology of normal swallowing will be presented followed by a description of disorders of swallowing (dysphagia). The current instrumental assessments available will also be outlined, with the aim of expanding on these in subsequent chapters to include descriptions of evolving objective measures (pharyngeal manometry and impedance) used in the assessment of swallowing, primarily in the adult population. The application of a new assessment method combining manometry and impedance will then be proposed for use with children, to assess dysphagia and provide objective information to characterise swallowing disorders in this unique population.

1.1 ANATOMY AND PHYSIOLOGY OF SWALLOW FUNCTION

This thesis discusses a new assessment technique for paediatric dysphagia. The assessment method used involves the insertion of a fine tube through the nasal cavity to be positioned in the throat. Sensors in this tube then measure movement of food and fluid during the swallow and the pressures involved during this process. In order to understand this method, the findings and the complexities of dysphagia assessment overall and a comprehensive understanding of anatomy and the normal swallow is required. It is also necessary to consider the differences between adult and paediatric anatomy. Therefore this is also discussed in the sections below.

The swallow is a complex process involving 26 pairs of muscles (Donner, Bosma & Robertson, 1985), five cranial nerves, and cervical nerves 1 and 2 (known as ansa cervicalis) (Arvedson & Brodsky, 1993). As the throat is a shared pathway for two vital functions (eating and breathing) the timing and interaction of these muscles of the mouth, jaw, tongue, palate, larynx and pharyngeal wall is crucial in order for food and fluids to move safely past the protected airway and into the oesophagus to satisfy the body's need for nutrition (Kahrilas, Clouse, & Hogan, 1994; McConnel, Cerenko, Jackson, & Guffin, 1988).

The muscles of deglutition and their innervation are discussed in the context of each of the major areas of the head and neck involved in swallowing. This comprises the nasal cavity, oral cavity, pharynx, larynx and upper oesophageal sphincter (UOS)/oesophagus. (The gross structures of the head and neck are pictured in Figure 1-1 and the numerous structures and muscles involved in swallowing, and their function and innervation are summarised in Table 1-1).

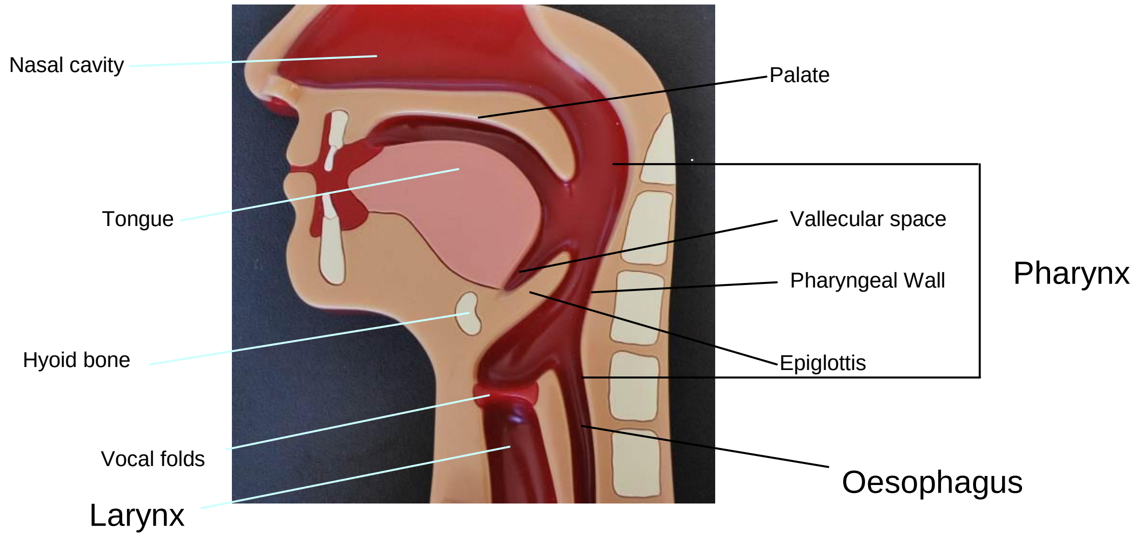


Figure 1-1: Key structures of the head and neck involved in the action of swallowing (Arvedson & Brodsky, 1993; Logemann, 1998). Photograph of Passy-Muir® Tracheostomy Observation Model, www.passy-muir.com

1.1.1 Nasal Cavity

The nasal cavity humidifies air breathed into the vocal tract and lungs. The maxilla (hard palate) forms the floor of the nasal cavity anteriorly, and the velum (soft palate) completes the palate posteriorly. The muscles of the velum (innervated by the Vagus Nerve, CNX) elevate the soft palate to occlude the nasal cavity during swallowing (and some speech sounds), and depress the palate to make contact with the tongue base during the oral phase of swallowing (Cichero, 2006a; Logemann, 1998).

1.1.2 Oral Cavity

The floor of the mouth consists of the mylohyoid, geniohyoid and anterior belly of digastric muscles, which attach to the mandible anteriorly and the hyoid posteriorly

Table 1-1: Cranial Nerves for innervation of muscles for swallowing

Nerves involved in swallowing	Oral Preparatory	Oral	Pharyngeal	Oesophageal
Trigeminal (V)		Masseter, Temporalis & lateral pterygoid relax for jaw to close. External pterygoid moves jaw forward. Sensory component provides feedback on touch to teeth, cheeks, anterior mouth & tongue.	Anterior movement of hyoid & larynx, which also permits closure of epiglottis over top of airway. Assistance from cervical nerves 1&2 for anterior hyoid movement.	Mylohyoid & anterior belly of digastric move hyoid forward with assistance from cervical nerves 1&2, to pull UOS open.
Facial (VII)	Saliva flow from submandibular and sublingual glands	Relaxation of Orbicularis Oris to allow bolus to enter, then contraction to maintain bolus in oral cavity. Stylohyoid and post. belly of digastric contribute to tongue movement for oral containment. Sensory component provides info on bolus position, & taste to anterior tongue.	Innervation of Stylohyoid & anterior belly of digastric for superior hyolaryngeal excursion. Retraction of base of tongue to posterior pharyngeal wall.	
Glossopharyngeal (IX)	Salivary flow from parotid		Faucial arch sensation (gag reflex) – swallow onset triggered.	
Vagus (X)	Recurrent laryngeal branch supplies interarytenoid and lateral cricoarytenoid for vocal fold adduction		Recurrent laryngeal branch supplies interarytenoid and lateral cricoarytenoid for true & false vocal fold adduction. Superior laryngeal nerve provides sensation to larynx, with sensory input to trachea at the level of the carina by the recurrent laryngeal nerve.	Relaxation of cricopharyngeus to allow opening of the UOS
Pharyngeal Plexus (IX & X)		Palatoglossus & tensor veli palatini contract for contact between soft palate and base of tongue for bolus containment in mouth.	Levator veli palatini for velopharyngeal closure. Superior, middle & inferior pharyngeal constrictor contraction to shorten pharynx. Sensation in oropharynx & hypopharynx.	Inferior pharyngeal constrictor contributes to UOS opening.
Hypoglossal (XII)		Styloglossus elevates tongue to contain bolus in mouth. Midline groove of intrinsic & extrinsic muscles of tongue, & placement of solid bolus between teeth. When bolus ready, hyoglossus tips tongue base, and propulsion from tongue tip to blade propels bolus into pharynx.	Innervation of Geniohyoid (assisted by cervical nerves 1&2) for anterior hyolaryngeal excursion, and strap muscles for superior hyolaryngeal excursion (also with cervical nerve 1&2 involvement).	

Information compiled from Arvedson & Brodsky (1993), Huckabee (2007) & Kahrilas (1994b).
UOS = Upper Oesophageal Sphincter

(Logemann, 1998). The hyoid bone, unattached to any other bone, is nestled in the base of the tongue and connected to the floor of mouth muscles and the larynx below. The hypoglossal nerve innervates the intrinsic and extrinsic muscles of the tongue, which control superior and lateral tongue movement, as well as tongue protrusion and retraction. The tongue pushes food between the teeth for grinding, mastication and mixing with saliva. Saliva is necessary for keeping the oral mucosa moist and aiding formation of a cohesive food bolus. The salivary glands (submandibular and sublingual) sit beneath the tongue and in the cheeks (parotid glands) (Logemann, 1998). The muscles of mastication are the temporalis, masseters, medial and lateral pterygoids, which are all supplied by the motor branch of the trigeminal nerve (cranial nerve V), which also provides sensation to the face, hard palate and anterior tongue. Lip closure for oral containment of the bolus is via the orbicularis oris, supplied by the facial nerve (cranial nerve VII), which also supplies sensation to the soft palate and part of the pharyngeal wall. Saliva flow from the submandibular and sublingual glands is also controlled by this nerve (Logemann, 1998).

1.1.3 Larynx

The larynx is the entry to the airway, which is protected superiorly by closure of the vocal folds and tilting of the epiglottis during swallowing. It is positioned anteriorly in the neck, the thyroid cartilage of the larynx being visible as the 'Adam's apple'. Elevation and excursion of the larynx by the floor of mouth and laryngeal strap muscles ensures the top of the airway is positioned under the tongue base as the food/fluid bolus passes, providing additional airway protection (Logemann, 1998). The larynx also has the additional function of voice for communication when air is pushed upwards from the lungs in a controlled manner past the vocal folds. Innervation of the larynx and vocal folds is via the recurrent laryngeal nerve and superior laryngeal nerve, both branches of the Vagus nerve (CN X). The stylopharyngeus muscle responsible for elevating the pharynx and larynx is supplied by the Glossopharyngeal nerve (CN IX) (Cichero, 2006a).

1.1.4 Pharyngeal structures

The pharyngeal region is often discussed in terms of the areas of nasopharynx, oropharynx and hypopharynx. The nasopharynx extends from the nasal cavity to the oropharynx, and the oropharynx is situated from the soft palate to the tip of the epiglottis. The region extending from the epiglottis to the UOS is the hypopharynx. The superior, middle and inferior pharyngeal constrictor muscles combine to form the posterior pharyngeal wall. The inferior constrictor is a combination of the thyropharyngeus muscle (superiorly) and cricopharyngeus muscle (inferiorly), the cricopharyngeus being the muscle that separates the pharynx from the oesophagus (Kahrilas, et al., 1994). Spaces known as the pyriform sinuses are formed at the point of lateral insertion of the inferior constrictor with the lateral walls of the thyroid cartilage (Kahrilas, et al., 1994). Innervation of the pharyngeal muscles is via the motor neurons originating from the nuclei of cranial nerves V, VII and XII, the nucleus ambiguus (vagal motor nucleus) and cervical vertebrae C1-C3 (Arvedson & Brodsky, 1993; Kahrilas, et al., 1994).

1.1.5 Oesophageal Structure

The oesophagus is a tubular structure made of striated and smooth muscle (Arvedson & Brodsky, 1993; Kahrilas, et al., 1994). It is a collapsed ‘tube’, positioned posterior to the larynx, its opening closed at rest by a band of muscle (the upper oesophageal sphincter). This sphincter relaxes and is pulled open by the action of the floor of mouth muscles elevating the larynx to allow food/fluid to pass through towards the stomach.

The oesophagus in an infant extends from cervical vertebrae four to six (C4-6), and ends at C9, but in adults is positioned one to two vertebrae higher (Hall, 2001). Motor and sensory innervation is via the recurrent laryngeal and superior laryngeal nerve branches of the Vagus nerve (cranial nerve X) (Arvedson & Brodsky, 1993; Kahrilas, et al., 1994).

1.1.6 Upper Oesophageal Sphincter (UOS)

The UOS is a zone of intraluminal high pressure, which lies at the junction of the pharynx and oesophagus in a region known as the pharyngo-oesophageal segment (PE segment, applying American spelling) (Bosma et al, 1986 cited in Hila, Castell & Castell, 2001). Kahrilas, Dodds, Dent, Logemann & Shaker (1988) reported on the high pressure zone at the approximate location of the cricopharyngeus muscle. In adults, this zone has been measured by manometry (tests of pressure) as ranging from between 2.5cm and 4.5cm in length. The cricopharyngeus is estimated to be 1-2cm wide (the zone where highest pressures are recorded), with the remainder of this region, known as the pharyngo-oesophageal segment, made up of muscles of the hypopharynx and/or oesophagus (Bosma et al, 1986, cited in Hila, et al., 2001; Kahrilas, 1994a). This muscle is attached to the cricoid cartilage anteriorly and, therefore, is required to become active with movement of the cricoid and laryngeal elevation during swallowing (Jacob, Kahrilas, Logemann, Shah, & Ha, 1989).

1.2 SWALLOW PHYSIOLOGY

The process of swallowing is often discussed in terms of four phases: oral preparatory, oral, pharyngeal and oesophageal. Despite being presented in this way, the functions described do not necessarily occur sequentially, but sometimes simultaneously. For example, velopharyngeal closure and laryngeal elevation occur together, as does opening of the UOS as the airway closes (Logemann, 1998). A disorder is possible at any or all of the phases described.

1.2.1 Oral Preparatory Phase

This phase is important for orientation to food and preparedness to eat or drink. It includes skills, such as smelling the food/drink, anticipating food/drink approaching the mouth and preparing to receive it, and receiving the bolus in the mouth without spillage anteriorly from the lips or posteriorly toward the pharynx. Solids are prepared through mastication as needed and mixing of the food with saliva. The cheeks close off the lateral sulci between the cheeks and gum line and the bolus is prepared for propulsion by the tongue (Cichero, 2006a; Logemann, 1998).

1.2.2 Oral Phase

The oral stage of deglutition involves control of the bolus in preparation for swallowing. Fluids need to be held in the centre of the mouth by the tongue forming a central groove. The tongue tip elevates (with or without lip closure) to create an anterior seal, preventing the bolus from escaping and contributing to a negative oral pressure at the commencement of the swallow (Logemann, 1998). It then forms a ramp and propels the bolus posteriorly until the involuntary phase of the swallow is triggered. This can occur at various sites and was once believed to be only at the level of the faucial arches in adults. It is now known to be possible to override this 'reflex' until such time as the bolus stimulates a 'critical point' in the hypopharynx where sensory receptors of the superior laryngeal nerve trigger the involuntary phase of the swallow, and the bolus is propelled through the UOS (Cichero, 2006a).

1.2.3 Pharyngeal phase

In normal adults the pharyngeal phase usually occurs in one second (Cichero, 2006a; Logemann, 1998). A number of movements occur almost simultaneously. The nasal cavity is closed off by elevation of the velum, pharyngeal pressure is increased by the base of tongue contacting the pharyngeal wall and the larynx elevates (Logemann, 1998). The arytenoids close, bringing the vocal folds together for airway protection, and the epiglottis closes over the laryngeal vestibule. Cricopharyngeal relaxation is necessary for adequate opening of the UOS by the laryngeal excursion. Compression and shortening of the pharynx together with the action of the pharyngeal constrictors push the bolus through the open UOS. In order for these processes to occur a pharyngeal swallow must be initiated reflexively (Logemann, 1998). If this does not happen, part of the bolus may flow into the spaces known as the valleculae and pyriform sinuses, and even the open airway. In this case, aspiration of food or fluid into the airway could occur before the swallow. Aspiration during the swallow may occur due to insufficient airway protection, and aspiration after the swallow can occur as a result of residue in the pharynx or pyriforms.

1.2.4 Oesophageal Phase

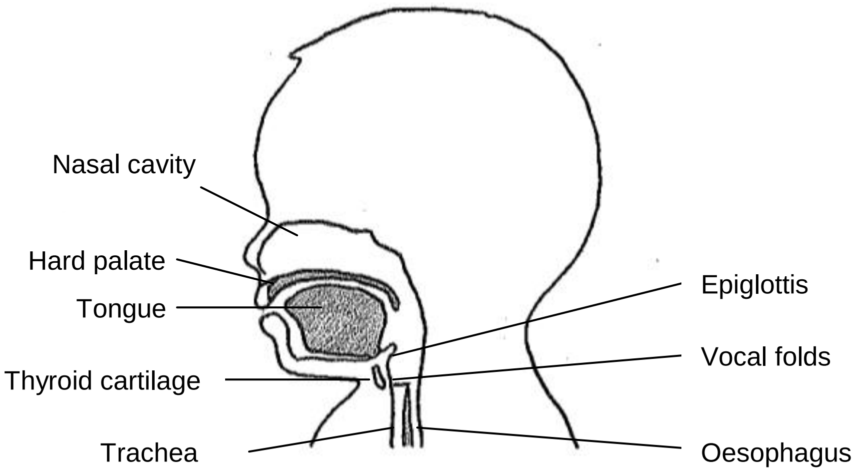
Oesophageal peristalsis, or a 'stripping wave', is stimulated by the swallow commencing, and continues through a series of inhibitions and excitations of various levels to clear the oesophagus from its proximal end to its entry into the stomach (Kahrilas, et al., 1994). However, this action may be different in young infants due to immaturity of the system. In a study of healthy premature infants, seventy percent of oesophageal contraction sequences were found to be non-peristaltic (Omari et al., 1995). While retrograde pressure waves were recorded during spontaneous events, swallow initiated peristalsis was essentially normal.

Passage of food or fluid through the UOS occurs due to a complex range of pressure changes through the PE segment. Numerous studies have examined the pressure changes in this area with diverse results. Videomanometry studies in adults have indicated that the normal resting pressure in the UOS region may be 12-66 mmHg (Ali et al., 1997); 54 +/- 12 mmHg (Shaw et al., 1995), or 89.6mmHg +/- 32.6 (Olsson, Nilsson, & Ekberg, 1995) and drops to a nadir of 2+/- 1 mmHg during the swallow (Shaw, et al., 1995) to allow passage of food and fluid. In a combined videofluoroscopy/manometry study, Kahrilas and colleagues (1988) reported that the UOS modifies its distension to accommodate boluses of different sizes. The UOS was found to remain open for longer periods and have prolonged relaxation during the swallow of larger boluses. The UOS action was described in terms of: relaxation (drop in UOS pressure to 0mmHg); Schluckatmung (further drop in pressure to nadir just before opening) (Postma, Butler, Belafsky, & Halum, 2004); opening (sudden increase in intraluminal pressure to close to atmospheric pressure); distension (positive intrabolus pressure soon after UOS relaxation); collapse (intrabolus pressure close to 0mmHg) and closure (same point in time as arrival of ‘pharyngeal peristaltic contractions’). These findings were supported by Jacob, Kahrilas, Logemann, Shah and Ha (1989) who also analysed the function of the UOS during swallowing in eight normal adults using combined manometry and videofluoroscopy, and achieved similar results.

The intrinsic pressure within the bolus is not needed to initiate UOS opening, but does contribute to maximal UOS opening to permit bolus passage (Cook, 1993; Logemann, 1998). Gravity does not usually contribute to bolus movement across the UOS (Brasseur & Dodds, 1991).

1.3 DIFFERENCES BETWEEN ADULT AND PAEDIATRIC PHARYNGEAL ANATOMY

Pharyngeal anatomy differs between child and adult. Growth and changes in the pharynx occur from birth up to at least the age of 4 years (Rommel, 2002). In an adult, the mouth and pharynx are almost at a 90 degree angle, whereas the infant and child oropharynx has a gradual curve. The distances between structures also increase during growth. In the infant, oral structures (i.e. tongue, cheeks) are touching and there is little need for significant laryngeal elevation due to the location of the larynx high in the neck (see Figure 1-2). The distance between the base of the tongue and the laryngeal inlet is approximately 5mm at 3 months of age, and increases to 9mm at 4 years of age (Rommel, 2002). Differences have also been identified in the action of muscles for swallowing. A pharyngeal pressure wave has been identified during the infant swallow, which is not seen in adults (Tuchman, 1994, cited in Cichero & Murdoch, 2006). These differences in structure and function have implications for airway protection and swallowing, not all of which are yet fully understood.



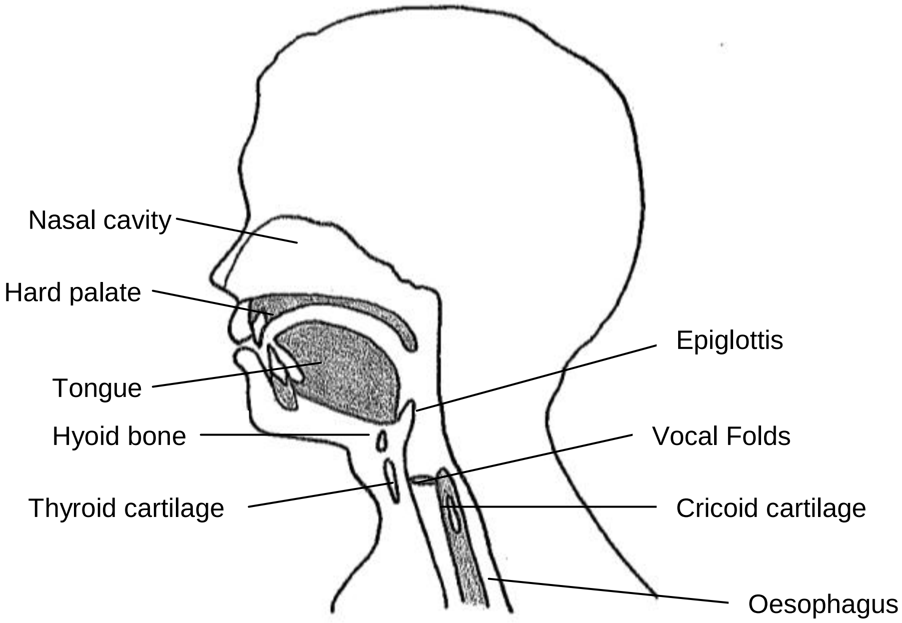


Figure 1-2: Anatomical differences between the infant and the adult mouth and pharynx.
Note the smaller intraoral space, higher larynx, and closer approximation of the tongue and epiglottis in the infant. ***Note.*** **Images adapted from** ***Pre-Feeding Skills 2nd Edition – A comprehensive resource for mealtime development*** **p. 52, by S. E. Morris and M. Dunn-Klein, 2000, Therapy Skill Builders. Copyright 2000 by Therapy Skill Builders. Adapted with permission.**

DISORDERED SWALLOWING

Now that the normal swallow has been summarised, some areas of swallowing difficulty will be outlined. Dysphagia can result from a breakdown in any one or combination of the phases mentioned above (i.e. oral preparatory, oral, pharyngeal or oesophageal).

1.3.1 Oral Dysphagia

Oral preparatory stage disorders include poor orientation to the food source, and lack of preparedness to accept the food or fluid. Dysfunction occurring in the oral phase can include poor lip control, resulting in oral escape of food or fluid, and inadequate use of the tongue for effective transfer of food for chewing. Poor oral control of the food or fluid bolus results in spread of food throughout the mouth and premature spilling over the tongue base, placing the patient at risk of aspiration before the swallow. Reduced tongue strength can also result in poor bolus propulsion.

1.3.2 Pharyngeal Dysphagia

Pharyngeal dysphagia occurs as a result of dysfunction in control within the nasopharynx, oropharynx and/or hypopharynx. This may result in food/fluid entering the nasal cavity, ineffective closure of the airway during swallowing, poor pharyngeal propulsion of the bolus, pharyngeal residue post-swallow and aspiration of food or fluid into the airway during the swallow.

1.3.3 Oesophageal Dysphagia

Oesophageal dysphagia is the impaired transit of a food or fluid bolus in the oesophagus, once the bolus has passed the UOS (Kearney, 2003). Those with oesophageal dysphagia often experience more difficulty swallowing solids than liquids. The speech pathologist may be requested to exclude oropharyngeal dysphagia in patients suspected of oesophageal dysphagia (Cichero, 2006c). Mechanical or motility disorders of the oesophagus can result in the presentation of dysphagia. Such disorders may include oesophageal strictures, foreign body, achalasia, eosinophilic oesophagitis and oesophageal spasm (Cichero, 2006c; Kearney, 2003; Yan & Shaffer, 2006).

1.4 ASSESSMENT OF DYSPHAGIA

1.4.1 Clinical Assessment

The aim of assessment and management of dysphagia is to describe the condition present, identify the patient's strengths and where possible rehabilitate function, or introduce compensatory strategies to maximise pleasurable oral feeding experiences.

Clinical assessment utilises the clinician's skills in assessing, collating and interpreting information from the patient and their medical history, sometimes also utilising pre-designed checklists and evaluation forms in order to maintain consistency and compare the patient's skills with normative data. During assessment of a paediatric patient's swallow, the child's mealtime environment and readiness for eating and drinking is observed, and oral preparatory and oral phases of swallowing are evaluated by the speech pathologist through examination of the oral reflexes and observation of feeding skills for liquids and solids. Possible dysfunction in the pharyngeal and oesophageal phases is hypothesized, taking into account the medical history, cognitive status, mealtime behaviour, self-feeding skills, parental report and observations during and after the feed (ASHA, 2000; Logemann, 1991). Assessment may include listening to swallow sounds with a stethoscope (cervical auscultation).

Changes in timing of swallow events or breathing quality may indicate risk for aspiration (Arvedson & Lefton-Greif, 1998; Borr, Hielscher-Fastaband, & Lücking, 2007; Logemann, 1998; Zenner, Losinski, & Mills, 1995). Cervical auscultation is a subjective measure designed to contribute useful information to the overall decision making process for further instrumental assessment (Borr, et al., 2007). Based on this clinical assessment of the patient, the need for an instrumental assessment is determined.

More recently, clinical assessment checklists have aimed to make this assessment more objective and/or standardised. The Dysphagia Disorders Survey© (DDS) (Sheppard, 2003) provides a percentile rank for the severity of feeding impairment in children from 2 years of age (see Appendix 1). Clinical assessment utilising such methods aids the therapist in determining the need for an instrumental swallowing assessment.

1.4.2 Instrumental Assessment

Following the clinical assessment, decisions about the patient's need for further objective diagnostic evaluation are made. The following assessments are possibilities in patient evaluation.

Ultrasound

This technique has only been shown to be useful for oral stage assessment (Logemann, 1998) as it relies on the transmission and reception of sound waves through body tissue (and therefore, cannot assess air filled spaces, such as the larynx and trachea) (Rommel, 2006). It is particularly effective for assessment of tongue, palate and hyoid movement and is well tolerated in children (Logemann, 1998; Rommel, 2006). No contrast agents or radiation exposure is required, but laryngeal penetration or aspiration of food or fluid cannot be assessed (Arvedson & Lefton-Greif, 1998). Specific training in interpretation of this method is required and it is not widely used as a standard assessment. Further research is required into standardising the landmarks observed using this technique (Rommel, 2006).

Scintigraphy

This assessment is able to indicate precise quantities of aspiration of saliva or gastro-oesophageal reflux (GOR) following swallowing of a radionuclide substance. However, it requires exposure to radiation, and pharyngeal and laryngeal structures are not visualised, therefore, no cause for aspiration can be identified (Arvedson & Lefton-Greif, 1998; Cichero & Langmore, 2006).

Barium Swallow

The barium swallow looks at oesophageal function through radiographic images of a swallowed radiopaque bolus. Gross pharyngeal dysfunction and episodes of aspiration into the airway may be reported incidentally, but the main goal for this assessment is to provide information on structure and function of the oesophagus, stomach and duodenum (Arvedson & Lefton-Greif, 1998; Cichero & Langmore, 2006). The patient is often positioned lying down during the study, and therefore the study does not simulate a real mealtime. Findings are not detailed enough to provide a mealtime management plan (Arvedson & Lefton-Greif, 1998).

Videofluoroscopic Swallow Study (VFSS)/Modified Barium Swallow (MBS)

The Videofluoroscopic Swallow Study (VFSS) is arguably the most frequently used instrumental assessment in the paediatric dysphagic population (Weir, et al., 2007). The VFSS was developed in the 1970s, after initial use of cineradiography from the 1930s onwards, and has been valued for its ability to capture an image of the fast moving bolus through the pharynx and UOS (Arvedson & Lefton-Greif, 1998; Cook & Kahrilas, 1999; Miller & Groher, 1993). In VFSS, a variety of food and fluid consistencies can be mixed with a radiopaque contrast, and then masticated and swallowed by the patient while a moving ‘x-ray’ image is recorded. Both the oral and pharyngeal stages of the swallow can be visualised through shadows of the anatomical structures involved (Logemann, 1998). The recorded images can then be reviewed frame by frame on completion of the study. The aim of the assessment is to identify abnormal swallow function and devise compensatory strategies, including dietary modification, to improve swallow skills and safety (Arvedson & Lefton-Greif, 1998; Cichero & Langmore, 2006; Logemann, 1998). However, due to the need to regulate the patient’s exposure to ionising radiation there is a time limit on acquiring images during this assessment method (Arvedson, 2004). This is especially important for children who, as a group, are particularly susceptible to organ damage from radiation (Huda, 2002; Mills, Tsai, Meyer, & Beldon, 2006), and the effect of radiation exposure over time in this population is currently unknown (Arvedson, 2004). This means that these images of swallowing can offer merely a “snapshot” in time, cannot be used as a screening assessment and an entire bottle or solid feed should never be assessed in this way. This is restrictive, as research studies have shown swallowing to be variable throughout a feed, with difficulties often presenting later in a feed (Newman, et al., 2001; O'Donoghue & Bagnall, 1999). It is impossible for all swallows of a feed to be visualised for a comprehensive assessment. From clinical experience, the addition of radiopaque contrast to the child's normal food and fluids sometimes results in reduced cooperation from the child which may, therefore, impact swallow function and the accuracy of the assessment. Additionally, the radiology suite itself is a very foreign environment to the child where contact with parents is constrained. These factors contribute to anxiety in the child and are, therefore, likely to impact the quality and efficacy of the assessment.

There are also a number of practical considerations which impact the efficacy of VFSS. These include a lack of standardised scoring procedures for use with VFSS and inter and intra-rater reliability issues. McCullough and others (2001) reported that intra-judge reliability was acceptable on measures of penetration-aspiration, tongue function, residue in the oral cavity and valleculae and hypopharyngeal and pyriform sinus residue. Inter-judge reliability, however, was variable and generally not acceptable for measures other than aspiration, and judges were more likely to agree on a normal result than an abnormal one (Kuhlemeier, Yates, & Palmer, 1998; McCullough, et al., 2001). It was recommended that training of judges be to a criterion, in order for results to be more reliable (McCullough, et al., 2001).

When using VFSS conclusions must be drawn from limited data (DeMatteo, et al., 2005) and perhaps the most valuable information gained is the presence or absence of aspiration (food or fluid entering the airway beyond the level of the vocal folds) (Kuhlemeier, et al., 1998). Dysphagic patients are known to be variable in swallowing abilities throughout the day and there is still no technique that predicts likelihood of aspiration. A normal VFSS does not mean that a child does not aspirate

(Boesch et al., 2006). The characteristics of the chronically aspirating child are frequently elusive, often until advanced stage lung disease occurs (Boesch, et al., 2006). Nevertheless, the therapist's goal during this short video swallow study procedure is to identify which compensatory strategies may benefit the individual and reduce the risk of laryngeal penetration or aspiration. While the therapist makes the best attempt possible to remove aspiration risk by modifying texture, positioning or swallow timing, VFSS is unable to provide information about the *pathophysiology* resulting in aspiration, such as describing discrete movements and abnormalities of oral and pharyngeal function (Kuhlemeier, et al., 1998). The strength of pharyngeal contraction, intrabolus pressure and degree of UOS relaxation cannot be determined with VFSS (Fung, Khong, To, Goh, & Wong, 2004), and claims such as "absent pharyngeal contraction" cannot be accurately declared, despite being reported when conducted without an objective measure of muscle function (Bülow, Olsson, & Ekberg, 2005). The use of an additional technique to provide more information regarding swallowing, currently unable to be derived from VFSS assessments, would be a considerable advance in the effective assessment and management of children with dysphagia.

Videoendoscopy (also known as Flexible Fibreoptic Examination of Swallowing – FEES)

Flexible Fibreoptic Examination of Swallowing (FEES) has become more widely used over the past couple of decades and is in many ways considered just as valuable as VFSS in terms of reliability and validity (Langmore, 2003; Rugiu, 2007). The convenience of using FEES in the clinic room use is appealing, as normal food and fluids can be used and there is no exposure to radiation.

During a FEES assessment a flexible tube containing a microcamera is inserted through the nose and can be positioned above or below the soft palate to view the pharynx and larynx before and after swallowing. Structural anomalies of the soft palate and vocal folds can be visualised, no contrast agent is required in the patient's food or fluid and multiple swallows can be assessed (Arvedson & Lefton-Greif, 1998; Cichero & Langmore, 2006). The actual timing of events during the swallow itself is not visualised, as the camera is obscured by the pharyngeal swallow action, however, the presence of residue in the pharynx or larynx after the swallow can be seen (Arvedson & Lefton-Greif, 1998; Logemann, 1998). Logemann (1998) reported that young children or those with cognitive impairments have difficulty complying with this procedure. However, while it does not provide information about the oral stage of the swallow (Arvedson & Lefton-Greif, 1998; Logemann, 1998), its advantages are lack of radiation exposure and accurate visualisation of the pharyngeal and laryngeal structures (Logemann, 1998).

Hartnick, Miller, Hartley & Willging (2000) reported on the use of FEES in 643 studies over six years involving children of an average age of 2.5 years. It was found to be a more difficult and time-consuming assessment method than with adults, both because of the need to hold the child still to insert the telescopic probe and increased difficulty inserting the probe because the narrower child's nares . If the child is uncooperative, similarly to VFSS, only small amounts of useful data may be gained from the FEES as crying may obscure the view of the larynx and hypopharynx. Thorough knowledge of paediatric laryngeal anatomy, changes over time and how it differs to the adult is needed to conduct a study accurately. Diagnosis of other laryngeal pathologies (e.g. subglottic stenosis, laryngeal cleft) is likely to incidentally be made using FEES, though in practice if there is suspicion of these disorders, evaluation using endoscopy is possible without requiring the child to participate in the swallowing component of the study. In comparison to VFSS, FEES is able to provide precise information about the location and amount of laryngeal penetration. However, the authors did not argue the superiority of FEES over VFSS, but instead described it as a useful complementary technique to other assessments used in the evaluation of dysphagia (Hartnick, et al., 2000).

Manometry

Manometry is one of the alternative methods of assessment that has been conducted in research studies of normal and disordered swallowing in adults. Manometry is the measurement of pressures, in this case within the pharynx and UOS, by means of a water perfused tube or a solid state pressure sensor catheter passed through the nasopharynx and positioned against the pharyngeal wall while straddling the UOS. Recordings of pressures are then taken during the swallowing of food and fluid boluses. Manometry provides additional information about the physiological basis for swallowing disorders by measuring the contraction of the pharyngeal muscles and the timing of this relative to the opening of the UOS (Castell, Dalton, & Castell, 1990). Though reduced traction on the UOS to initiate opening can be implied from VFSS (by failed anterior movement of the hyoid), poor UOS *relaxation* cannot be interpreted by VFSS, only manometry (Cook & Kahrilas, 1999).

In summary, the assessment techniques currently used in cases of paediatric swallowing disorders (clinical assessment as well as instrumental assessments, specifically VFSS and FEES) have their advantages and definite application to treatment strategies. However, limitations are present in applying these assessments, which were developed for adult swallow evaluation, to the paediatric population. Exposure to radiation, lack of standardised procedures and failure to identify pathophysiology of swallowing disorders leave room for further assessment techniques to complement the existing methods commonly used. The following section will discuss the history of manometry in further detail, and a newly devised assessment method previously used in the oesophagus and now applied to use in the pharynx (impedance). The combination of these instrumental techniques will then be discussed and the method outlined for their application as a novel instrumental assessment for the evaluation of swallowing disorders in children.

2 USE OF PHARYNGEAL MANOMETRY AND VIDEOMANOMETRY TO ASSESS SWALLOWING

2.1 Principles of Pressure Measurement

The aim of manometry is to draw conclusions about the function of muscles during the passage of a bolus by analysing pressures recorded at various points along the lumen (Brasseur & Dodds, 1991). Manometry, the measurement of change in pressure over time, provides information regarding the ‘biomechanics’ of bolus transport (Fox & Bredenoord, 2008). When focusing on bolus flow through the pharynx and oesophagus, the pressures generated are those within the moving bolus (hydrodynamic pressure or intrabolus pressure), the contact pressure from the muscles beneath the luminal wall against the instrument measuring pressure, and the pressure gradient across the pharyngo-oesophageal (PE) segment (i.e. the movement of the bolus from a region of high to low pressure) (Brasseur & Dodds, 1991; Fox & Bredenoord, 2008). These pressures are generated during the swallow due to the differences in size of oral, pharyngeal and hypopharyngeal spaces and the movement of the bolus through these spaces. Pressures alter as the size of these spaces changes with the movement of the oral and pharyngeal structures, propelling the bolus through the pharynx and oesophagus, and into the stomach.

This section of the thesis will cover the developmental progress in the use of manometry, beginning with discussion of the early assessments of oesophageal motility through to the application of manometry to pharyngeal swallowing. The development of the use of manometry in assessment of swallowing has been fraught with many technical difficulties, but as a result of this trial and error process, has led to the effective assessment technique known as high resolution manometry where closely spaced pressure sensors record pressures along the pharyngo-oesophageal segment.

2.2 CONVENTIONAL OESOPHAGEAL MANOMETRY

Prior to the development of manometric assessment techniques for clinical use, investigation into oesophageal function was conducted using radiological techniques as described earlier (Cook & Kahrilas, 1999). The need to limit patient exposure to ionising radiation necessitated short assessment periods and therefore detailed analysis of bolus flow was limited (Dent, 1976; Hila, et al., 2001). In addition, motility problems could only be inferred during X-ray studies. Development of manometric systems for the assessment of oesophageal motility and lower oesophageal sphincter (LOS) movement began in the early 20th century with the use of large balloon catheters placed at the level of the LOS in animal studies (Dent, 2007). The results of these experiments were then applied to research in humans to measure oesophageal motility and the contraction of the LOS (Hila, et al., 2001; Kahrilas, et al., 1994). However, it was only in the late 20th century that reliable manometric methods became available. Complications, such as difficulties in precise placement of the device in the region of the sphincter and mucous plugging in some devices, which occluded the single sensor, rendered the results inaccurate (Dent, 2007). A variety of methods were, therefore, trialled before the more consistent method of assessment via perfusion manometry in the LOS was used (Dent, 2007).

In the 1960s LOS pressure was able to be reliably measured using constant perfusion manometry with intraluminal transducers (sensors imbedded within the catheter lumen rather than water perfused sensors) and this development of a reliable manometric method spawned further research into this area of sphincter function (Dent, 2007). However, clinical use of intraluminal sensors was still limited due to fragility of the catheters and high cost. Technical advances mean that these catheters are now more readily able to be used in the clinical setting.

The use of manometric catheters inserted transnasally to rest within the tubular oesophagus enabled the collection of continuous data regarding the pressures generated to move a bolus, information that had not been available using radiology (Dent, 2007; Fox & Bredenoord, 2008). However, as stated earlier, the high pressure zones of the UOS and LOS are complex regions, which change in size and shape during the passage of a bolus, and this complexity of structure provides challenges in assessing the region. The zone of high pressure to be measured at the LOS is 1-2 cm long in adults, and a sensor must be located within this region and not be displaced during movement of the sphincter inferiorly during respiration and more significantly, during swallowing (Dent, 2007; Fox & Bredenoord, 2008). The early perfusion and intraluminal sensor catheters incorporated relatively few sensors that were widely spaced at 3-5cm apart (Dent, 2007; Fox & Bredenoord, 2008). Single sensor catheters were also unsuitable for measurement of sphincter relaxation (Kahrilas, 1995 in Dent, 2007). Pull-through catheters that drew the manometry sensors across the high pressure zone avoided the problem of sensor displacement, but the action of drawing the device through this region was found to influence pressures including those at the level of the UOS, therefore, distorting recordings (Dent, 2007; Kahrilas, Dent, Dodds, Hogan, & Arndorfer, 1987). Furthermore, this technique only assessed UOS pressure at rest and sphincter relaxation could not be reliably measured using this method. To circumvent this problem Dent (1976) devised the water perfused sleeve sensor. During water-perfusion manometry the structures involved in swallowing compress a water filled tube/catheter resulting in increased resistance to water flow within the tube (Dent, 1976). This sensor measuring 5cm in length, was able to span the entire suspected high pressure zone and reliably record the highest pressure anywhere along its length (Dent, 1976). It replaced the single sensor of previous studies and enabled continuous pressure measurement within the LOS despite axial movement, therefore, minimising recording error. The application of the use of such a sensor in the UOS of normal adults was sensitive enough to detect differences between duration of UOS relaxation for wet versus dry swallows (Kahrilas, et al., 1987). These perfusion catheters were still relatively large, on average 4-5 mm in outer diameter containing lumina of 0.6 – 0.8 mm in diameter, a size that can be uncomfortable for adults (Chen, Omari, Holloway, Checklin, & Dent, 1998), and not possible for use in children.

Pathological conditions of the oesophagus were also more effectively characterised with these new techniques. The use of sleeve-sidehole catheters made it possible to measure UOS and LOS resting tone and the degree and timing of relaxation of the UOS/LOS in relation to peristalsis (Kahrilas, et al., 1994). Disorders, such as achalasia [failure of the oesophageal sphincter to relax (McCord, Staiano, & Clouse, 1991)] and diffuse oesophageal spasm were objectively characterised. The development of innovative catheters had direct implications for treatment. The identification of a physiologic basis for bolus transit difficulties could ensure that treatment is specifically targeted at the problem, rather than the symptoms.

2.3 HIGH RESOLUTION MANOMETRY IN THE OESOPHAGUS

With the advancement of technology, the use of catheters with a greater number of sensors (and therefore, “high resolution”) became possible as computers were able to store data from many more channels and present the information in a more meaningful way, specifically in the form of colour and line pressure iso-contour plots. It also provided further information on disorders of oesophageal function. The HRM catheter contains a greater total number of pressure sensors, and these pressure sensors are more closely spaced (< 2cm) (Fox & Bredenoord, 2008). This is of benefit in contrast to the widely spaced sensors (ranging in number from 5-8 recording channels per catheter, which were not closely spaced enough to assess swallow dynamics) of conventional manometry, as oesophageal dysmotility may be limited to only a short segment of the oesophagus, which could be overlooked with the use of lower resolution manometry (Fox & Bredenoord, 2008; Fox et al., 2004). Thirty six channel solid-state catheters have now been developed for assessments of the oesophagus. Unfortunately catheters with large sensor arrays also have large diameters (4-5mm) and, therefore, are too large for use in infants and children (Fox & Bredenoord, 2008; Fox, et al., 2004).

Miniaturisation of perfusion catheters in the mid-1990s enabled multi-channel perfusion manometry to be performed in infants and children (Chen, et al., 1998; Omari, et al., 1995). A change to smaller catheters also had benefits for ease of conducting manometry in adults, though the recording accuracy of micromanometric catheters required further development to be suitable for assessment of the differing features of adult oesophageal motility (Chen, et al., 1998).

2.3.1 Application to Pharyngeal Studies

Measurement of coordination between pharyngeal pressure generation and UOS relaxation during swallowing has also been conducted using catheters with multiple sensors (Castell, et al., 1990). These sensors located within the manometric assembly at set intervals along the pharyngeal wall have enabled measurement of pharyngeal contractions during swallowing, hence providing a pressure pattern of forces generated by the muscles in this region (Brasseur & Dodds, 1991). Pressure relationships between the pharyngeal baseline pressure, peak pharyngeal pressure, UOS resting pressure, UOS nadir pressure during a swallow and oesophageal baseline pressure, are measured (Castell, et al., 1990). The coordination of the swallow can, therefore, be assessed by examining the timing of pharyngeal contraction and UOS relaxation.

Pharyngeal manometry has provided valuable information regarding the pressures involved during swallowing. The pharyngeal constrictors, tongue, palate and larynx all contribute to deglutitive pharyngeal pressures (McConnel, 1988). The role of gravity is minimal (Brasseur & Dodds, 1991). As the hyoid bone moves forward during swallow initiation, the PE segment resting pressure decreases (McConnel, et al., 1988). The vallecular space is widened by the anterior movement of the hyoid, and the bolus moves toward the pharynx. As the hyoid moves anteriorly, prior to the bolus passing through the UOS to the oesophagus, the pressure at the level of the PE segment drops below atmospheric pressure (McConnel, et al., 1988). The tongue then acts as a pump to propel the bolus through the pharynx and UOS. The pharyngeal constrictors contract as a clearing mechanism once the bolus has already passed (McConnel, et al., 1988). Where there is an increase in pharyngeal intrabolus pressure, this is an indication of reduced sphincter compliance. Pharyngeal pressures are required to propel the bolus through the relaxed UOS, and will increase further if there is additional resistance at the level of the UOS (Ali et al., 1996; Williams, Grehan, Hersch, Andre, & Cook, 2003).

2.4 VIDEOMANOMETRY

Combined videomanometry (videofluoroscopy together with manometry) has enabled a more reliable picture of pharyngeal function than manometry alone, as pharyngeal pressures are measured while bolus flow is visualised (Brasseur & Dodds, 1991; Ravich, 1995). As in oesophageal manometry studies, the purpose of pharyngeal videomanometry is to define the physiological basis for the presenting symptoms of swallowing difficulty in order to provide treatment, which targets the cause of the problem rather than merely the symptomatic presentation (Fox, et al., 2004). Where the oesophagus is a tubular structure with a single muscle sheath of combined skeletal and smooth muscle (Brasseur & Dodds, 1991; Fox, et al., 2004; Kahrilas, et al., 1994), the pharynx is composed of a number of muscles, which function together to perform the complex act of swallowing. The complexity of this coordinated timing and the shape of the cavity made early measurements without visualisation difficult. One of the main challenges in the interpretation of initial studies using manometry was linking pressure measurements to particular pharyngeal structures and then determining how these pressures influence bolus flow (McConnel, 1988). Videomanometry has contributed to the reduction of measurement errors in manometric studies (e.g. such as inaccuracies due to the catheter elevating with the larynx), improving the technique (Pal, Williams, Cook, & Brasseur, 2003; Ravich, 1995). During videofluoroscopy the catheter and its correct placement in the UOS can be visualised, enabling accurate pressure measurement due to the certainty of catheter location. The pressure patterns indicating correct placement have now become more readily and accurately identifiable. Such improvements in technique were reported by Kahrilas, Dodds, Dent, Logemann and Shaker (1988) who confirmed that assessment using intraluminal manometry together with videofluoroscopy allowed for more accurate interpretation of sphincteric opening and bolus flow across the UOS in adults. In particular, they reported on sphincter modulation, and therefore, prolonged laryngeal elevation to accommodate boluses of larger volumes. This seminal study has provided us with additional information of muscle function during the swallow, not available on either fluoroscopy or manometry alone.

2.4.1 What does pharyngeal videomanometry measure?

Research studies utilising videomanometry have provided detail about the structure and function of the pharyngeal and upper oesophageal regions. Pharyngeal videomanometry examines the coordination of the pharyngeal and upper oesophageal sphincter during swallowing by measuring the strength and duration of the pharyngeal contraction, the degree of upper oesophageal sphincter relaxation and the timing of these events (Cook et al., 1992; Postma, et al., 2004). Pharyngeal videomanometry has provided further understanding of the role of pressures in, and mechanics of, swallow function. The resulting spatio-temporal colour plots directly relate to features of muscle control in the PE segment and bolus transport, including clearance or abnormal bolus flow (Williams, Pal, Brasseur, & Cook, 2001). Absent pharyngeal swallow, reduced pharyngeal contractility and insufficient or absent UOS relaxation can also be detected by the isocontour plots patterns generated by manometric recordings (Williams, et al., 2003). The timing of pharyngeal contraction is also important for a normal swallow to clear a bolus. Whereas a videofluoroscopic study may suggest an absent pharyngeal stripping wave, manometry may indicate that it is present, but that the timing is uncoordinated in relation to other key swallowing parameters (Pal, et al., 2003).

The crucial areas for placement of pressure sensors during the pharyngeal swallow are the tongue base, low hypopharynx (at the region of the laryngeal inlet) and the cricopharyngeal segment (McConnel, et al., 1988). Additional sensors in the oesophagus track the bolus movement toward the stomach. Catheters with side holes corresponding to these regions provide the relevant information required about the swallow (Salassa, DeVault, & McConnel, 1998). Computer programs are then utilised to measure the relationship between the relevant pressures, including pharyngeal baseline pressure, peak pharyngeal pressure, UOS resting pressure, UOS nadir during a swallow and oesophageal baseline pressure (Castell, et al., 1990). Continued advances in computerised analysis have contributed to more accurate recording of pharyngeal pressures (Olsson, et al., 1995). A visual display of pressure measurements via spatiotemporal/contour plots can then be paired with the image obtained on videofluoroscopy (Fox, et al., 2004).

Differential diagnosis of pharyngeal swallowing disorders becomes possible with the use of videomanometry, as duration and coordination of UOS opening and pharyngeal contraction can be quantified. Therefore, UOS compliance problems can be hypothesized if coordination of the swallow is otherwise manometrically normal (Cook, et al., 1992). Increased intrabolus pressure indicates reduced UOS opening on manometry. This is due to the UOS resisting opening against the pressure within the bolus. As the bolus needs to maintain the same rate of flow through a narrower opening to the oesophagus, the intrabolus pressure increases (Cook, et al., 1992).

Studies using videomanometry have demonstrated that the pharyngeal walls alone are not responsible for bolus propulsive forces (as are the walls of the lower GI tract in oesophageal studies) (Fisher, Hendrix, Hunt, & Murrills, 1978; Kahrilas, Lin, Logemann, Ergun, & Facchini, 1993; McConnel, 1988). The driving force supplied by movement of the tongue and negative pressures generated from the PE segment are more important (Jacob, et al., 1989; Kahrilas, et al., 1993; McConnel, 1988). The pharyngeal walls contract only once the bolus has already left the oropharynx, reported as 0.15 seconds later by Hiss and Huckabee (2005), and are therefore likely to have a clearing action rather than a bolus propulsive action (McConnel, 1988). This was confirmed in a later study where pharyngeal shortening through muscle contractions during the swallow was shown to act as a clearing mechanism, as contraction occurred only as the bolus tail was leaving the pharynx (Kahrilas, Logemann, Lin, & Ergun, 1992).

2.5 Application of Videomanometry to assessment of swallowing in Children

For validation purposes, videofluoroscopy has been combined with manometry in adults (Kahrilas, et al., 1988; Kahrilas, et al., 1992). Studies in infants and children have only been conducted since the late 20th century, following advances in design of tubing (catheters), now small enough to be placed in the paediatric nasopharynx and pharynx (Davidson, Dent, & Willing, 1991; Omari, et al., 1995). For ethical reasons, radiological assessment of swallows in the normal paediatric population is not possible. Instead, manometry studies in infants have examined pressures in the oesophagus and upper oesophageal sphincter (UOS) without the use of videofluoroscopy (Davidson, et al., 1991; Omari, et al., 1995). Development of High Resolution Manometry (HRM) catheters (tubing containing a greater number of perfused side holes in the pharynx and UOS to measure pressures) has allowed more accurate recordings.

While there are numerous reports of the use of videomanometry and/or manometry in adults, there are limited data for children. The first reported study of children's UOS function was the use of a perfused side-hole pull-through manometric catheter in sedated infants without the use of videofluoroscopy (Sondheimer, 1983). This study did not control for the effects of sedation and infant stress, which have since been found to influence UOS pressures (Davidson, et al., 1991; Omari et al., 1999; Willing, Furukawa, Davidson, & Dent, 1994). Davidson and others (1991) reported on the first measurements of upper oesophageal pressure using sleeve-assembly and manometry in non-sedated children. This study indicated that UOS pressure increased during distressed states, such as crying in infants.

The development of micro-manometric water-perfused assemblies and miniaturised solid-state pressure sensors has made HRM possible in premature neonates and young infants (Omari, et al., 1995). Resting UOS pressure in normal infants has been found to range from 18mmHg (Davidson, et al., 1991) to 46 mmHg (Jadcherla & Shaker, 2001) and decreased to 34mmHg during dry swallows (Jadcherla & Shaker, 2001). Omari and others (1999) also reported on a UOS high pressure zone at rest in healthy premature infants [15.2mmHg (range of 2-26 mmHg)], which increased during crying, but decreased during dry swallows (1.1mmHg at nadir). This was similar to patterns of UOS relaxation seen in normal adults. Based on these assessments, the proposed reason these premature infants experienced some feeding difficulty was the insufficient generation of intrabolus pressure from tongue propulsion of the saliva bolus (Omari, et al., 1999).

Rommel, Dejaeger, Bellon, Smet and Veereman-Wauters (2006) reported on the first use of high resolution videomanometry to assess liquid swallowing in dysphagic infants and children. This pilot study assessed the liquid swallow of eight infant patients between the ages of 2 and 28 months using a solid state manometric catheter and perfused manometric sleeve assembly. Manometric readings were recorded with simultaneous videofluoroscopy. The design of the unique assembly took into account the anatomical differences between the child and adult oro-pharyngeal structures, such as the closer approximation between the tongue-base and larynx (as measured by the study of Rommel, Bellon, Hermans, Smet, Meyer, Feenstra and others [2003]). The photographs in Figure 2-1 show placement of a manometric catheter in infants and Figure 2-2 illustrates the recordings gained during such a study.

Figure 2- 1: Photographs of a manometric catheter placed transnasally in a young infant, and in place during videofluoroscopy in another infant (Photographs courtesy of the Women's and Children's Hospital Gastroenterology Department, South Australia)

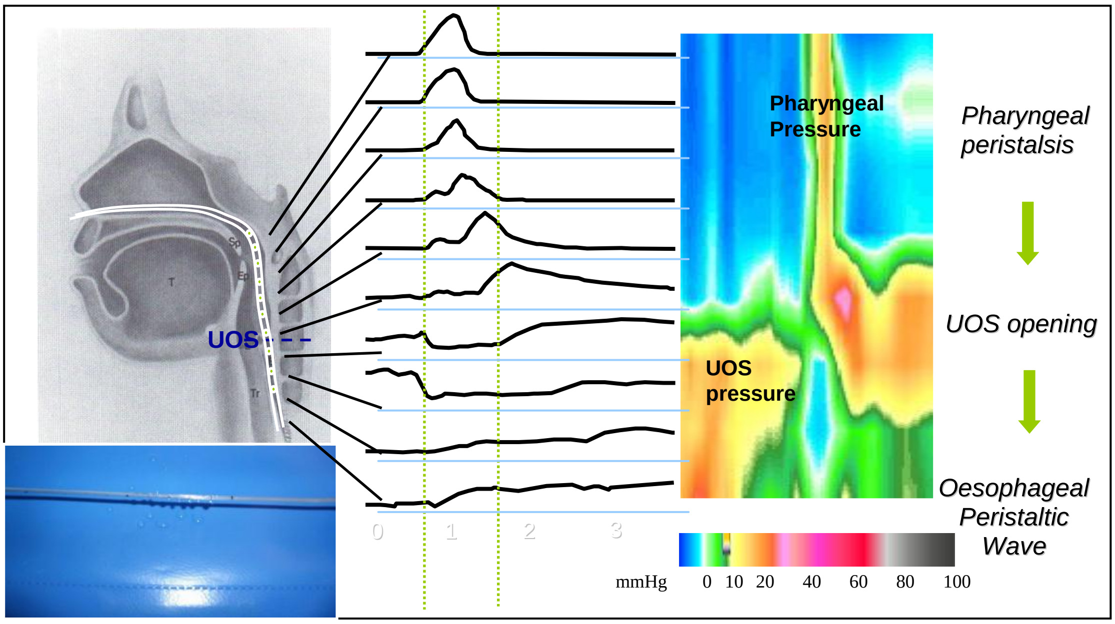


Figure 2- 2: Representation of a manometric catheter in place in an infant. The photograph below the infant diagram shows the manometric catheter. Note how each side hole on the catheter corresponds with a waveform on the videomanometry recording. These waveforms are then also represented in the form of a colour plot. As can be seen in the key below the colour plot, areas of low pressure are represented as blue or green, the pressures of the UOS and pharyngeal contractions are seen as yellow to orange or pink areas. Black indicates extremely high pressures. At the top of colour plot, the yellow/orange area indicates pharyngeal contraction, the break in the yellow section and change to green and blue indicates relaxation of the UOS, followed by the pressure of the oesophageal peristaltic wave. (UOS = Upper Oesophageal Sphincter). (Photographs courtesy of the Women's and Children's Hospital Gastroenterology Department, South Australia)

The role of videomanometry in assessment of the paediatric swallow is to characterise movement of the pharyngeal wall, and its coordination with UOS opening during the swallow of a bolus (Omari et al., 2006b; Rommel, 2006). High resolution manometry in infants has been demonstrated to be an effective assessment method for providing information about the physiological basis for dysphagia (Rommel, et al., 2006). Important information added to videofluoroscopy through the use of manometry included measurements of pharyngeal contraction duration, duration of swallow induced UOS relaxation, time from onset of UOS relaxation to maximum UOS relaxation and duration of UOS maximal relaxation (Rommel, et al., 2006). The results of pressure measures in this study by Rommel and colleagues included:

- *Basal/Resting UOS pressure* ranging from 14-165 mmHg, which was higher than previous studies in infants and children. This was attributed to the possible distress felt by dysphagic infants during the task of feeding, which they were likely to find unpleasant due to the swallowing difficulty experienced.

- *Tongue driving force*. The force generated by tongue and pharyngeal walls to propel the bolus from the oropharynx to the hypopharynx. Weak propulsion can result in delayed oropharyngeal transit, which can then lead to increased aspiration risk. Pressures in this study were 10 mmHg, which is within the range of pressures recorded in adults.

- *Amplitude of pharyngeal contraction*. These pressures increase when there is less compliance at the level of the UOS. In this study the amplitude of pharyngeal contraction was reported to be 107 mmHg (range 40-242 mmHg). Previous studies in adults have indicated even higher pressures (Ali, et al., 1996).

- *Maximal swallow induced UOS relaxation (nadir)*. This pilot study in infants recorded a nadir pressure of 22 mmHg. This pressure was not as low as may be expected. It is possible that increased resistance at the level of the UOS resulted in a higher nadir pressure.

Rommel and colleagues (2006) concluded that videomanometry could be used with infants and children to measure pharyngeal contractility and UOS tone and relaxation, as it can in adults. Similarities to manometric studies of adult swallowing were noted, such as vertical pharyngeal shortening and post-bolus contraction of the posterior pharyngeal wall to ensure bolus clearance (F. McConnel, 1988; Rommel, et al., 2006). It was also noted, however, that laryngeal elevation and hyoid movement were more difficult to detect in these children when compared with adult videofluoroscopic studies. A finding of higher tongue driving force than has been recorded in adults was attributed to the assembly being in a smaller pharyngeal cavity (that of infants *cf* adults) and/or the fact that the upright position of the epiglottis in infants reduces the size of the pharyngeal cavity. Despite this, tongue driving force was found to correlate well with oropharyngeal transit time, corresponding to findings of studies in adults, which have suggested that delayed oropharyngeal transit is due to weak bolus propulsion by the tongue base (Rommel, et al., 2006). Greater pharyngeal contraction amplitude, in contrast to previous studies in sedated infants (Sondheimer, 1983) was also reported and was jointly attributed to the fact that the children were studied while awake together with the use of solid state transducers, which provide a more sensitive reading. In adults, increased pharyngeal contraction has indicated poor UOS compliance, such as in studies of adults with Parkinson's disease (Ali, et al., 1996).

The development of manometry and its use with adults and children has provided useful diagnostic information, particularly regarding the function of the pharyngeal constrictors and UOS during swallowing. It has complemented the already established information about the normal swallow, as assessed with instrumental methods, such as videofluoroscopy. However, the need for research to establish normal values for pharyngeal and oesophageal pressures during paediatric swallowing is clear. Its clinical value for assessment of disordered swallowing in infants and children is yet to be clarified. It is anticipated that development of such data will enable initiation of new therapy techniques to improve swallow rehabilitation and quality of life for these patients.

3 MULTICHANNEL INTRALUMINAL IMPEDANCE (MII)

Multi-channel intraluminal impedance (MII) is an assessment method, which has been coupled with manometry, to assess bolus clearance through the oesophagus (Conchillo, Nguyen, Samson, Holloway, & Smout, 2005; Fass et al., 1994; Nguyen et al., 2005; Nguyen et al., 1997; Silny, 1991; Tutuian & Castell, 2004). The use of manometry in the diagnosis of oesophageal disorders has been well documented (Clouse, Staiano, Alrakawi, & Haroian, 2000; Pandolfino & Kahrilas, 2005). However, manometry recordings of pressure differences within the oesophagus of patients with or without reflux are not always significant, and this has led to the hypothesis that intraluminal pressure is only one defining characteristic of oesophageal motility (Fass, et al., 1994). Multi-channel intraluminal impedance is capable of providing additional information about bolus passage through the oesophagus.

3.1 WHAT IS MII?

Intraluminal impedance is the inverse measurement of intraluminal conductivity (Nguyen, Domingues, & Lammert, 2006). This means that bolus movement through the oesophagus (or pharynx) is detectable due to the differing impedance characteristics (or conductivity) of air (present in the pharynx at rest), saliva, food/fluid and the muscular wall, which surround the impedance electrodes on a narrow tube (catheter) present in the oesophagus during bolus transit (Nguyen, Silny, & Matern, 1999). (See figure 3-1 for an image of an impedance catheter and this catheter in place during a combined impedance/videofluoroscopy study.) The evenly spaced electrodes encircle the catheter, and are connected to fine wires within the tube (Nguyen, et al., 1999; Silny, 1991). These electrodes are what record changes in impedance as air, food or fluid passes by. The area from one impedance electrode to the next is known as the ‘impedance segment’, and each pair of electrodes in such an impedance segment is connected via these wires to an ‘impedance voltage transducer’ linked to a computer for data recording. Electrical signals are recorded in Ohms (Ω) and analysed by the computer system to be presented in a waveform, which provides a ‘virtual’ display of bolus transit (Nguyen, et al., 1999). An example of this waveform can be seen in the following chapter in Figure 4-8.

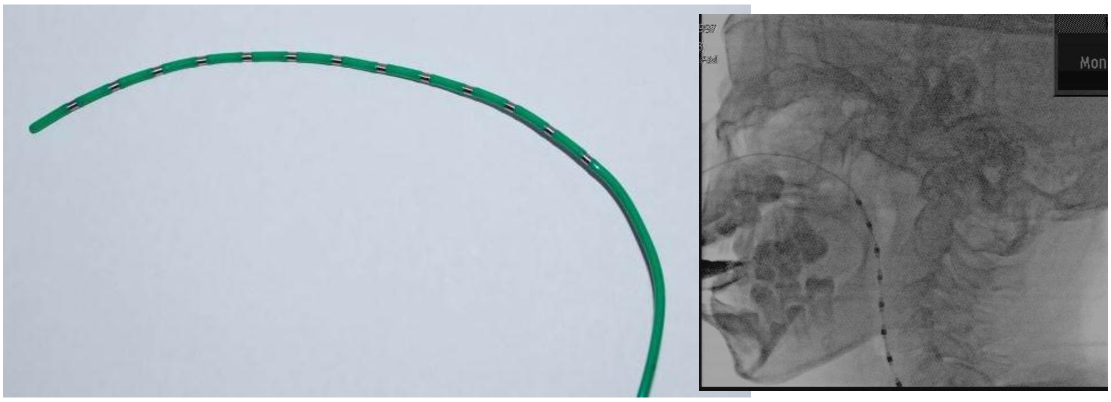


Figure 3-1: Images of an impedance catheter (1.9mm diameter) and the same catheter in place during videofluoroscopy in a 10 year old child. The impedance sensors can be seen as the dark spots throughout the pharynx on videofluoroscopy. (Images courtesy of the Women’s and Children’s Hospital, South Australia).

A change in impedance is recorded when the electrodes in an impedance segment are connected via a passing food/fluid bolus. For example, in contrast with the oesophageal wall, air has minimal electrical conductivity (Nguyen, et al., 1999). Food and fluid have high electrical conductivity. A bolus of high conductivity will connect the segments as it passes by, hence resulting in reduced impedance to electrical conductivity. Therefore, during impedance measurements, a propagated increase in impedance is seen when the air passes by the electrodes. As food or fluid passes by the pairs of electrodes there are intervals where two or more electrodes are in contact with the food/fluid simultaneously, and this results in a drop in impedance (Fass, et al., 1994; Nguyen, et al., 1997; Skopnik et al., 1996). When the bolus clears, or if there is an air pocket passing the electrodes, the impedance will again increase (Kahrilas, 2001) (see Figure 3-2).

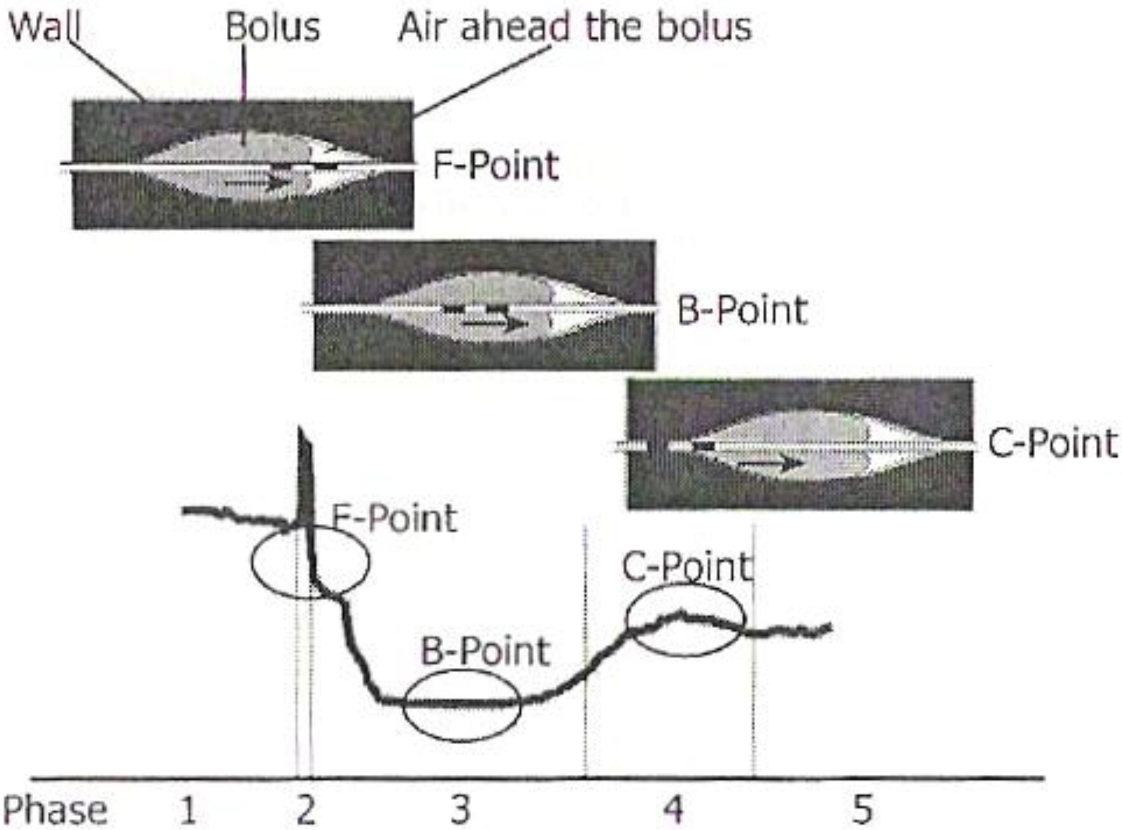


Figure 3-2: Bolus transit past an impedance segment.
Note the grey bolus within the oesophageal lumen. The narrow, horizontal strip is the impedance catheter. The two black segments on this strip indicate impedance rings. The F point is the bolus head. The rise in impedance on the graph signifies the air preceding the fluid bolus (NB. Air is not always present before a bolus). There is a return to baseline before a drop in impedance at the B point. This indicates that the bolus is in contact with two segments, resulting in reduced impedance. As the oesophageal wall contracts (C point), the bolus leaves the impedance segment resulting in an impedance increase (Nguyen, et al., 2006). ***Note.*** **From "Technological insights: combined impedance manometry for esophageal motility testing – current results and further implications," by H. N. Nguyen, G. R. S. Domingues and F. Lammert, 2006,** ***World Journal of Gastroenterology, 12,*** **p. 6268. Copyright 2006 by The WJG Press. Reprinted with permission.**

Oesophageal impedance characteristics have been reported as a pattern of five phases, which can be plotted on a graph (See Figure 3-3).

Phase 1

The oesophagus is at rest. There is a moderately high impedance reading due to electrodes resting against the mucosa within the closed oesophagus (Szczesniak et al., 2008).

Phase 2

Air bolus precedes the food/fluid bolus, resulting in a rise in impedance.

Phase 3

The solid/liquid bolus is in contact with two or more impedance rings. A drop to 50% of baseline impedance value is considered to indicate bolus entry into the impedance segment (Tutuian et al., 2003) (see Figure 3-3).

Phase 4

Contraction of oesophageal wall is evident, and the bolus is cleared. There is a correlation with the peak in the manometry graph at the same point. There is recovery of impedance to above the 50% level.

Phase 5

There is a gradual return to a relaxed oesophageal wall and resting level impedance values (Fass, et al., 1994; Nguyen, et al., 1997; Nguyen, et al., 1999; Tutuian, et al., 2003; Yigit, Quiroga, & Oelschlager, 2006).

Impedance assessments can, therefore, track the bolus movement as the bolus passes each impedance segment (Fass, et al., 1994). In this way the direction and speed of bolus passage is able to be measured, information that is not available from manometry recordings.

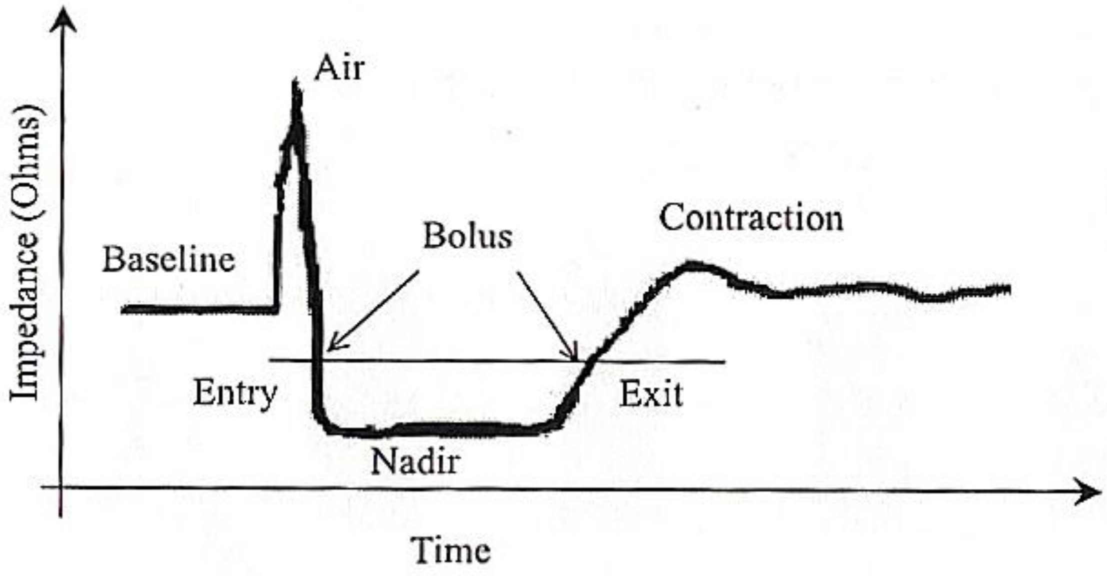


Figure 3-3: Impedance recording during bolus flow through an impedance segment. The graph illustrates the typical pattern seen when a bolus enters an impedance segment. Bolus entry is indicated at the point where impedance value (0hms) is 50% of baseline, relative to nadir. Bolus exit from the segment is indicated by a recovery to at least 50%. *Note.* From "Effects of position on oesophageal function: studies using combined manometry and multichannel intraluminal impedance," by R. Tutuian, J. P. Elton, D. O. Castell, R. Matthew Gideon, J. A. Castell and P. O. Katz, 2003, *Neurogastroenterology and Motility, 15*, p. 65. Copyright 2003 by Blackwell Publishing Ltd. Reprinted with permission.

The movement of boluses of varying viscosity and their rate of transport is also evident in impedance waveforms, in addition to direction of food/fluid bolus and air movement (Nguyen et al., 2004; Nguyen, et al., 1999). Results on impedance recordings for boluses of varying viscosities have indicated constant bolus transit time throughout the oesophagus for fluids, but longer clearance times for semi-solids (Nguyen, et al., 1997; Srinivasan et al., 2001). For example, the greater the viscosity of the bolus, the greater is the intraluminal resistance during bolus flow, and therefore, the slower transit of the bolus. However, more rapid transit time could be expected in the upright position, especially for transit in the proximal oesophagus, which is increased by pharyngeal propulsion of the bolus (Nguyen, et al., 1997). Fass and colleagues (1994) recommended a water swallow following viscous boluses to clear possible residue from the catheter, which could distort results.

3.2 USE OF OESOPHAGEAL IMPEDANCE IN CLINICAL RESEARCH

Where intraluminal manometry provides information about strength of muscle contractions in the oesophagus or pharynx, impedance provides the additional information regarding degree of oesophageal wall movement and bolus clearance (Fass, et al., 1994). Impedance techniques have the unique ability to provide valuable information about disorders of the lower oesophagus and lower oesophageal sphincter not available with manometric assessments alone (Nguyen, et al., 2004; Yigit, et al., 2006), and the mechanisms of dysfunction in disorders, such as non-obstructive oesophageal dysphagia are more effectively characterised with the addition of impedance (Kahrilas, et al., 1994; Nguyen, et al., 2004).

Multi-channel intraluminal impedance is a valid assessment of bolus flow, and more specifically disordered flow (Fass, et al., 1994). However, accurate assessment of bolus flow through the oesophagus requires methods to measure oesophageal contractions and degree of movement (as measured by manometry) in addition to the flow of the bolus (Fass, et al., 1994). Abnormal oesophageal peristalsis as assessed by manometry is not necessarily an indicator for dysphagia, but MII measurements of poor oesophageal clearance are (Yigit, et al., 2006). Multichannel intraluminal impedance provides objective, reproducible information on oesophageal clearance not available from the exclusive use of manometry, and may at times indicate oesophageal motility problems missed by manometry assessments (Yigit, et al., 2006). Therefore, it is useful to combine impedance and manometry in order to measure both bolus flow and oesophageal motility (Fass, et al., 1994; Nguyen, et al., 2004; Omari et al., 2006a).

Multi-channel intraluminal impedance has been used in studies examining oesophageal motility in both adult and paediatric patients with GOR (Fass, et al., 1994; Omari et al., 2004; Skopnik, et al., 1996). Assessment of reflux in infants has routinely been conducted by pH probe, but Skopnik et al. (1996) found that impedance was able to detect both non-acid reflux episodes (which are missed by the pH probe, a favoured assessment tool for GOR), and level of acid rise in the oesophagus in addition to bolus clearance. Differentiation between air or refluxate episodes in adults has also become possible to detect via impedance due to the different waveform pattern seen as fluid or air boluses pass the electrodes (Sifrim, Silny, Holloway, & Janssens, 1999). Consequently, characteristics of disorders resulting in reduced oesophageal motility have been identified and have enabled the design of more effective assessment techniques. Achalasia (first named by Lendrum in 1937 when he discovered failed LOS function in cases of apparent oesophageal obstruction [McCord, et al., 1991]) is another disorder where specific characteristics, such as low baseline impedance reading, ‘air trapping’ (abnormal air flow in the oesophagus), failed bolus transport and regurgitation can be identified by the use of impedance (Nguyen, et al., 2004). Impedance studies have also shown that patients with GOR have had reduced oesophageal motility (Fass, et al., 1994).

3.3 Combined Impedance and Manometry – Pharyngeal Applications

Combined MII and manometry has now also been used to examine the pharyngeal stage of swallowing. A validation study of the use of joint impedance and manometry with simultaneous videofluoroscopy has been conducted in healthy adults to assess bolus passage through the pharynx and UOS during swallowing (Omari, et al., 2006a). Placement of a single MII and manometry catheter across two very different anatomical regions (the pharynx, an air filled cavity, and the oesophagus, a closed tube at rest) posed additional complications for the study of this structurally and functionally complex area. The UOS and upper oesophagus encircled the catheter, but the pharyngeal wall had incomplete catheter contact. Tongue contact with the posterior pharyngeal wall (and hence, also the catheter) impacted on complete impedance recovery, meaning that complete recovery only occurred once the pharynx opened again post-swallow. Nevertheless, this study indicated that bolus head and tail movement as seen on videofluoroscopy correlated with a drop and rise in impedance as the bolus moved past the recording segments. While entry of the bolus head into the *pharynx* was accurately indicated by impedance drop, impedance recovery to 50% of baseline, to indicate pharyngeal clearance of the bolus, did not occur until the pharyngeal contractions ceased and all pharyngeal pressures returned to baseline. However, bolus passage through the *UOS and proximal oesophagus* was accurately recorded with impedance patterns of drop and recovery when compared with the videofluoroscopic image. Impedance recordings were most reliable for semi-solid and solid boluses. Thin fluids tended to contain air during swallowing and impedance recordings were, therefore, less precise (Omari, et al., 2006b).

While bolus movement through the oesophagus can be accurately timed using combined MII and manometry, validation of this technique in the pharynx is in the early stages. To date, results of combined MII/manometry have correlated well with radiological evaluation of bolus clearance in the UOS and oesophagus (Omari, et al., 2006b; Szczesniak et al., 2009). Validation studies have been conducted in both normal swallowing adults and dysphagic adults using combined MII and VFSS (Szczesniak, et al., 2008; Szczesniak, et al., 2009). Cut-offs for impedance drop and recovery in the pharynx (signalling bolus presence) in normal adults were found to be different to the standard 50% drop and recovery to 50% of baseline criteria set for oesophageal impedance. A 50% cut-off for pharyngeal impedance correlated with VFSS with only fair agreement (K=0.35). The best agreement was for the proximal oesophagus (K=0.41, moderate agreement), with results for the hypopharynx and UOS being 0.33 and 0.37 respectively. Cut-off criteria at 71% baseline in the hypopharynx, 72% in the UOS and 80% in the proximal oesophagus were found to improve Kappa agreement to 0.59, 0.67 and 0.65 respectively (moderate to substantial agreement) (Szczesniak, et al., 2008).

Research in dysphagic adults has indicated that post-swallow pharyngeal residue is detectable from impedance measurements (Szczesniak, et al., 2009). Impedance recovery was reduced due to residue, which remained present on electrodes post swallow. These studies were conducted using a combined impedance and manometry catheter, which enabled evaluation of the biomechanics of bolus transit through the PE segment (Szczesniak, et al., 2009). Figure 3-4 illustrates the recordings achieved with combined manometry and impedance. For dysphagic patients, the cut-off points were found to be most accurate for correlation with VFSS at the 50% and 20% impedance recovery points. These patients had post-bolus residue, resulting in slower impedance recovery and for this reason it was decided that cut-off points needed to be different for patients with dysphagia when compared with adults with normal swallows.

Though unable to predict penetration or aspiration, the impedance results did accurately indicate presence of pharyngeal residue, therefore serving as a useful clinical indicator for possible risk of aspiration. The clinical application of using impedance alone would be beneficial for patients requiring regular review, such as those undergoing swallow rehabilitation or those with deteriorating swallowing due to neurological disease as it is a time effective evaluation, can assess a wide range of consistencies without time constraint, while also avoiding the need for radiation exposure (Szczesniak, et al., 2009). The benefits of combining spatio-temporal manometry plots and spatio-temporal impedance plots as a visual display of flow through the PE segment were also emphasized. Impedance drop and recovery as well as information regarding pharyngeal contraction and UOS opening would be clear from such visual displays, removing the need for set criteria, such as a percentage drop from baseline for impedance recordings.

While unable to replace VFSS in all situations, assessments using manometry and impedance are able to provide further information about the disordered swallow by analysing relationships between bolus flow and clearance, pharyngeal bolus clearance and the coordination between UOS opening and relaxation (Nguyen, et al., 1999; Szczesniak, et al., 2008; Szczesniak, et al., 2009).

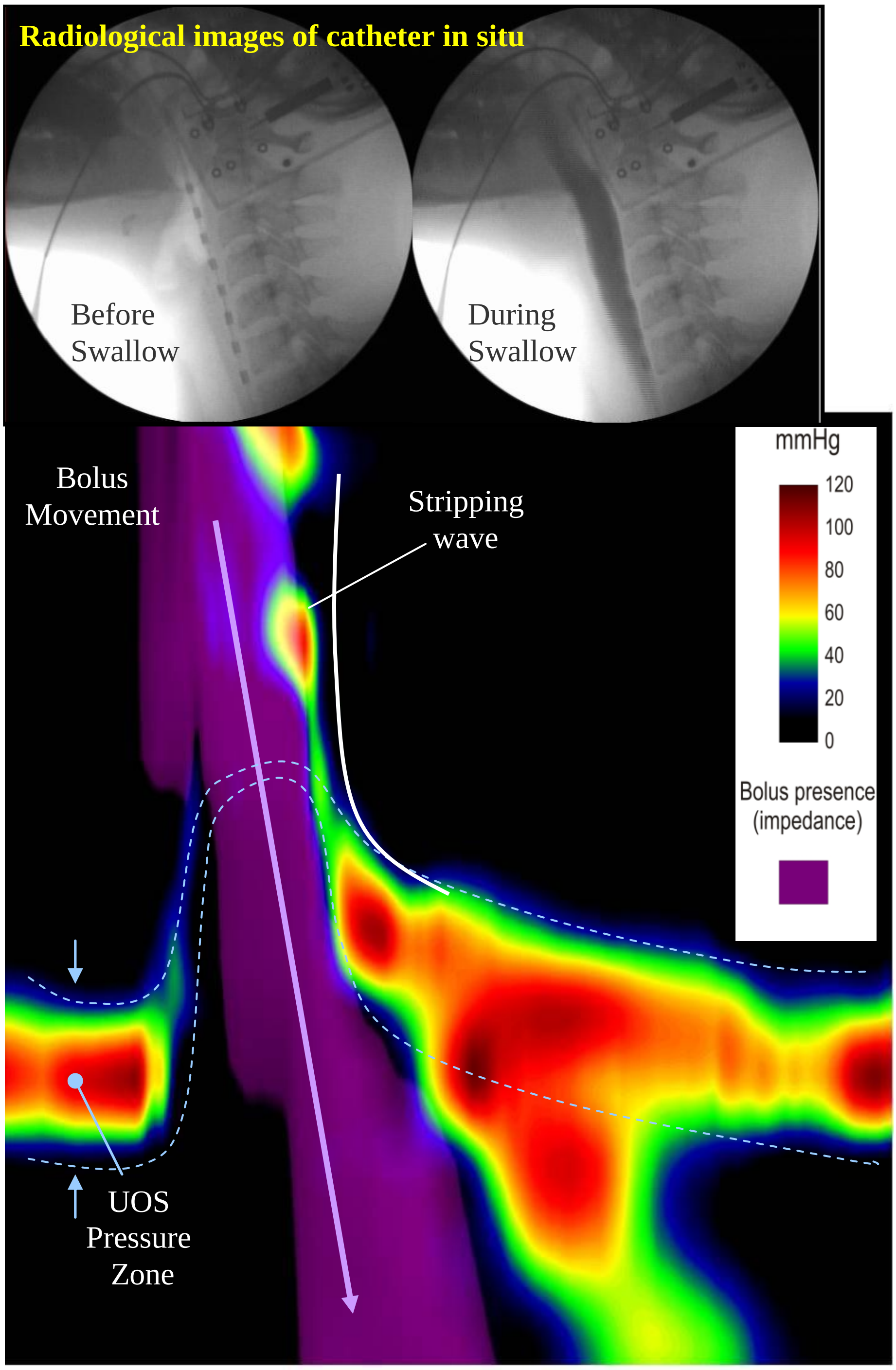


Figure 3-4: Illustration of bolus flow through the pharynx using videomanometry and impedance. The radiological images show placement of the combined manometry and impedance catheter in the hypopharynx, straddling the PE segment. The colour plot below these images illustrates the manometric pressures of bolus passage through the UOS and bolus movement through the hypopharynx as recorded by impedance. (Illustration courtesy Dr Taher Omari, Women's and Children's Hospital Gastroenterology Department, Adelaide, South Australia)

3.4 THE CASE FOR VIDEOMANOMETRY & IMPEDANCE IN CHILDREN

Assessment and management of swallowing disorders is one of the key areas focused on by speech pathologists working with children in an acute setting. Swallowing is an extremely complex process of bolus passage from the oral cavity through to the oesophagus. Numerous muscles and nerves work together to produce contractions of the tongue and pharynx, initiate laryngeal elevation, and together with the movement of the bolus create pressure changes to move the food or liquid toward the oesophagus. Swallowing difficulties are disruptive to quality of life, impact nutrition and chest health, and at their worst can significantly reduce lung function and ultimately result in reduced life span and death. The age and range of children experiencing dysphagia varies widely, but the group experiencing most swallowing difficulties is that of children with neurological conditions. Feeding difficulties affect over half of children with neurological impairment (such as cerebral palsy), and swallowing disorders are present in up to 76% of children with severe brain injury (Morgan, Mageandran, et al., 2009; Morgan, et al., 2003; Sullivan, et al., 2000). Pharyngeal stage swallowing difficulties are common within this group (Rogers, et al., 1994; Sullivan, et al., 2000) and the degree of disability correlates with the severity of dysphagia (Sullivan, et al., 2000). Substantial research regarding dysphagia has been conducted, however, much of this has been with the adult population and applied to children. This is problematic as paediatric patients have unique characteristics and require specialised treatment, which is not necessarily a direct translation from the knowledge existing regarding adult conditions (DeMatteo, et al., 2005; Newman, et al., 2001). The ethical principles of autonomy and beneficence are more difficult to engage in paediatric studies, often due to the fact that the cognitive status and/or age of the child may prevent him/her from personally agreeing to the study (Morgan, Reilly, Eadie, Watts, & Simpson, 2009). It is, therefore, also difficult to recruit the numbers necessary for a comprehensive study. Morgan and others (2009) reported that only 34% of parents surveyed would consent to a non-essential medical study involving functional Magnetic Resonance Imaging (MRI), therefore requiring that three times the usual number of participants would need to be approached in order to recruit enough participants to match an adult study Morgan, et al., 2009). An investigation such as the current study using manometry and impedance cannot be directly compared to similar ones with adults, as comparison of normal participants and dysphagic individuals are unable to be made using VFSS due to the ethical constraints of exposing normal children to unnecessary radiation exposure. Therefore, in the investigations reported in this thesis children with clinical signs of dysphagia were studied with the long-term aim to apply the outcomes to improve assessment and treatment of other dysphagic individuals.

The aim of the body of work presented in this thesis was to contribute knowledge regarding the assessment of paediatric swallowing disorders, with the long term goal of impacting therapy and management. Currently the most widely accepted forms of assessment of dysphagia in this group are the VFSS and FEES. Though convenient and not requiring the use of radiology, FEES is not commonly used in the paediatric population generally or in those with neurological disorders due to issues regarding compliance with the procedure (Logemann, 1998). Investigations using videofluoroscopic swallow studies also experience problems with compliance as children are required to be positioned upright in a specific fluoroscopy screening field and eat food or drink combined with contrast within a constrained time frame in a radiology suite. Concerns regarding the use of VFSS include variable inter-rater reliability (Kuhlemeier, et al., 1998; McCullough, et al., 2001; Stoeckli, Huisman, Seifert, & Martin-Harris, 2003) and the fact that it does not describe the biomechanics of dysfunction. However, the benefits of VFSS are that anatomical structures can be viewed, passage of the bolus is visualised from the oral cavity through to the oesophagus and modifications and therapeutic manoeuvres can be trialled during the study (Logemann, 1998). For children in particular, the issue of radiation exposure must be considered, especially if the child is to have repeat studies throughout childhood (Weir, et al., 2007). Careful consideration of the risks versus benefits is currently required if radiological studies are to be used to investigate swallowing (Weir, et al., 2007). An alternative technique where radiation exposure did not need to be considered, therefore, would be advantageous. Alternative methods of determining pharyngeal dysphagia and risk of aspiration and, therefore, also its impact on health and wellbeing would be extremely beneficial for this group. Reassessment at regular intervals for those with chronic conditions or rapidly altering conditions, such as those in rehabilitation or those with degenerative conditions is desirable. As manometry (Kahrilas, et al., 1994) and impedance are used in oesophageal studies, particularly in assessment of adults, many centres have the equipment needed to carry out the proposed evaluation. If this approach can be demonstrated to be reliable and valid, it would have a tremendous impact on the ability to assess children's swallowing without radiology.

If the use of combined manometry and impedance can be shown to be clinically valuable in the assessment of the paediatric swallow new directions for the evolution of therapy techniques may also be possible. With the development of such a technique, through this study and beyond, there is the potential for uncovering new mechanisms for swallow dysfunction, and therefore, also the possibility of developing novel therapy options. Current therapy for swallowing difficulties includes compensatory strategies (e.g. altering the child's position, pacing feeding, thickening fluids, modifying food consistency and texture); surgical procedures (e.g. cricopharyngeal myotomy) and offering tastes for pleasure and swallow training with the use of alternative feeding (via nasogastric or gastrostomy tube) for nutrition, which occurs in cases of severe dysphagia (Arvedson & Lefton-Greif, 1998; Cichero & Murdoch, 2006; Hill, Hughes, & Milford, 2004; Logemann, 1998; Muraji et al., 2002). By providing objective information about the swallow, it may then be possible to carry out further assessments to indicate the relative benefits of each therapy type, or indicate the most appropriate technique for management of the disorder.

3.5 HYPOTHESES AND AIMS

In the current novel study, the goal was to use HRM and MII to quantify pressures generated during swallowing, and to measure bolus clearance or failed clearance in the pharynx in infants and children by use of a single catheter. The combination of manometry and impedance has proved useful in providing information additional to that available in VFSS assessment, such as assessment of bolus flow and clearance in a validation study in adults (Omari, et al., 2006b). By combining the two methods, an objective assessment of pharyngeal and upper oesophageal function can occur, and the aim is for progress towards the refinement of a non-radiological assessment of swallowing disorders in children.

The proposed technique is similar in method to the high resolution videomanometry pilot study conducted by Rommel, Dejaeger and others (2006) and the validation of combined videomanometry and impedance as conducted in the pilot study in adults by Omari et al (2006b) and adults with dysphagia (Szczesniak, et al., 2009). The combined manometry/impedance catheter will record data during simultaneous VFSS with paediatric dysphagic patients. VFSS will act as the example of 'true' bolus flow through the pharynx and UOS against which the other techniques can be compared.

Hypotheses

- Multi-channel intraluminal impedance is able to detect bolus flow or failure to flow during swallowing in infants and children with dysphagia.
- Combined HRM and MII enable objective characterisation of patho-physiological swallow patterns in children without the use of radiology.

Aims

- To validate impedance (MII) as a method of assessing bolus flow or failure to flow through the pharynx and UOS of infants and children with pharyngo-oesophageal swallowing disorders. It is hoped that this technique will enable identification of diagnostic criteria for the assessment of swallowing disorders in children and will, therefore, identify the pathophysiology for failed bolus flow. This will provide a clearer diagnosis of dysphagia in infants and children than is currently possible with videofluoroscopy alone.

- To validate a new diagnostic technique of combined MII and HRM to diagnose childhood swallowing disorders without radiology.

Objective

- To contribute to the knowledge base on paediatric dysphagia in order to promote development of more comprehensive and clinically valuable assessment tools.

4 METHODOLOGY

This iterative project combined VFSS with manometry or impedance to assess swallowing in paediatric dysphagic patients. The participant recruitment, clinical assessment and videofluoroscopy and then manometry or impedance studies are described in the subsections below. Stage 1 outlines videomanometry studies and Stage 2 describes impedance, comprising sections discussing conductivity characteristics of foods and fluids, inter-rater agreement of videofluoroscopy and correlation of videofluoroscopy and impedance. The final impedance section discusses the new assessment using “Flow Interval” to determine a patient’s dysphagia and aspiration risk.

The same recruitment and clinical assessment procedure was utilised for all participants in each stage of the project and simultaneous videofluoroscopy was conducted while each catheter was in place in the pharyngo-oesophageal segment. It was only the catheter type and data analysis for each sub-study that differed. The flow diagram below outlines the recruitment through assessment process (Figure 4-1).

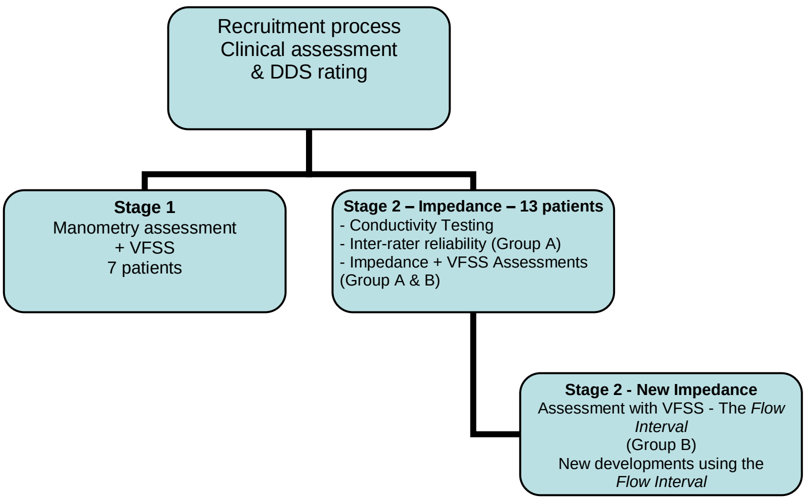


Figure 4-1: Pathway from recruitment through to assessment for the study as a whole. DDS = Dysphagia Disorders Survey, VFSS = Videofluoroscopic Swallow Study

A total of 29 participants were recruited for the combined VFSS studies with either manometry or impedance. The participants (19 male and 10 female) were recruited from the referral base for VFSS at the Women's and Children's Hospital (WCH), Adelaide, South Australia and had a mean age of 3 years 4 months (range: 1 month to 13 years). All exhibited symptoms of dysphagia on clinical assessment and had been referred for a VFSS by their paediatrician. The specific medical details for each participant are described in the respective sections below. The study was approved by the WCH Ethics Committee (WCH ethics approval Rec 1367). Following the assessments with videomanometry or impedance with VFSS 19 participants were deemed appropriate for useful data analysis. This was due to the unpredictability of doing clinical studies with children, as well as some technical complications throughout the course of the study.

4.1.1 Recruitment Procedure

Any infant or child (aged 0-18 yrs.) referred for a videofluoroscopic swallow study at the WCH was offered the opportunity to participate in this research assessment. The majority of patients referred for videofluoroscopy at the hospital are infants and toddlers (who often have developmental, medical or structural impairments impacting swallowing) and a smaller percentage of older children with chronic swallowing disorders as a result of neurological impairment.

The details of the study were discussed by the researcher with a parent/caregiver of each child. Each parent was given the option of having another person present during this discussion. Parents/carers declined their child's participation in the study for the following reasons: "he/she has already been through enough tests" (this was frequently the case for children who had had surgeries, pH probe, endoscopies and other such examinations); “the time is unsuitable”; and “I don’t think he/she will tolerate the test”. There were also occasions where the study was not conducted due to the child having autism or a severe eating aversion, absent clinical signs of dysphagia on speech pathology assessment (physician requested videofluoroscopy despite this), or a language barrier preventing all details being presented clearly to the family despite interpreter use. In addition, potential participants may not have been included in the research study because they required an urgent VFSS needing to be conducted at a time when the research equipment was unavailable. Following Stage 1 of the study (which involved seven participants), it was decided to give preference to older children who also had neurological disorders, as the characteristic of poor bolus flow would be likely to be more readily assessed in these individuals (Rogers, et al., 1994).

4.1.2 Exclusion criteria

Children with current significant craniofacial defects or a history thereof, respiratory distress with the need for ventilation, 24 hour CPAP or oxygen or those who had a tracheostomy in place were excluded from the study. Craniofacial defects can make placement of the catheter difficult and a tracheostomy significantly influences the pressures during swallowing. The medical status of children with significant respiratory distress is often too unstable to conduct the proposed assessment and in such cases outside this research assessment, a standard VFSS would not usually be conducted. The investigator also made some judgements of patient suitability based on patient compliance with clinical assessment. For example, if the child did not sit still to eat, refused all oral examination and subjective assessment of swallow sounds (cervical auscultation) or refused to eat, they were thought unlikely to cooperate for the combined placement of impedance catheter and videofluoroscopy. Such decisions are also made in the running of the usual hospital clinic, as young children (toddlers especially) may find it daunting to sit in the radiology suite for eating. Subsequently, children within this age group are frequently non-compliant with the assessment. It is always important that clinical judgement is used for decision making around use of the VFSS so that it is utilised appropriately in order to provide the most clinically useful information while minimising radiation exposure to the children concerned (Arvedson & Lefton-Greif, 1998; Logemann, 1998).

4.1.3 Clinical Assessment

As in normal practice at the WCH, all patients who were referred for a VFSS at the hospital clinic were contacted via telephone and/or letter to arrange a time for clinical assessment prior to the booking of a radiology appointment. The details of the research study were discussed at this clinical assessment appointment and the caregiver was provided with written information (see Appendix 2), and the opportunity to discuss the procedure with another family member or friend prior to agreeing to take part in the study. They were advised that withdrawal from the study at any time was always an option and would in no way impact their child's future treatment at the hospital. Consent forms (see Appendix 3) were signed either at this appointment, at home and posted in by the parent/carer or on the day of VFSS and manometry and/or impedance testing.

The clinical assessment included examination of oral structures and reflexes, and observation of the child's normal mealtime. Parents/carers were asked to bring a range of the child's normal foods, and any foods that appeared to be particularly challenging or problematic for the child. In general, foods were across the categories of smooth/pureed, mashed, mixed consistencies (e.g. soup with lumpy pieces), soft solids (e.g. sandwich, banana) and hard solids (e.g. biscuits, raw apple). The child's usual drink was also brought to this assessment session (e.g. sipper cup and juice, bottle and teat plus milk, therapy cut-out cup plus water).

A case history was taken, noting relevant markers of swallowing difficulty. This included: frequent respiratory infections, gastro-oesophageal reflux (GOR), coughing with eating or drinking, food refusal, choking and gagging and significant weight loss. For those under 2 years of age, observation of oral reflexes and feeding observation was conducted and recorded on a WCH feeding assessment form (See Appendix 4). The Dysphagia Disorders Survey (DDS) was selected as an assessment tool for scoring eating and drinking skills of children older than 2 years of age (Sheppard, 2003). In this assessment children are rated on a scale from Level 1 (No Disorder) to Level 5 (Profound Disorder). They are then given a percentile rank within these levels (e.g. a moderate level disorder at the 95th percentile means that a child is at the severe end within the range of children with moderate dysphagia). (See Appendix 1 for definitions of each level and an example of the score sheet). Cervical auscultation (Borr, et al., 2007; Cichero, 2006b) was used during each assessment where possible and tolerated by the individual. Relevant recommendations for safety of oral intake were also made during this assessment session. An appointment for the manometry or impedance component of the assessment plus VFSS was made on conclusion of the clinical assessment. This follow-up radiology appointment was generally made within 1-2 weeks of clinical assessment (VFSS clinics are only run at the hospital a maximum of two times per week). Participants were requested to fast for a 4 hour period prior to the appointment time (as is usual procedure for VFSS at the Women's and Children's Hospital) to ensure they were sufficiently hungry to cooperate to the best of their ability for the study.

4.1.4 Videofluoroscopy Protocol

Radiopaque contrast (Omnipaque™ 300mg I/ml – Amersham Health Ltd, Auckland, New Zealand) was added to the child's usual food or fluid in a 50% contrast 50% food/fluid mix. A standard quantity of Novartis Resource® ThickenUp® Food Thickener or Nutricia Karicare® Food Thickener was added to ensure a familiar consistency of food (the Omnipaque™ is liquid and, therefore, thins food consistencies). The VFSS was performed in the lateral position using a Toshiba Biplane Digital Fluorography system (Model DFP-2000A) while the child was positioned in a supportive seating system (Tumble Forms® Feeding Seats, positioned on a custom designed mechanical lift chair [H. Dunbar, Hazzard Engineering, Lonsdale, SA, Australia]) to ensure best positioning for each child in relation to the screening cameras (See Figure 4-2). The anatomical structures screened in lateral view comprised the lips anteriorly, the hard palate superiorly, the cervical spine posteriorly and the proximal cervical oesophagus inferiorly. Exact bolus size during the study was unable to be specified as generally children are unable to comply with such restrictions at mealtimes. Additionally, if such specifications were enforced (e.g. bolus size, timing of swallows) it would likely result in an assessment that did not resemble each child's 'normal' feeding situation. The aim was for each child to take at least three swallows of each consistency requiring assessment of swallowing safety (based on the clinical assessment). The choice of textures for each child's study was dependent on what they would normally consume in a mealtime. For example, infants of 6-8 months may have consumed thin, thickened fluid and a pureed food during the study whereas a toddler may have consumed similar fluids, but also a chewable solid (e.g. sandwich). Infants were generally fed from a bottle, whereas older children drank from their usual cup. The aim was for each bolus size to be at least 2-3mls, as recommended for VFSS by Arvedson and Lefton-Greif (1998) (except for young infants who typically take 0.5ml to 1ml boluses [Wolf & Glass, 1992]). The total fluoroscopy time did not exceed 2 minutes per patient.

Figure 4-2: Tumble Forms® seating positioned in the videofluoroscopy suite

Data Analysis - Videofluoroscopy

Videofluoroscopy swallow images were acquired at 25 frames/sec. A swallow was labelled "primary swallow" on videofluoroscopy when it was one that occurred first in a sequence following presentation of the bolus to the child's mouth. If this initial bolus did not completely clear the oral cavity, tongue-base, valleculae and/or pyriform sinus, the clearing swallow that followed was labelled a "secondary swallow". If a secondary swallow occurred during screening time, these swallows were also analysed.

Aspiration and/or penetration and pharyngeal residue was scored for each swallow, blind to the impedance/manometry findings. The 8-Point Penetration Aspiration Scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996) was used to define degree of penetration and response to material entering the airway. A score of 1 equalled no penetration or aspiration, a score of 2-5 equalled penetration of varying degrees and scores of 6-8 marked aspiration (material below the vocal fold level) (See Appendix 5). For the purposes of this study, scores for individual swallows within patients were totalled and the mean calculated to derive an "Aspiration-Penetration" (AP) score for each patient.

Post-swallow residue was scored on a 6 point scale, devised specifically for this study, which indicated presence or absence of post-swallow residue in the valleculae, pyriform sinus and/or pharyngeal wall. A score of 1 was assigned for no bolus residue present. Other scores up to 6 classified the region or regions of residue (e.g. posterior pharyngeal wall; pyriform sinus; valleculae, pyriform sinus and pharyngeal wall) (See Appendix 6 for full description of scores). Again, for the purposes of this study, scores for individual swallows within patients were totalled and the mean calculated to derive a “Bolus Residue” (BR) score for each patient.

4.2 METHODS – PHARYNGEAL VIDEOMANOMETRY

Participants

Seven children aged from 5 months to 21 months (average age 12.3 months, 3 male and 4 female) were enrolled in Stage 1 of the study. All presented for clinical assessment of swallowing and informed consent forms were completed with the child’s parent/caregiver. Swallowing difficulties ranged from gagging and vomiting when eating lumpy foods to presumed reduced pharyngeal clearance due to neurological disorders. Patients with apparent sequelae of swallowing difficulties, such as recurrent lower respiratory infections were also assessed. The DDS assessment form was not used with these patients as all were under two years of age. The taking of prescribed medication for purposes such as anti-seizure control and gastro-oesophageal reflux was maintained during the study. Table 4-1 below summarises the study participants and medical history.

Measurement Techniques – Videomanometry

Research assessments were conducted using a custom-designed silicone rubber manometry assembly (catheter) in combination with the VFSS examination. This assembly was 2.5mm in diameter with seven water-perfused recording side holes. Straddling the middle of the sidehole array were three stainless steel impedance rings 4mm in length, spaced 20mm apart. The spacing of the rings was designed to minimise any possible irritation to the child’s nasal passage and pharynx on placement of the catheter (See Figure 4-3). The presence of the rings permitted visual localisation of recording sites relative to anatomical structure and bolus movement.

Table 4-1: Patients enrolled in videomanometry studies

	Age	Medical Issues	Medications	Clinical Assessment	VFSS
Patient 1 Male	8 months	Bronchiolitis episodes	Omeprazole	Low oral tone, occasional cough following fluid swallow.	Swallow trigger at pyriforms for fluids. Laryngeal penetration of thin and thickened fluids.
Patient 2 Female	16 months	Arthrogryposis multiplex congenita, hypotonia, lower respiratory infections; gastrostomy, obstructive sleep apnoea	Omeprazole, Microlax	Low oral tone, drooling, suspected aspiration of food/fluid	Aspiration of trace amounts. Minimal food or fluid accepted.
Patient 3 Female	5 months	Central sleep apnoea, GOR	Nil	Coughing during fluid swallows	Aspiration of thin fluids
Patient 4 Female	11 months	LRTI, Interarytenoid groove/laryngeal cleft	Nil	Normal oromotor, Cough & wheeze with thin fluids	Aspiration of thin and slightly thick fluid. Laryngeal penetration of puree.
Patient 5 Male	15 months	Hypoxic-ischaemic event with physical and cognitive sequelae	Phenobarbitone, Diazepam	Moist breath sounds following fluids.	Thin fluid aspiration, delayed swallow initiation for solids.
Patient 6 Male	10 months	Infantile spasms, Projectile vomiting	Vigabatrin	Coughing during eating and drinking, delayed oromotor skills	Aspiration of thin fluids. Laryngeal penetration of thin & thick fluids.
Patient 7 Female	21 months	Recurrent pneumonias, Repaired TOF, oesophageal strictures requiring dilatation. Planned Nissen's fundoplication & Gastrostomy	Lactulose, Paraffin emulsion	Occasional cough with fluids.	Delayed swallow trigger at pyriforms. No penetration or aspiration.

TOF = Tracheoesophageal fistula, GOR = Gastro-oesophageal reflux, LRTI = Lower respiratory tract infection, VFSS = Videofluoroscopic Swallow Study

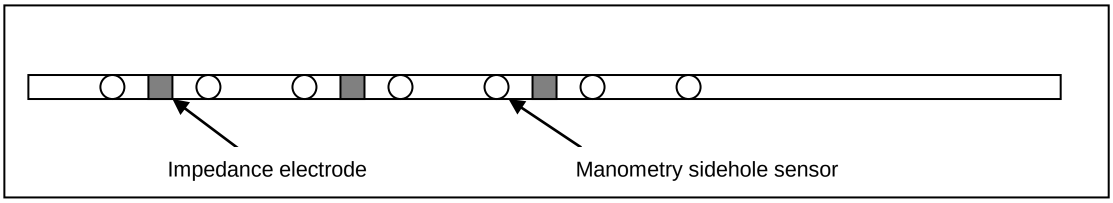


Figure 4-3: Manometric catheter. Diagram of 25mm diameter manometric catheter containing 3 impedance electrode sensors.

The manometry system was manually calibrated at atmospheric pressure 0 mmHg and then pressurised to 100 mmHg in order to set the parameters for recordings by the catheter and transducers using the *Trace!® V1.2* computer software (Prof. G. Hebbard, Royal Melbourne Hospital, Melbourne, Australia). The transducers converted the pressure received at each recording side hole within the water filled catheter to an electrical signal, which was then converted to digital waveform seen on the computer system. Following calibration, the catheter was attached to the manifold via the transducers and the entire system was perfused with degassed distilled water via a low-compliance pneumohydraulic perfusion pump (Dentsleeve; Wayville, South Australia) at 0.04 ml/minute, 15 psi (See Figure 4-4). The assembly was perfused for a minimum of half an hour prior to placement through the child's nasopharynx. This perfusion time was required to ensure the removal of air bubbles, which become trapped in the water and can distort recordings.

Figure 4 – 4: The low-compliance pneumohydraulic perfusion pump. The reservoir on the left of the image is attached to catheter and manifold for perfusion manometry.

Experimental Protocol

The participants fasted for a minimum of 4 hours prior to the assessment. Infants were fasted for maximum time between usual feed times (i.e. 3-4 hours). The catheter tip was dipped in lubricant and passed transnasally in each patient by a nurse until all side holes were located in the oesophagus (as visible from the onscreen manometry pressure recordings). The catheter was then withdrawn slowly until the segments of interest were located in the pharynx and above the proximal margin of the UOS (as evident by the pressure waveforms on the computer system), so that pressure changes could be recorded across the pharyngo-oesophageal segment (velopharynx to the proximal oesophagus). The external section of the catheter was then taped in place on the face until the study was complete (generally in place for a maximum of 1 hour: The length of time with the tube in place was also impacted by extraneous factors, such as waiting time in Radiology in addition to variations in VFSS study length between individuals). For all studies, once placement of the catheter was successful, the child was moved to the radiology suite for videomanometry. Throughout the study, the system was perfused at a rate of 0.04ml/min at a pressure of 15psi.

Data Analysis - Videomanometry

The videofluoroscopy images were acquired on the computer system allowing simultaneous recording manometry (*Trace!* ® version 1.2, Prof G Hebbard, Royal Melbourne Hospital, Melbourne, Australia) at 25 frames per second. Hence the VFSS findings of aspiration and pharyngeal residue could be correlated with manometry during later analysis. Manometry files were analysed, recording the basal pharyngeal and UOS pressures, peak pressure at amplitude of pharyngeal contraction and UOS nadir pressure. Figure 4-5 illustrates the manometric catheter in place in an infant's pharynx and the corresponding waveforms.

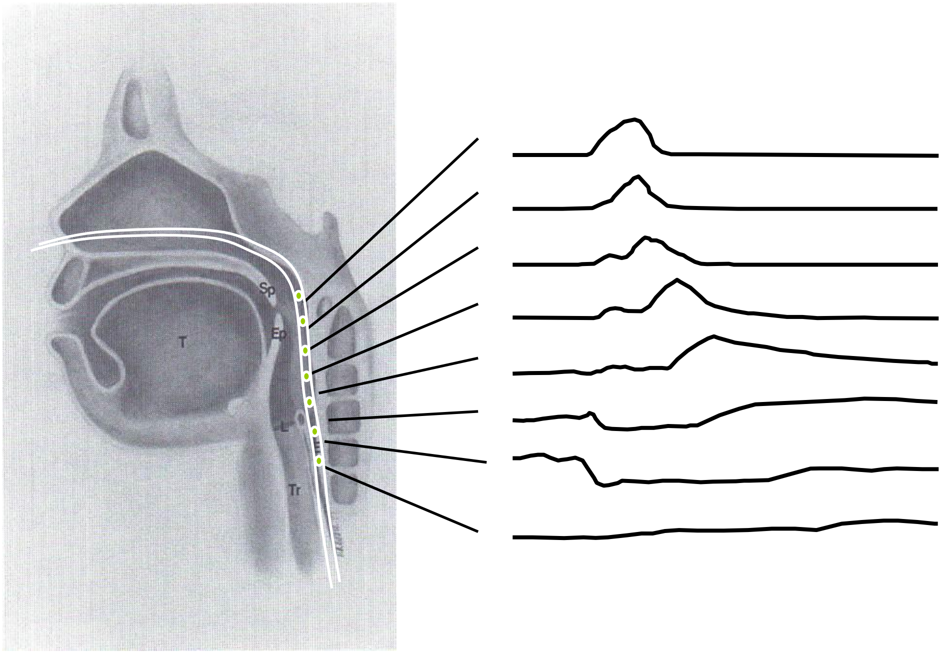


Figure 4-5: Diagram of a manometry catheter in place in an infant. The corresponding manometry waveforms can be seen on a line plot. Each manometric sensor corresponds to a particular region in the pharynx. Peaks in the line plot are seen with pharyngeal contraction. A drop in pressure is seen at the UOS.
Sp= soft palate, Ep = epiglottis, L = larynx, Tr = trachea, T = tongue.

4.3 METHODS - IMPEDANCE STUDIES

The second stage of studies did not include manometry, but an impedance only catheter with the use of simultaneous videofluoroscopy recordings as previously conducted by Omari and others (2006b) in their validation of this method with adults. This method, (which also involved manometry in the adult studies, but only included impedance in the paediatric assessments discussed here) showed that bolus transit could be accurately recorded across the UOS and below. In these studies impedance only recordings were utilised due to technical limitations with combining the pressure and impedance in a catheter of small size. The use of two catheters (i.e. one for manometry and one for impedance) was not feasible.

4.3.1 Bolus Conductivity Testing - Impedance characteristics of foods and fluids

Prior to assessments with patients, conductivity of various foods and fluids was tested to determine any significant differences in impedance characteristics of common foods and fluids. Differences could potentially impact impedance recordings and the respective drop/recovery of impedance during swallows of foods or fluids. Impedance assessments require that food/fluid boluses swallowed are sufficiently conductive to enable tracking of the bolus flow by the electrodes.

Methodology

Bolus conductivity tests were performed in the laboratory of the Gastroenterology Department, WCH. During each bolus conductivity test, a 10 ml test tube vial was filled to the top with one of 18 different foods and fluids. The electrodes of the impedance only catheter (Unisensor USA Inc, Portsmouth, NH), 1.9mm diameter with 13 impedance electrodes (2mm long x 2mm wide) (See Figures 4-6 and 4-7), were immersed in the food/fluid until a drop in impedance from baseline was recorded. The baseline value for each food or fluid was then collected together with the nadir value (the lowest point on the graph during the drop from baseline) for each food and fluid. The catheter was removed from the food/fluid and cleaned before commencing the next trial.

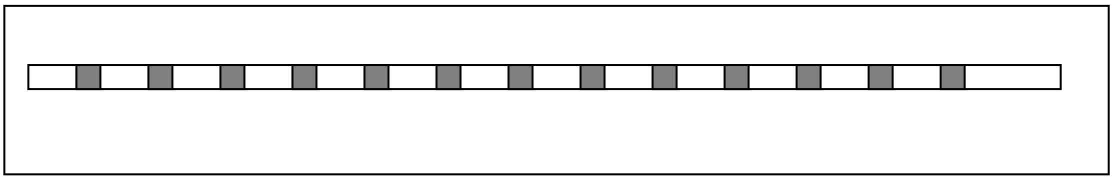


Figure 4-6: Diagram of an impedance catheter. The catheter used in this study measured 1.9mm in diameter and contained 13 electrodes (2mm long x 2mm wide).

Figure 4-7: Photograph of impedance catheter containing 13 impedance electrodes.

The following 18 different foods and fluids were selected for testing as they were considered representative of foods and fluids brought to paediatric VFSS assessments by parents: Water, water & cordial (4 parts water to 1 part cordial), full cream cow's milk, S26 infant formula, "Big M" chocolate flavoured milk, apple juice, apple juice diluted with water, pureed pear, custard, mashed potato, Heinz tinned spaghetti with tomato sauce and cheese, Omnipaque™ contrast agent, Polibar™, Sandhill® viscous bolus, 'Powerade®' isotonic solution, Karicare® AR infant formula, and Karicare® infant formula (cold and warm). These were then also mixed with Omnipaque™ contrast in a 50% mix (as is the procedure for the standard VFSSs conducted at the WCH).

Analysis

Foods/fluids impedance recordings were required to drop to a conductivity level of

1000 Ohms (and preferably 500 Ohms) in order to be sufficiently tracked by impedance recordings through the pharynx. All foods and fluids were scored as being above or below this criterion. Figure 4-8 illustrates an example of a recording at one impedance segment. Figure 4-9 is an example of a group of impedance segment recordings as seen on the *BioVIEW*® impedance system (Sandhill® Scientific, Denver, Colorado, USA).

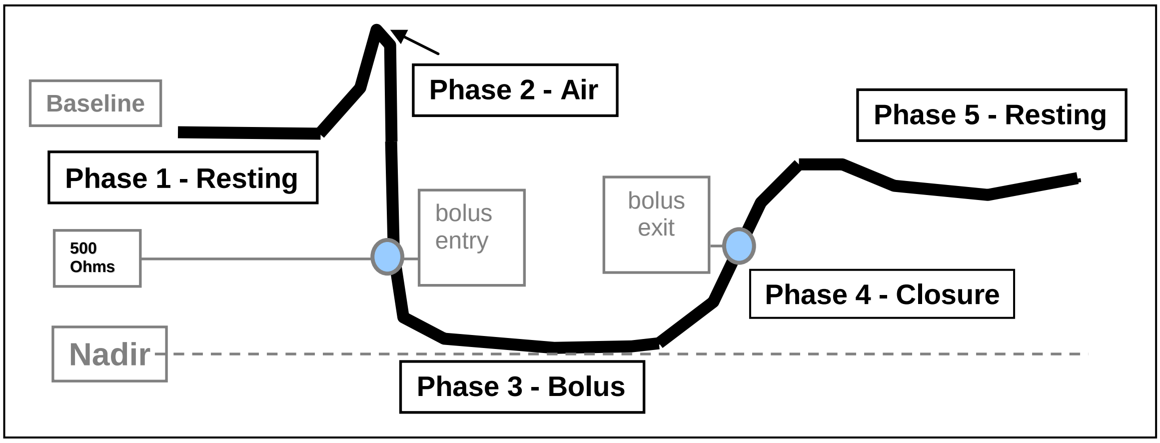


Figure 4-8: Diagrammatic illustration of impedance recording at one impedance segment. An example of a 500 Ohms cut-off is labelled (where the bolus entry is signalled as a drop in impedance). Impedance remains at nadir (the lowest point) while there is bolus presence in the impedance segment. A rise in impedance is seen as the bolus leaves the segment.

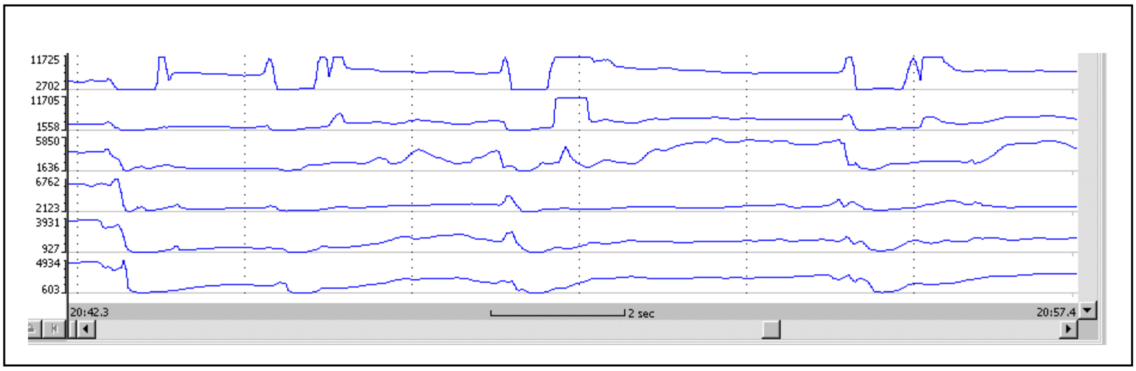


Figure 4-9: An example of impedance waveforms recorded across 6 impedance segments using the *BioVIEW*® impedance system. The x axis indicates baseline and nadir Ohms values for each impedance segment.

4.4 IMPEDANCE ASSESSMENTS DURING BOLUS SWALLOWS

Stage 2 of the studies involved recruitment and clinical assessment for the paediatric participants via the method outlined previously for manometry studies, however, impedance assessment rather than manometry was combined with VFSS. This stage involved two assessment groups of participants (Group A and Group B). Group A was analysed using the first technique described below, and Group B was scored using two different techniques, which are outlined and contrasted in the following sections.

4.4.1 Assessment Group A – MII vs VFSS

Seven patients (3 female and 4 male) ranging from 8 months to 6 years, 7 months (mean age 3 years 1 month) were assessed using combined impedance and VFSS (see Table 4-1). The majority of participants had neurological conditions. The DDS scores (Sheppard, 2003) for the four patients over 2 years of age were in the moderate to severe range. The swallowing difficulties noted during case history discussion and clinical assessment were coughing with eating and drinking, chest signs of possible aspiration of food/fluid and suspicion of silent aspiration. Those with moderate to severe dysphagia required food consistency modification in order to eat orally and for some this was supplemented by gastrostomy feeding. Table 4-2 provides the age, medical details and assessment information for the patients in this component of the study.

Impedance Measurement Techniques

Research assessments with Group A patients were conducted using a custom-designed impedance assembly (Unisensor, Attikon, Switzerland) passed transnasally

Table 4-2: Medical details of children in Group A impedance assessments

	Age	Medical Issues	Medications	Clinical Assessment DDS Rating	VFSS
Patient 1 Male	15 mths	Epilepsy, plagiocephaly, developmental delay, translation of chromosomes 3-6. Large tonsils, planned tonsillectomy, right convergent squint	Phenobarbitone	DDS N/A, clinical assessment indicated low oral tone, tongue thrusting, coughing with fluids.	Delayed swallow trigger. Penetration and silent aspiration of thin fluid. Occasional nasopharyngeal reflux for puree. Trace vallecular residue for puree.
Patient 2 Female	14 mths	Frontal lobe atrophy on CT, subdural abscess+craniotomy, Opacity on chest x-ray	Nil	DDS N/A, suspected aspiration of thin fluid	Thin fluid aspiration
Patient 3 Male	3 yrs 4 mths	Atypical febrile convulsions, Chronic cough, FTT, apnoeas since first days of life, Tonsillectomy; over-bite, submucous cleft to be treated	Nil	DDS = Moderate Chronic cough, choking on food.	Slow oral phase. Delayed swallow trigger at pyriforms. No penetration or aspiration.
Patient 4 Female	6 yrs 1 mth	Monosomy 1p36, chromosomal abnormality, low tone, Submucous cleft palate, chest infections	Phenobarbitone	DDS=Profound disorder 50th percentile, silent aspiration suspected	Nasal regurgitation, delayed swallow trigger at pyriforms, laryngeal penetration, no aspiration. Pharyngeal residue post-swallow requiring a 2nd or 3rd swallow to clear.
Patient 5 Female	6 yrs 7 mths	Microcephaly & global developmental delay, Atrial Septal Defect, Tonsillectomy & adenoidectomy, SN hearing loss, Nissen's & Gastrostomy,	Periactin, Losec, Dexamphetamine	DDS = Severe Disorder, 50th percentile	Laryngeal penetration and silent aspiration of thin fluid. Vallecular residue for mashed and pureed foods.
Patient 6 Male	2 yrs 11 mths	Fetal Valproate syndrome, Laryngomalacia, Nissen's fundoplication & gastrostomy recurrent chest infections, asthma	Zantac, Ventolin, Seretide.	DDS = profound disorder, 5th percentile, poor oral control of fluids, multiple swallows for purees, limited oral food/fluid experience	Small bolus sizes accepted. No frank aspiration.
Patient 7 Male	8 mths	Polymicrogyria throughout cerebral hemispheres	Nil	Suspected aspiration of thin fluid.	Aspiration of thin fluid. Some minor pharyngeal residue for purees & mashed foods.

FTT = Failure to Thrive, DDS=Dysphagia Disorders Survey (Sheppard, 2003)

to straddle the PE segment (velopharynx to proximal oesophagus) in combination with the VFSS examination. This impedance assembly was the same as the one described previously (See section 4.3.1). As well as measuring impedance during bolus transit through the pharynx, these rings enabled precise visual localisation of the bolus relative to the impedance segments during VFSS. This was an important feature to aid later analysis. This impedance assembly was connected to the *BioVIEW®* impedance system (Sandhill® Scientific, Denver, Colorado, USA) so that recordings could be documented and analysed. Video images were recorded simultaneously via *Trace!® V1.2* computer software (Prof. G. Hebbard, Royal Melbourne Hospital, Melbourne, Australia).

Impedance protocol

As with the manometry protocol, participants fasted for four hours prior to the placement of the catheter. The impedance assembly was then inserted transnasally and positioned so that impedance segment 3 was located above the margin of the UOS at rest. This was in order to record impedance changes across the PE segment during bolus swallows. The patient was then transferred to the Radiology suite for the VFSS component of the study. Figure 4-10 shows a VFSS image with the impedance catheter in place.

VFSS protocol

The VFSS protocol was identical to VFSS for manometry studies as previously described. Each food or fluid bolus offered during the combined impedance and VFSS study contained 1% saline to aid conductivity for detection by impedance sensors.

Method of Analysis – Correlating VFSS & Impedance recordings

Comparison and correlation of impedance recordings and videofluoroscopy was conducted via the same analysis techniques used in the validation studies of pharyngeal impedance in adults (Omari, et al., 2006b; Szczesniak, et al., 2008; Szczesniak, et al., 2009). The impedance studies were analysed for correlation between "known" bolus presence evident on videofluoroscopy and the pharyngoesophageal impedance change recorded at each impedance segment (the section spanning two impedance electrodes). Videofluoroscopic images were analysed frame by frame (every 0.08 seconds) and used as the indicator of true bolus movement. Presence or absence of the bolus at each impedance segment from the oropharynx to the oesophagus (labelled as Z1 through Z6 in the example in Figure 4-13) was recorded at this 0.08sec interval for each VFSS study (e.g: Time *0* was where the bolus first entered the most proximal impedance segment). Bolus movement through the pharynx was, therefore, characterised by bolus entry visualised at the first electrode ring of an impedance segment in the hypopharynx (impedance segment varied a little due to variations in patient size and any complications or extended time taken to place the catheter) to bolus exit at the first impedance segment past the level of the UOS distally.

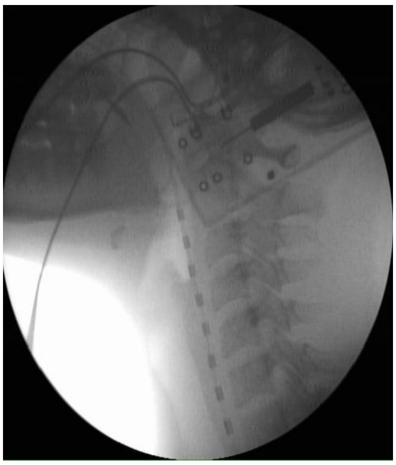


Figure 4-10: VFSS image of impedance catheter in place in the pharynx.

Raw impedance values were recorded at the baseline (prior to bolus swallow), and were also captured at nadir (during bolus swallow, as the bolus passing by the electrodes results in a drop) and at specific points during the swallow relating to bolus entry and bolus clearance (as visualised on VFSS). In order to assess whether impedance tracings alone could track the bolus, measurements were also taken as impedance estimates of the VFSS parameters of bolus entry, timing of bolus clearance and bolus transit times. Bolus entry at an impedance segment was based on a fall in impedance from baseline to < 50% of the baseline/nadir difference, or on a fall in impedance from baseline to a value of 500 Ohms or less. Impedance parameters for bolus clearance were set at > 50% impedance recovery or > 500 Ohms. The impedance parameters were set at these levels for ease of use with the analysis software accompanying the impedance system. The use of two levels of analysis (50% cut-off and 500 Ohms cut-off) was to compare whether one analysis cut-off point would be more effective than the other. The level of agreement between VFSS bolus presence and impedance assessment of bolus presence/absence was determined using Cohen's Kappa coefficient. Levels of agreement relate to Kappa values as follows: 0.00 = no agreement, 0.00-0.2 = slight agreement, 0.21-0.40 = fair, 0.41-0.60 = moderate, 0.61-0.8 = substantial, 0.81-1.00 = almost perfect (Landis & Koch, 1977).

An example of the analysis used is presented in Figure 4-11 below. This series of tables exhibits the three sets of data used to analyse each swallow for one patient – the videofluoroscopy image, the raw Ohms impedance values (i.e. impedance drop from baseline) and percentage drop from baseline impedance values. The shaded area in the "Videofluoroscopy" section indicates the bolus presence at each

0.08second interval and the location of the bolus presence in the pharynx (i.e. HP=hypopharynx, UOS=Upper Oesophageal Sphincter). The section of Figure 4-13 headed "Impedance" includes the baseline and nadir in Ohms for each Impedance segment (Z1-Z5). The boxes below each time interval display the difference between the baseline and nadir Ohms at each segment during the swallowing of the bolus (a drop indicating bolus presence at that segment). The boxes displaying a number of 500 Ohms (or less) are highlighted for comparison with the videofluoroscopic analysis of bolus presence. The final section in Figure 4-13 shows percentage drop in impedance from baseline at each time interval. As a criterion of 50% or below was set for this study, all boxes with a figure of 50% or below are highlighted for comparison with videofluoroscopy.

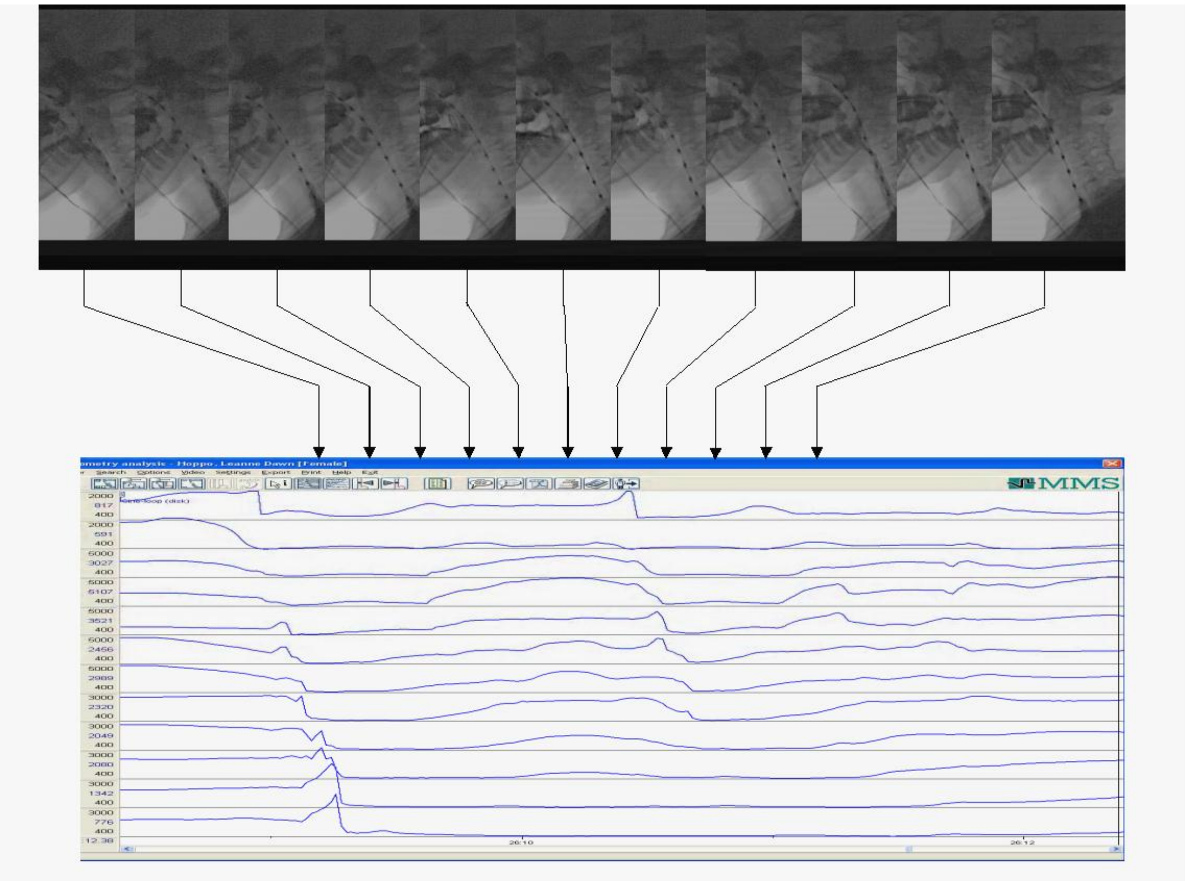
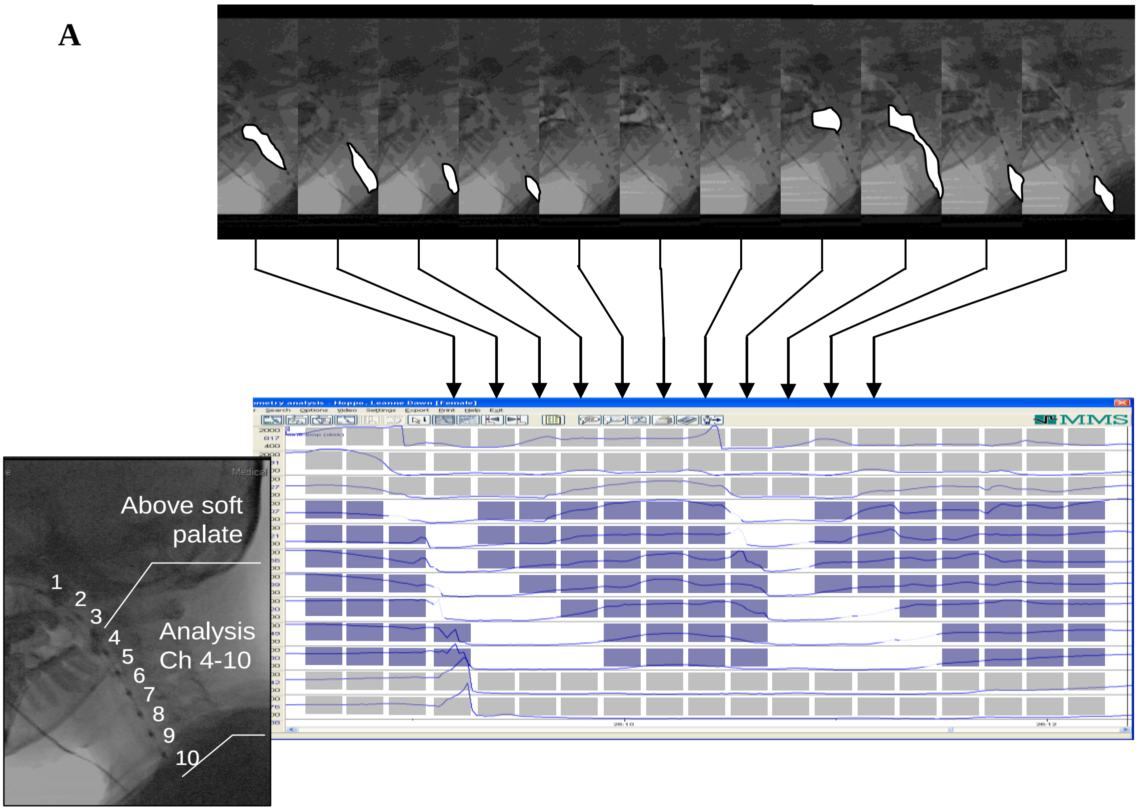


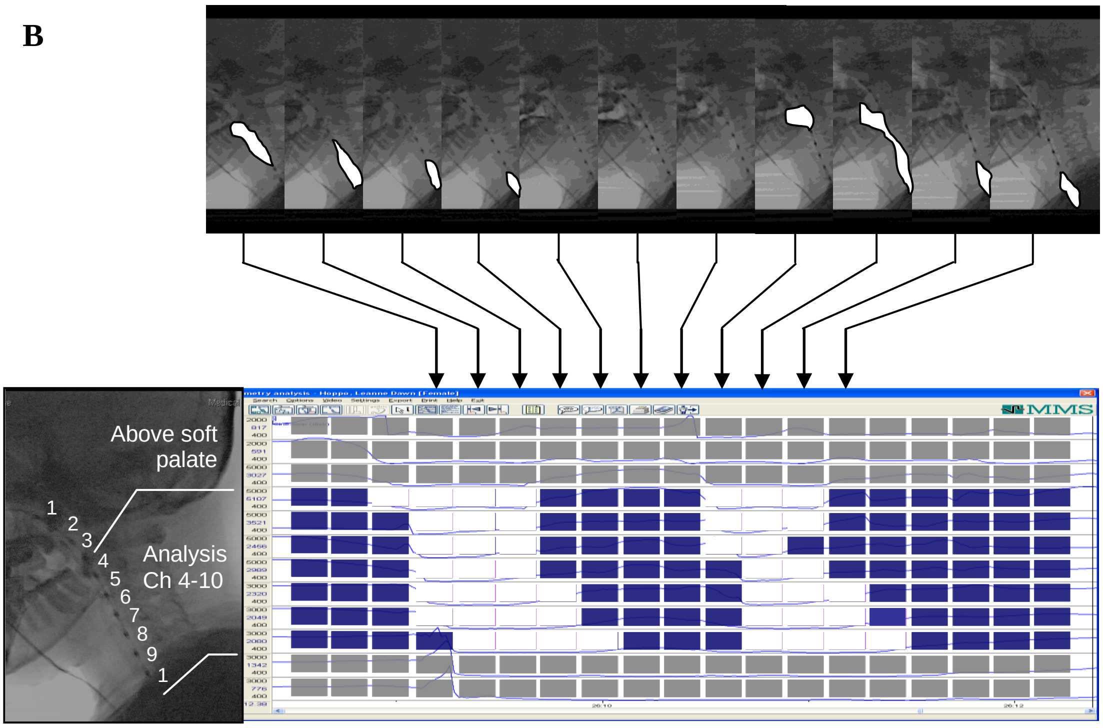
Figure 4-11: An example of videofluoroscopy image analysis of two boluses swallowed (viewed frame by frame) and the corresponding impedance plot for the same two swallows.

A



Above soft
palate
1
2
3
4
5
6
7
8
9
10
Analysis
Ch 4-10
MMS

B



Above soft
palate
1
2
3
4
5
6
7
8
9
1
Analysis
Ch 4-10
MMS

C

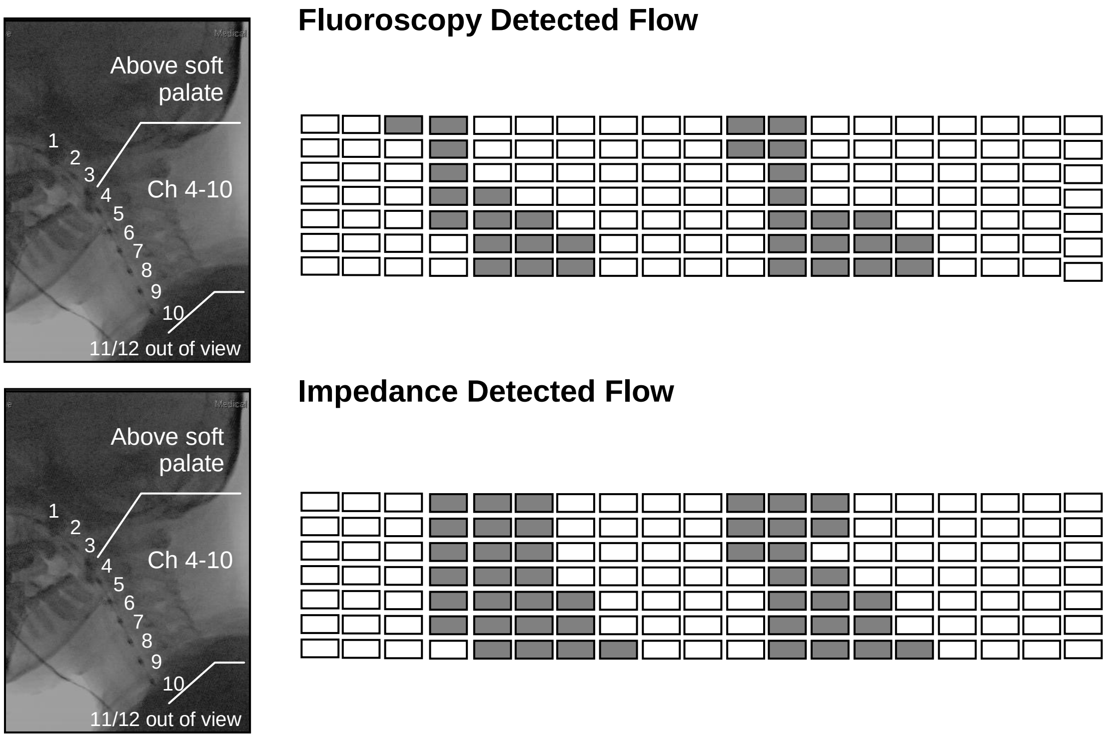


Figure 4-12: Example of VFSS detected bolus flow and impedance detected bolus flow during two swallows for the purposes of data analysis.
A. Highlighted image of bolus flow through the pharynx during videofluoroscopy. In the VFSS image on the left, analysis channels from 4-10 are visible on the impedance catheter positioned across PE segment. The impedance channels have a super-imposed image of VFSS determined flow in the form of a matrix. B. The same boluses as in (A) passing through the pharynx with impedance detected flow highlighted on the matrix. C. Diagram contrasting VFSS detected flow and impedance detected flow on the matrix.

VIDEOFLUOROSCOPY/IMPEDANCE
Time Swallow Commenced: 13.38
Swallow Type: mashed baked beans, swallow 2

1= Bolus present at 1 sensor
2 = Bolus present at 2 sensors
0 = Bolus not present

VIDEOFLUOROSCOPY

		Time in 0.08sec Intervals																				
Location of Impedance segments		0.08	0.16	0.24	0.32	0.4	0.48	0.56	0.64	0.72	0.8	0.88	0.96	1.04	1.12	1.2	1.28	1.36	1.44	1.52	1.6	1.68
HP	Z1	0	0	2	2	2	2	2	2	2	2	2	0	0	1	1	1	0	0	0	0	0
HP	Z2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
HP	Z3	2	2	2	2	2	2	1	0	0	0	2	2	2	2	2	2	2	2	2	2	2
HP	Z4	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UOS	Z5	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

IMPEDANCE
Raw Ohms difference from baseline

			Time in 0.08sec Intervals																				
Segment	Baseline	Nadir	0.08	0.16	0.24	0.32	0.4	0.48	0.56	0.64	0.72	0.8	0.88	0.96	1.04	1.12	1.2	1.28	1.36	1.44	1.52	1.6	1.68
Z1	3596	540	713	398	14	0	7	104	378	1165	1374	1167	825	775	827	922	994	1047	1058	1096	1104	1150	1257
Z2	2721	531	144	117	29	9	0	18	92	189	345	387	333	322	372	466	469	506	506	505	497	569	588
Z3	1886	625	0	102	323	447	496	466	310	236	236	245	236	231	241	283	287	284	286	283	275	308	423
Z4	2227	678	0	14	338	601	841	1082	1087	982	1008	1018	1023	1018	1020	1027	1027	1027	1029	1042	1064	1066	1113
Z5	1887	495	176	161	0	9	137	350	574	715	860	946	1051	1091	1118	1152	1159	1171	1170	1174	1182	1191	1188

Percentage Impedance drop relative to baseline

			Time in 0.08sec Intervals																				
Segment	Baseline	Nadir	0.08	0.16	0.24	0.32	0.4	0.48	0.56	0.64	0.72	0.8	0.88	0.96	1.04	1.12	1.2	1.28	1.36	1.44	1.52	1.6	1.68
Z1	3596	540	23%	13%	0%	0%	0%	3%	12%	38%	45%	38%	27%	25%	27%	30%	33%	34%	35%	36%	36%	38%	41%
Z2	2721	531	7%	5%	1%	0%	0%	1%	4%	9%	16%	18%	15%	15%	17%	21%	21%	23%	23%	23%	23%	26%	27%
Z3	1886	625	0%	8%	26%	35%	39%	37%	25%	19%	19%	19%	19%	18%	19%	22%	23%	23%	23%	22%	22%	24%	34%
Z4	2227	678	0%	1%	22%	39%	54%	70%	70%	63%	65%	66%	66%	66%	66%	66%	66%	66%	66%	67%	69%	69%	72%
Z5	1887	495	13%	12%	0%	1%	10%	25%	41%	51%	62%	68%	76%	78%	80%	83%	83%	84%	84%	84%	85%	86%	85%

Figure 4-13: Example of impedance analysis in one patient's swallow.
This was the form of data analysis used for correlation of bolus presence in videofluoroscopy with Impedance (in raw Ohms) and percentage drop in Ohms from baseline. ***HP = hypopharynx, UOS = Upper Oesophageal Sphincter, Z1 to Z5 =*** **Impedance segment 1 to impedance segment 5**

4.4.2 Assessment Group B – Inter-rater Agreement

Six patients aged 22 months to 13 yrs. 5 months (average age 6.5 years) were assessed using an impedance only catheter (Unisensor USA Inc., Portsmouth, NH) 1.9mm diameter with 13 impedance electrodes (2mm long x 2mm wide) straddling the PE segment (velopharynx to proximal oesophagus). The patient medical details are summarised in Table 4-3. All had neurological disorders and five of the six patients assessed using the DDS (Sheppard, 2003) had swallowing disorders in the moderate to profound range.

Method

Analysis for Group B took place with the use of two independent raters scoring the presence or absence of the bolus at each impedance segment in the pharynx (viewed on VFSS). As previously, this was compared with the computer analysis of the impedance data at each impedance segment. Two independent observers (one speech pathologist and one paediatrician) rated the VFSS and impedance individually and were blinded to each other's analysis. Each impedance segment present in the hypopharynx was analysed frame by frame in the VFSS image for bolus presence or absence. Swallow performance was not rated by these observers. Bolus presence ranged from complete bolus clearly present in an impedance segment to judgment of the tail of the bolus leaving the segment. The number of impedance segments in the hypopharynx varied between patients due to the different age and size of the participants, but ranged from four to six. This analysis was then temporally correlated with the impedance Ohms recording at that segment.

Table 4-3: Medical details of Children in Group B Impedance Assessments

	Medical Issues	Medications	Clinical AssessmentDDS Rating	VFSS
Patient 1 **22 mths, Male**	Ex-Prem 34/40, Down's Syndrome, Severe OSAS – requiring overnight oxygen, hypothyroidism, GOR	Thyroxine, Omeprazole 10mg	DDS N/A Likely aspiration of thin fluids, mild difficulty	Silent aspiration of thin fluid 6/17 swallows
Patient 2 **3 yrs 11 mths, Male**	Spastic CP with quadriplegia, Global developmental delay, epilepsy.	Lamotrigine, Sodium Valproate, Phenobarbitone	DDS: 95%ile, Severe Disorder	Penetration & silent aspiration of thin and slightly thick fluids
Patient 3 **6 yrs 2 mths, Male**	Ex-prem 24/40, CLD, asthma, GORD, CP with cerebellar ataxia, history of sleep apnoea	Baclofen and L Dopa	DDS score: moderate	Penetration & silent aspiration for thin and slightly thick fluid.
Patient 4 **2 yrs 10 mths, Male**	Hypoxic brain injury (diffuse encephalopathy), seizures, Global Developmental Delay, obstructive sleep apnoea.	Phenobarbitone, Valproate 140mg	Coughing with thin fluids, suspected aspiration, purees only DDS: Severe Disorder, 25th percentile	Epiglottic undercoating for thin fluids. No aspiration.
Patient 5 **10 yrs 9 mths, Male**	Global Developmental Delay, CP with spastic quadriplegia, Epilepsy		DDS: Profound disorder	Aspiration of all consistencies, - fluids and smooth solids.
Patient 6 **13 yrs 5 mths, Male**	Severe developmental delay	Sodium Valproate 500mg	DDS: Severe disorder, 25th percentile	Aspiration of thin and thickened fluids when in large consecutive sips.

DDS = Dysphagia Disorder Survey (Sheppard, 2002), CLD = Chronic Lung Disease, CP = Cerebral Palsy, OSAS = Obstructive Sleep Apnea Syndrome, GOR = Gastro-oesophageal reflux.

4.5 IMPEDANCE - ANALYSIS USING FLOW INTERVAL

The results of the same six patients assessed in the Group B studies (Table 4-3) were evaluated again using a new analysis technique. In order to avoid the difficulty in analysing impedance data relative to baselines, a technique was devised to assess the shape of impedance drop and recovery over several impedance segments located in the distal pharynx.

Videofluoroscopy was used in conjunction with impedance assessments and aspiration and/or penetration and pharyngeal residue was again scored for each swallow, as per the method described previously (see section 4.1.4) involving the Penetration/Aspiration Scale (Rosenbek, et al., 1996) and the Bolus Residue Score.

The new method of analysis resulted in a “Flow Interval” score to describe the impedance results for this study group. Impedance recordings were temporally correlated exactly with VFSS recordings. MATLAB® (version 7.9.0.529; The MathWorks Inc.) was used to analyse the impedance recordings derived from the *BioVIEW®* impedance recording system and then converted to ASCII text format. Analysis of the data from each impedance segment commenced at 0.25 secs prior to swallow onset (identified by anterior hyoid movement) and ceased 2.5 secs after swallow onset. The impedance drop and recovery recorded at each impedance segment seen within the pharynx on videofluoroscopy was used to create a ‘shape’ of impedance change throughout this ‘region of interest’ (ROI) from tongue base to upper margin of the UOS.

The impedance Flow Interval was determined with a method broadly based on one previously described for measurement of UES relaxation interval from pressure used in solid-state high resolution manometry recordings in normal adults (Ghosh, Pandolfino, Zhang, Jarosz, & Kahrilas, 2006). Just as recordings in the pharynx are complicated due to the anatomical structure, manometric recordings of UOS contractility are complicated by the asymmetry and rapid contraction of this region. The fact that the sphincter also moves in an orad direction (towards the mouth) during relaxation makes measurement via a sensor difficult (Ghosh, et al., 2006). The algorithm devised by Ghosh and others (2006) enabled objective identification of intrabolus pressure, a significant feature of UOS function during swallowing, by being able to consistently isolate the greatest pressure within the UOS. Though some negative pressures may be present at the inferior margin of the UOS these are often balanced by higher proximal pressures (Ghosh, et al., 2006). Pressure was measured at each manometric sensor throughout the hypopharynx and UOS region at 0.05 second intervals. The cumulative relaxation interval was measured in 0.5mmHg intervals at each pressure level from -10 to 50mmHg. The pressure at the 50th percentile of the relaxation interval was labelled the median intrabolus pressure.

The Flow Interval applies this idea to impedance recordings through the measurement of the maximum impedances at each point along the ROI from tongue base to the proximal margin of the UOS (Figure 4-14A and 4-14C). This technique involved standardising the raw impedance data to the median impedance (therefore presenting impedance recordings as median standardised units [msu] rather than Ohms). This means that for each impedance segment, the greatest impedance recording at each time interval was recorded and plotted. Impedance thresholds for analysis were progressively increased in steps of 0.01msu (total range of 0-2msu) to create an impedance versus cumulative time plot (Figure 4-14E). The amount of time impedance was below each step level was then determined from this plot, and a third-order polynomial equation (the typical equation for a curve with one inflexion) was used to mathematically describe the plot. The flow interval was then calculated by finding the cumulative time of the inflexion point of a smoothed best-fit curve (Figure 4-14E).

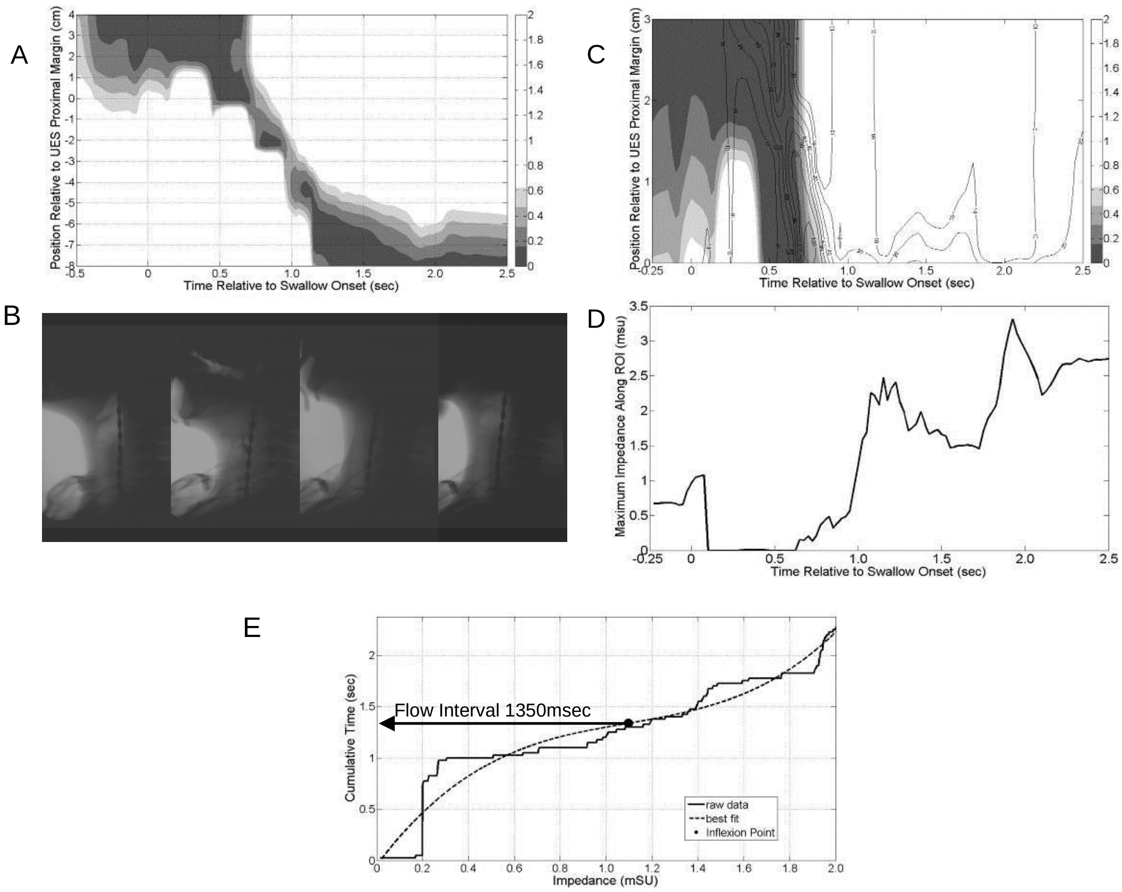


Figure 4-14: Determining the Flow Interval.
A. Impedance changes in the "Range of Interest" represented in the form of a two-tone impedance isocontour plot following standardisation of impedance data to the median impedance. B. Fluoroscopy images of the impedance segments within the ROI. C. Maximum impedances within the ROI measured at all time intervals. D. Temporal plot of all maximum impedances. E. The impedance *vs* cumulative time plot. The cumulative time of the inflexion point of a smoothed best-fit curve objectively calculates the Flow Interval.

5 RESULTS

The results are documented in an order which mirrors the presentation of each stage of the study in the methodology section. Videofluoroscopy and manometry are discussed first, followed by impedance (including food and fluid conductivity characteristics), and the results of the different impedance analysis methods trialled. Finally, the results of a new technique (the Flow Interval) used to objectively define aspiration risk during swallowing are presented.

5.1 VIDEOFLUOROSCOPY

Throughout the study as a whole, 19 patients were studied and a total of 295 swallows were analysed for penetration or aspiration, and scored for bolus residue. The majority of swallows (66%) were triggered at the level of the valleculae. The mean penetration/aspiration score was significantly higher for swallows triggered at the level of the pyriform sinus. Bolus residue scores were not significantly different between trigger at valleculae, laryngeal inlet and pyriform sinus.

Table 5-1: Level of Initiation of Pharyngeal Swallow and Aspiration/Penetration (AP) and Bolus Residue (BR) Scores

Level of initiation of Pharyngeal Swallow	Number of Swallows	Mean AP Score	Mean BR score
Valleculae	66% (195/295)	1.5	1.5
Laryngeal Inlet	14% (42/295)	1.5	1.6
Pyriform Sinus	20% (58/295)	3.5	1.4

5.2 PHARYNGEAL VIDEOMANOMETRY

All 7 participants in stage 1 of the study tolerated catheter placement and participated in the combined videomanometric studies, though the catheter insertion process was uncomfortable for a short time. Once it was in place, patients were relaxed and generally ignored its presence. Patients in this group had swallowing difficulties resulting from a variety of origins, and only two had neurological disorders. Analysis for patient 2 was not possible due to the patient's limited swallowing experience, minute bolus sizes visualised and minimal amounts of food and fluid accepted during the study. This is not an unusual result for a 16 month old and experience with oral intake (nil by mouth for some time prior to VFSS, with limited oral trials with her speech pathologist due to concerns regarding high aspiration risk).

Four of the six patients analysed for combined manometry and VFSS experienced penetration and aspiration at some point during the study (Patients 1, 3, 4 and 6). The aspiration/penetration scores (AP) are listed in Table 5-2. All those who aspirated did so with thin fluid. Patient 4 also aspirated puree. A swallow trigger at the pyriforms was associated with increased risk of aspiration. In several patients penetration and/or aspiration occurred without residue being present hence bolus residue was not a good predictor of penetration or aspiration into the airway.

Relationship between aspiration /penetration and pharyngeal/oesophageal pressures

Patients 4 to 7 had particularly low UOS basal pressures. Two patients with the highest AP scores (Patient 4, AP=2.8 and Patient 6, AP=2.7) had the lowest UOS basal pressures (17.8mmHg and 14.8mmHg respectively). The other two patients with relatively high AP scores (Patient 1, AP=1.9 and Patient 3, AP=1.9) had elevated UOS basal pressures (32.2mmHg and 29.9mmHg).

Table 5-2: Mean Aspiration Penetration Scores and Mean Bolus Residue scores for participants in videomanometry.

	Mean AP (Aspiration/Penetration) Score	Mean BR (Bolus Residue) Score
Patient 1	1.9	1
Patient 2	Analysis N/A	Analysis N/A
Patient 3	1.9	1
Patient 4	2.8	1.3
Patient 5	1.6	1
Patient 6	2.7	1
Patient 7	1	1

Table 5-3 outlines the manometric pressures recorded in this study and also the results of studies conducted in asymptomatic swallowers of a similar age to the children in this study, by Rommel (2002). The UOS basal pressures in the Rommel (2002) study ranged from 30-78, but for the studies in Stage 1 of the present study, basal pressures were lower and ranged from 14 - 32.24mmHg. In contrast, Stage 1 study UOS nadir pressures were higher (13-20mmHg) than the asymptomatic swallowers (3-11mmHg). Pharyngeal pressures overall were low when compared with the pharyngeal pressures in the Rommel (2002) study. Those with the greatest AP scores had the lowest pharyngeal pressures. The one patient whose pharyngeal pressures fell within the comparative range was within the low end (26.9mmHg in a comparative range of 24-58mmHg). Figure 5-1 illustrates the results from this study compared with the results for asymptomatic swallows in the study by Rommel (2002).

Table 5-3: Comparison of manometry results for this study and previous study by Rommel (2002)

Participants	VFSS Diagnosis	Characteristics of Swallow – HRM		
		UOS Parameters		Pharyngeal Parameters
		BP mmHg	RN (mmHg)	Peak Pharyngeal Pressure (mmHg)
Five patients with various pathologies (Rommel study)	No aspiration	Range 30-78	Range 3-11	Range 24-58
Patient 1	AP Score: 1.92 BR Score: 1	32	19	20
Patient 3	AP Score: 2.71 BR Score: 1	30	20	15
Patient 4	AP Score: 1.6 BR Score: 1	18	18	19
Patient 5	AP Score: 2.826 BR Score: 1.268	22	17	16
Patient 6	AP Score: 1.94 BR Score: 1	15	13	27
Patient 7	AP Scorer: 1 BR Score: 1	28	20	19

UOS= Upper Oesophageal Sphincter, BP = basal UOS pressure, RN=UOS relaxation nadir pressure

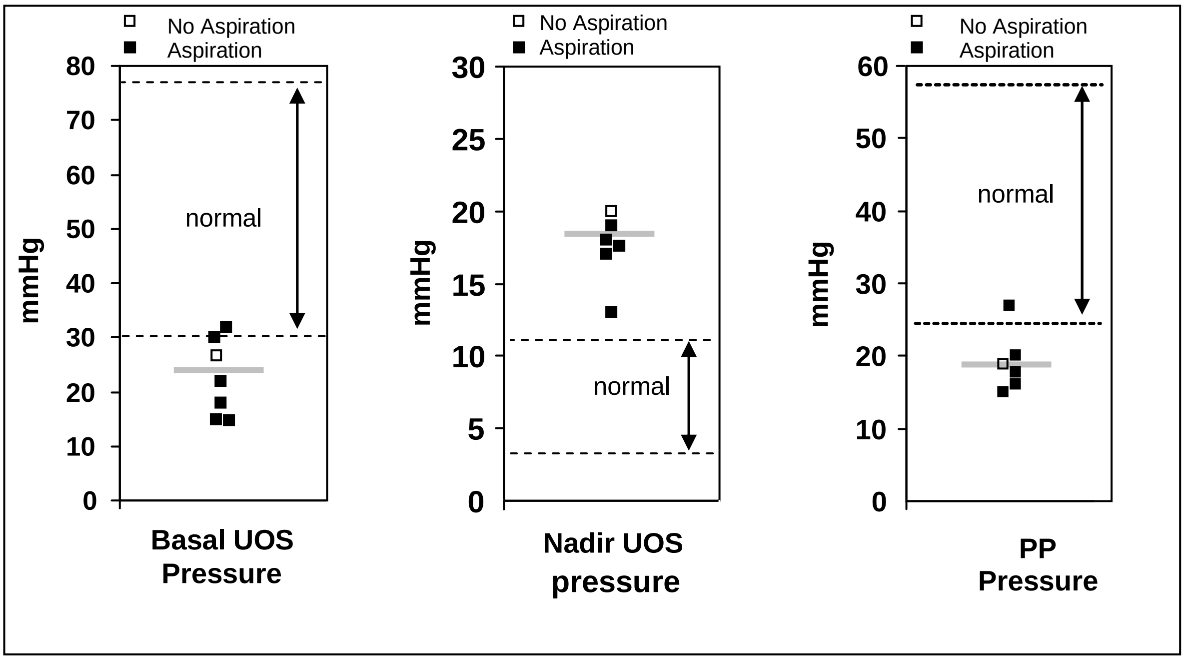


Figure 5-1: Manometry results for aspirators and non-aspirators in this study.
The three charts each indicate 'normal' range for pressures in asymptomatic swallowers as recorded in manometry studies by Rommel (2002).
UOS=Upper Oesophageal Sphincter, PP = Peak Pharyngeal.

5.3 IMPEDANCE

5.3.1 Food/Fluid Conductivity

Of all the foods and fluids tested, 10/18 (55%) exhibited conductivity levels of 1000 Ohms or less. Water, water & cordial, full cream cow's milk, S26 Infant formula, apple juice, diluted apple juice and Powerade® were all above 1000 Ohms. The addition of Karicare® Food thickener further reduced conductivity, however, by only very small amounts. Interestingly, Omnipaque™ radiology contrast exhibited a significantly lower conductivity, recording a drop to only 10200 Ohms from a baseline around 11000 Ω (See Table 5-5). This has significant implications for the assessments using impedance. As Omnipaque™ is the contrast added to all fluids (and the majority of foods) in a 50/50 fluid/contrast mix to enable visualisation of the boluses swallowed on VFSS, impedance recordings may have been less accurate if the bolus was less conductive. Alternately, Polibar™ radiopaque contrast had high conductivity with a drop to 606 Ω. Figure 5-2 shows the difference between Omnipaque™, Polibar™, the Sandhill® Viscous Bolus (used for oesophageal impedance studies) and Saline. With the exception of the significantly lower conductivity of Omnipaque™, all are relatively well matched. An additional note of interest is that during testing, temperature and thickening agents were found to have little impact on bolus conductivity. The conductivity of all fluid (with and without Karicare® Food Thickener) and food boluses plus the addition of Omnipaque™ and Polibar™ to food and fluids can be seen in Tables 5-4 and 5-5. Figures 5-2, 5-3 and 5-4 illustrate the differences in conductivity of the various fluids and solids. The addition of Omnipaque™ resulted in the impedance of all fluids rising above a level of 1000 Ohms. The conductivity of food items was also lowered, but a level below 1000 Ohms was maintained despite the addition of Omnipaque™.

Table 5-4: Impedance characteristics of contrast agents and normal foods and fluids with and without thickener added

	Ohms	<1000 Ohms	Percentage of baseline Karicare Food Thickener Added	With Karicare <1000 Ohms
Water	3043	×	3642	×
Water & Cordial	2074	×	2192	×
Full cream cow's milk	564	✓	590	✓
Infant formula S26	1238	×	1077	×
Big M Flavoured Milk	653	✓	614	✓
Apple Juice	1044	×	1117	×
Diluted Apple Juice	1490	×	1320	×
Puree Pear	653	✓		
Custard	560	✓		
Mashed Potato	494	✓		
Lumpy solid	212	✓		
Omnipaque™	10199	×		
Polibar®	606	✓		
Sandhill® Viscous Bolus	459	✓		
Powerade® Isotonic Solution	1335	×	1463	×
Karicare® AR	816	✓		
Karicare®	846	✓	893	✓
Warm Karicare®	576	×		

Table 5-5: Impedance values of foods/fluids plus Omnipaque™

	Ohms	Conduction <1000 Ohms
Water	5236	×
Water & Cordial	3675	×
Full cream cow's milk	1250	×
Infant formula S26	1936	×
Big M Flavoured Milk	1517	×
Apple Juice	1965	×
Diluted Apple Juice	2951	×
Puree Pear	2063	×
Custard	907	✓
Mashed Potato	527	✓
Lumpy solid	304	✓
Omnipaque™(pure)	10199	×
Sandhill® Viscous Bolus	633	✓
Powerade® Isotonic solution	3003	×
Karicare® AR	1240	×
Karicare®	2089	×

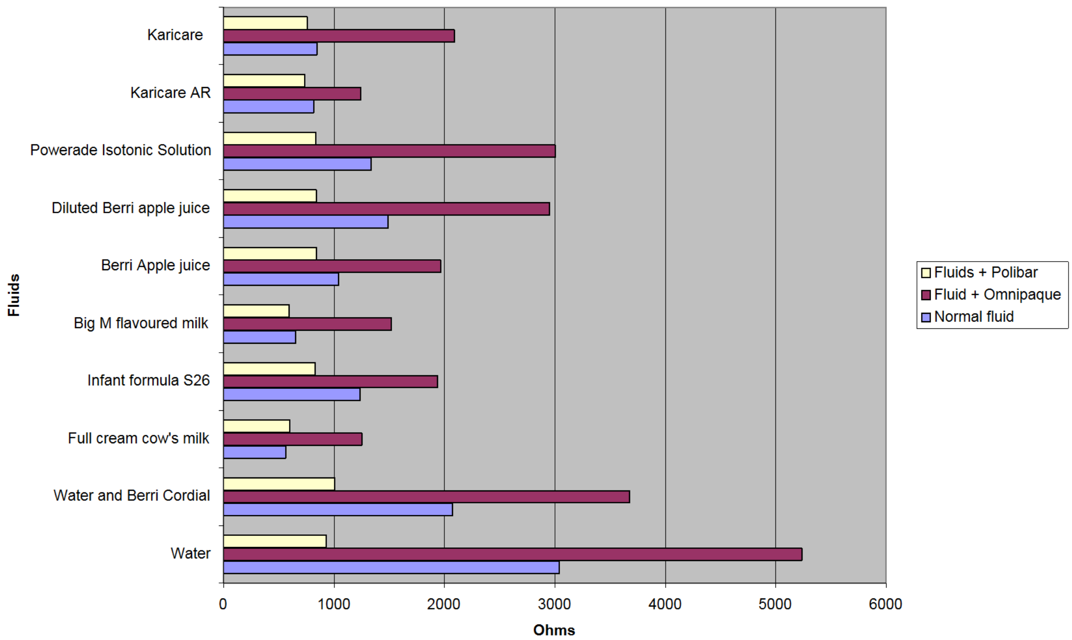


Figure 5-2: Conductivity of Fluids with and without radiopaque contrast added. Omnipaque™ consistently stands out as being of low conductivity no matter which fluid it is added to.

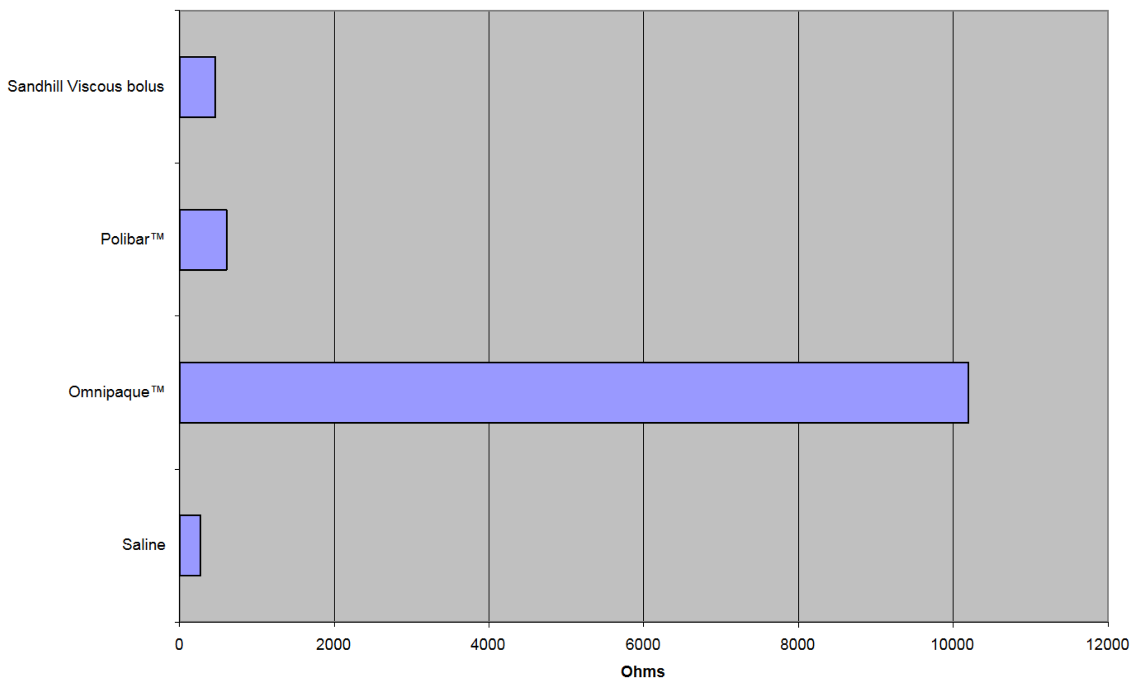


Figure 5-3: Conductivity of Contrast Agents and Saline

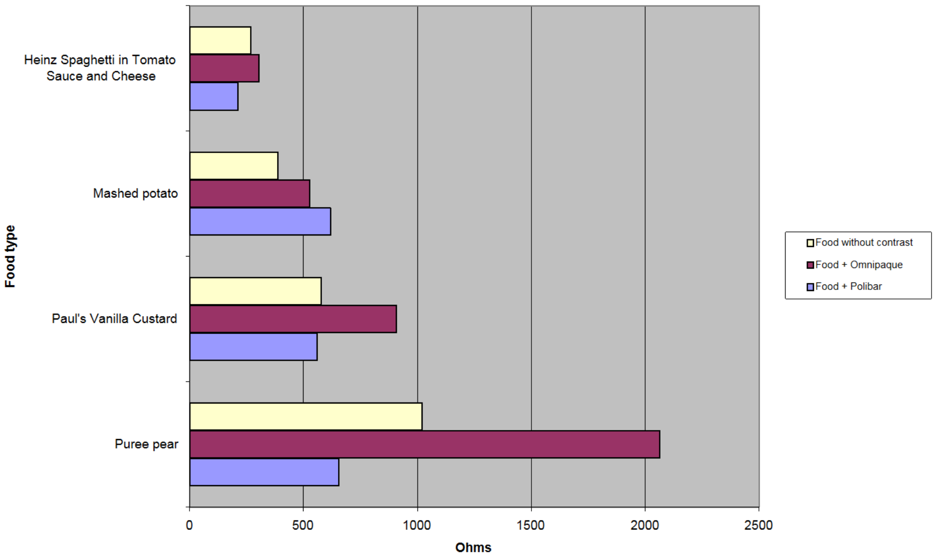


Figure 5-4: Conductivity of Foods alone and with added Omnipaque™ or Polibar

As a result of this testing of foods and fluids, the boluses offered in the Impedance and VFSS studies following this experiment contained 1% saline to aid conductivity and reduce the impact of Omnipaque™ on impedance values.

5.3.2 Group A Impedance Results – MII vs VFSS

A total of 45 swallows were analysed for videofluoroscopy and impedance in the seven patients assessed in Group A. These were all primary swallows (i.e. the first swallow in a sequence). There was minimal bolus residue in the pharynx post swallow for these patients, but aspiration and penetration was present for 12.5% of swallows. The summary of aspiration and bolus residue scores can be seen below in Table 5-6. Because a short interval is required between each bolus swallow so that the impedance baseline can 'reset' before recording another swallow it was not possible to analyse all swallows gathered during each combined VFSS and impedance study for impedance values. Some data, particularly for infants drinking in a suckle run of multiple consecutive swallows, could not be analysed.

Table 5-6: Aspiration and Bolus Residue Scores for Participants in Group A Impedance Studies

	Mean AP Aspiration/Penetration (AP) Score	Mean BR Bolus Residue (BR) Score
Patient 1	1.75	1
Patient 2	1.75	1.25
Patient 3	1	1
Patient 4	1.24	2.59
Patient 5	1.64	1.45
Patient 6	1	1.17
Patient 7	1.93	1.75

When examining the scores for impedance drop, at the 500 Ω criterion level there was fair agreement between the presence of bolus seen on the VFSS and impedance detection of the bolus (Kappa=0.3673). Fair agreement (Kappa=0.3252) was also the result for the criterion set at a level of 50% or below. The agreement did vary for consistencies of food and fluid, and these are outlined in Table 5-7 below.

Table 5-7: Differences in VFSS & Impedance Kappa agreement for varying food/fluid types

Criterion Level	Thin Fluid	Thick Fluid	Custard/Puree/ Mash	Puree + lumps, baked beans	Toast, Muffin
<500 Ohms	0.4783 (Moderate)	0.3476 (Fair)	0.305 (Fair)	0.4512 (Moderate)	0.7613 (Substantial)
<50%	0.222 (Fair)	0.3328 (Fair)	0.3781 (Fair)	0.364 (Fair)	0.2221 (Slight)

The most notable agreement was for solid boluses, particularly for toast and muffin (Substantial, Kappa=0.76 at 500Ω criterion level). There was also moderate agreement for both pureed/mashed foods and thin fluid. Additionally, for some isolated swallows there was greater agreement. An example of this was in Patient 4 (baked beans swallow) where there was substantial agreement (Cohen’s Kappa = 0.79). For this patient, at the time of bolus entry the impedance dropped to between

0 Ω and 492 Ω when bolus was present, and recovery values ranged from 603 Ω to 1389 Ω.

Overall, the level of agreement recorded at both the 500 Ω and 50% criterion levels was only fair and not sufficient to track a food or fluid through the pharynx reliably using an impedance catheter without VFSS.

5.3.3 Group B Impedance Results – Inter-rater agreement

A total of 43 swallows across the six patients in the second group were analysed. The mean agreement for the two observers across the total number of patients was moderate (Kappa=0.5693). The K agreement for observer analysis of impedance in each patient is outlined in Table 5-8. It is important to note that this was only for each rater analysing whether bolus was present or absent at each impedance segment across the PE segment. It was not an analysis of swallow function on VFSS.

Table 5-8: Analysis of VFSS and Impedance agreement between 2 observers for bolus presence

Participant	Kappa agreement between 2 Observers
Patient 1	0.73
Patient 2	0.46
Patient 3	0.61
Patient 4	0.63
Patient 5	0.46
Patient 6	0.53

5.3.4 Bolus Flow Interval Results

A total of 71 swallows were analysed from the 6 patients assessed with the 1.9mm impedance only catheter and simultaneous videofluoroscopy. Fifty eight of these swallows (~ 80%) were primary swallows and 13 (~ 20 %) secondary swallows, where the bolus had not been cleared from the pharynx during the primary swallow.

The median Flow Interval was 211ms (range of 70 ms to 625 ms). This Flow Interval was longer for patient swallows with pharyngeal residue compared to those without residue, but was not statistically significant (p= 0.338). Swallows where there was penetration or aspiration present, however, also had a longer flow interval and this was statistically significant (p=0.05) (Table 5-9 summarises the results of residue scores, aspiration and penetration and the relative Flow Interval score). Therefore, this longer Flow Interval is possibly a marker of aspiration risk more so than bolus residue in the pharynx. Figure 5-5 illustrates the results of the Flow Interval for swallows with and without aspiration and bolus residue.

Table 5-9: Residue Scores, Aspiration Penetration Scores and final Flow Interval scores.

	Swallows WITHOUT Residue	Swallows WITH residue (p-value vs NO residue)	Swallows WITHOUT Asp-Pen	Swallows WITH Asp-Pen (p-value vs NO Asp-Pen)
No of swallows	32	39	60	11
Residue Score	1 [1,1]	4 (<0.001) [2,6]	1 [1,4]	6 (0.005) [2,6]
Asp-Pen Score	1 [1,1]	1 (0.008) [1,2]	1 [1,1]	5 (<0.001) [2,7]
Flow Interval (msec)	202 [93, 356]	269 (0.338) [61, 763]	172 [59, 362]	697 (0.05) [361, 794]

Asp-Pen = Aspiration-Penetration

Location of swallow trigger and penetration/aspiration was also analysed. Fifty-two swallows of the total 71 were triggered at the valleculae, 11 at the laryngeal inlet and 8 at the pyriform sinus. A trigger at the pyriform sinus (a score of 2, with a range of 1 to 6.5) was a significant indicator of penetration/aspiration when compared with a swallow trigger at the valleculae [1 (1,1)] ($p<0.05$ using Pairwise Multiple Comparison Procedures – Dunn's Method). Aspiration was present more frequently during the swallow, versus before or after ($p < 0.05$).

Statistical analysis

Non-parametric grouped data were presented as medians [inter-quartile range] and compared using the Mann-Whitney Rank Sum Test. For multiple comparisons Kruskal-Wallis ANOVA on ranks with pair-wise multiple analysis procedures (Dunn's method) was used. Correlation was determined using Spearman Rank Order Correlation. The association of variables with presence of aspiration was assessed using Multiple Logistic Regression and ANOVA with Odds Ratio (95% CI).

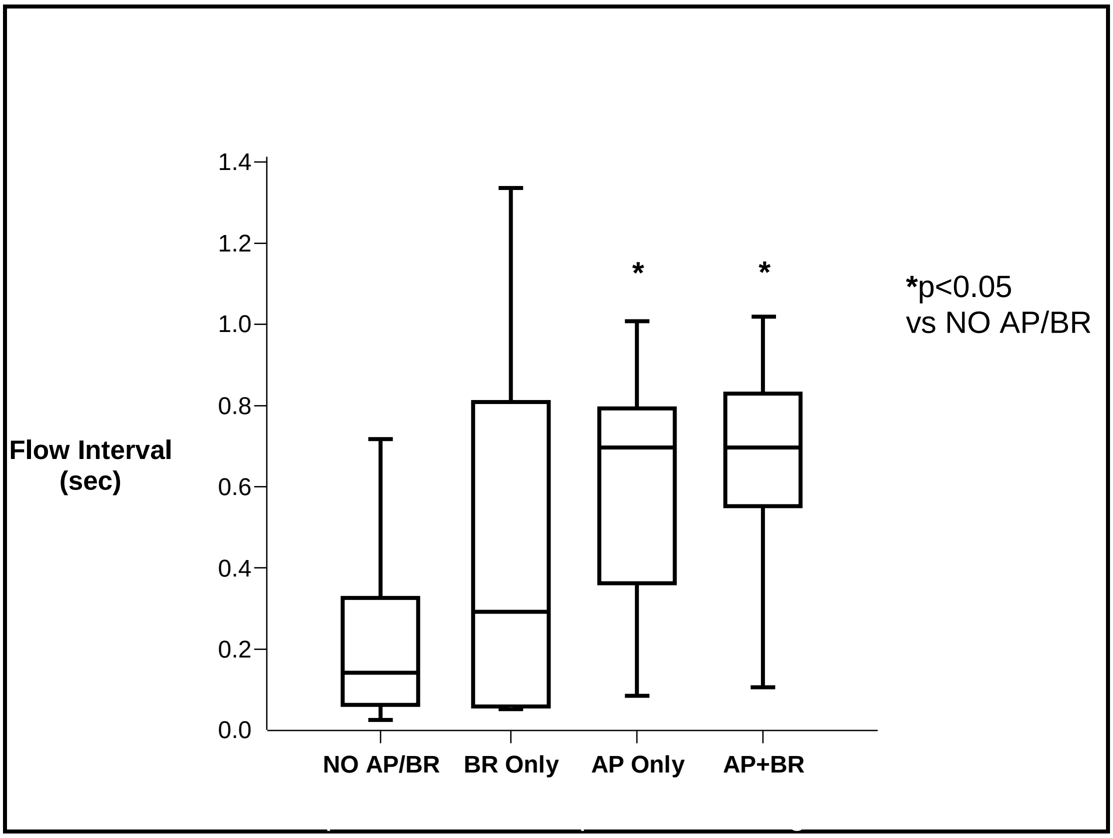


Figure 5.5: Flow Interval results for participants in Group B Impedance studies.
Flow interval was significantly longer ($p < 0.05$) for those patients who experienced aspiration or penetration, or aspiration or penetration in combination with bolus residue.
AP = Aspiration/Penetration, BR = Bolus Residue.

5.4 RELATED ASSESSMENTS USING IMPEDANCE & FLOW INTERVAL

Research in the area of dysphagia continues to evolve. As technology develops, a greater range of possibilities become available to the investigator. This is the case for catheters used in the pharynx and oesophagus. As has been discussed in Chapters 2 and 3, a variety of catheter designs have been trialled throughout the decades since the first use of manometry and impedance. Changes in design have occurred in order to more effectively assess the complex regions of the pharynx and upper and lower oesophageal sphincters.

The assessments conducted in the impedance studies described in Section 4.3 of this thesis used a catheter of 1.9mm in diameter. It was considered that a catheter of greater diameter combining both impedance and manometry was unlikely to be tolerated in young children; and as a single catheter had not yet been devised and it was not feasible to use two catheters (one for impedance and one for manometry), impedance only studies were conducted. However, recent developments since the collation of the data for this project have resulted in a new combined impedance and manometry catheter. This new catheter of larger diameter (3.2mm) has been contrasted with the catheter discussed in this thesis in the study reported by Noll, Rommel, Davidson and Omari (2011). While still too large to be used with infants under 12 months of age, the new combined impedance and manometry catheter was used to assess swallowing in six children (mean age 7.5 yrs.) with neurological disease by researchers based overseas (Noll, Rommel, Davidson, & Omari, 2011). The children were assessed in Leuven, Belgium and underwent a protocol nearly identical to the one described here. The catheter used was a 3.2mm diameter (10

French) impedance-manometry catheter (Unisensor USA Inc., Portsmouth, NH) containing 13 impedance electrodes (4mm L x 3.2mm W) spaced at 2cm intervals. The manometry component of this catheter incorporated 25 pressure sensors spaced at 1cm intervals. Assessment using this catheter was carried out with simultaneous videofluoroscopy. Aspiration and penetration was assessed using the 8 point penetration-aspiration scale (Rosenbek, et al., 1996). Pharyngeal residue was assessed through analysis of the VFSS image and calculated using the same 6-point scale as described previously. Overall results were then calculated in relation to the Flow Interval described above. The catheter recordings on this newly devised catheter showed a longer Flow Interval in relation to *both* residue and aspiration, therefore indicating that the second catheter configuration was better suited to predicting aspiration risk than the impedance only catheter (Noll, et al., 2011). This catheter was thought superior due to the larger outer diameter (3.2mm vs 2mm) with electrodes spaced at a greater distance (2cm vs 1cm), and greater rigidity in the catheter overall making it likely the catheter would remain in contact with the posterior pharyngeal wall (Noll, et al., 2011). Ensuring continuous contact with bolus and/or mucosa means a higher baseline impedance value and a greater depth of impedance change during swallowing. This resulted in a longer Flow Interval. The use of manometry in the study enabled identification of the ‘region of interest’ in the pharynx, highlighting the potential for use of this combined technique without radiology to define this zone. Therefore, it is possible that this method of assessment could complement current assessment techniques, but further validation of catheter design is necessary.

6 DISCUSSION

Swallowing disorders have a significant impact on the health and quality of life of children with neurological conditions (Sullivan, et al., 2000). The current most common instrumental assessment method in this population is the VFSS. While this provides an image of the swallowing disorder the biomechanics behind the dysphagia are not defined and aspiration risk is subjectively determined. The present investigation proposed the combined use of manometry and impedance (with the use of VFSS as a comparator) for assessment of pharyngeal stage swallowing disorders in children presenting for instrumental swallowing assessment. While combined manometry and impedance was not successful in this study (prior to the further research in Belgium), pharyngeal impedance and the calculation of “Flow Interval” showed that it may be possible to objectively determine the severity level of a patient’s dysphagia and aspiration risk non-radiologically.

Swallow physiology

A number of previous studies have discussed swallow trigger location and its relationship to penetration and aspiration (Han, Paik, & Park, 2001; Leonard & McKenzie, 2006; Lundy et al., 1999). In this study overall, on examination of the VFSS images in isolation, a swallow trigger at the pyriforms was typically associated with aspiration ($p < 0.05$ Kruskal Wallis One Way Analysis of Variance on Ranks). This is similar to findings in adult dysphagic VFSS. Aspiration has been found to be more frequently present during longer pharyngeal transit time (Han, et al., 2001; Lundy, et al., 1999), and delay between hyoid movement and bolus transit time has also been linked with aspiration in dysphagic adults (Leonard & McKenzie, 2006).

While delayed bolus transit time is only one factor in dysphagia and subsequent aspiration risk, it is important to have paediatric VFSS parameters for such characteristics of known aspiration risk when devising new assessment strategies. In the technique of combined manometry and impedance, pressure recording information could be combined with impedance recordings of bolus transit time and location of bolus in the pharynx at the time of swallow initiation. Therefore, such a technique would enable objective description of swallow function and reason for aspiration, as well as potential risk for aspiration. When considering subsequent therapeutic management of aspiration, assessment of the effectiveness of techniques, such as the supraglottic swallow, a technique commonly used to manage delayed pharyngeal swallow (Bülow, Olsson, & Ekberg, 2001; Lundy, et al., 1999) could be assessed without radiation.

Videomanometry

Videomanometry was only used in the first stage of assessments and was unable to be combined with impedance in this study. However, useful information was gained and compared with previous data of videomanometry use in children. A manometry catheter (also containing impedance electrodes) was used with the first group of patients only, who had an average age of 12.3 months. The basal pharyngeal pressures, basal oesophageal pressures and peak pharyngeal pressures were compared with a reference range derived from five children from the pilot studies performed with similar equipment by Rommel (2002). These children were asymptomatic of dysphagia with no evidence of aspiration or bolus residue on VFSS. While these patients had various pathologies, an asymptomatic swallow was defined as having normal bolus propulsion, no aspiration or penetration and no pharyngeal residue post-swallow. It was observed that basal pharyngeal pressures were lower in the current study and nadir pressures were higher when compared with these asymptomatic swallowers. However, basal UOS pressures for four of the six patients were similar to the results seen in studies of normal infants – a range from 18mmHg (Davidson, et al., 1991) to 46mmHg (Jadcherla & Shaker, 2001). Overall, while there is limited data from this small number of participants to be conclusive, it is possible that reduced pharyngeal contraction pressures with resistance at the level of the UOS is present for the group of six patients analysed with videomanometry in this study. Such pharyngo-oesophageal pressure features could be indicators of the dysphagia experienced by these children. Reduced pharyngeal propulsion of the bolus together with insufficient opening of the UOS could theoretically result in aspiration, and in the children in this study aspiration/penetration scores were highest for those with the lowest pharyngeal pressures. Assessment of larger numbers of dysphagic children would be of benefit in order to further examine this pattern. Subsequent evaluations in this project focused on the novel assessment of pharyngeal impedance only in children. The size of the child's pharynx was deemed insufficient to comfortably accommodate a catheter containing the number of perfusion holes and impedance sensors necessary for a combined study. Ongoing swallow assessments following catheter development for this age group will further define the manometric parameters and provide clinically more applicable results for the understanding of pressure patterns in the paediatric pharynx.

Impedance

Conductivity of Foods and Fluids

An important consideration for impedance assessments was the conductivity of different foods and fluids. Subjectively it appeared that solid boluses tended to be more conductive than puree or thin and thickened fluid boluses. It was particularly notable that the conductivity of Omnipaque^{TM} radiopaque contrast was lower than saline and other fluids and foods. If impedance studies were being conducted in isolation (i.e. without combined VFSS) Omnipaque^{TM} would not be added, but the fact that this radiopaque contrast agent was found to increase impedance was an important discovery for this study conducted *with* VFSS. As a result, 0.1% saline was added to all assessment boluses offered during VFSS containing Omnipaque^{TM}. Future experiments using this radiological contrast agent with impedance should take into account the impact this could have on impedance recordings.

The aim to validate impedance as a method of assessing bolus flow or failure to flow through the pharynx and UOS of infants and children with pharyngo-oesophageal swallowing disorders was met in part. As it would be an extremely valuable clinical tool to determine the risk of aspiration in dysphagic patients, the goal was to describe a specific new approach for the assessment of pharyngeal impedance waveforms sensitive enough to detect pharyngeal residue and indicate those at risk of clinically significant aspiration. Impedance studies with Groups A and B utilised the analysis cut-off criteria described in oesophageal impedance studies (Fass, et al., 1994; Nguyen, et al., 1997; Nguyen, et al., 1999; Tutuian, et al., 2003) (i.e. impedance change relative to baseline impedance) indicating presence or absence of bolus at each segment. The criteria of 50% drop from baseline or a drop to 500 Ohms were found to be inadequate for assessment in the pharynx. This was a similar result to adult studies (Omari, et al., 2006a, 2006b; Szczesniak, et al., 2008), which showed that transit was detectable across the UOS and in the upper oesophagus, but not reliably in the pharynx. Tongue base contact with the pharyngeal wall results in a prolonged impedance drop, making it appear as though bolus is still present when in fact the bolus has already passed (Omari, et al., 2006b). Such factors also appear to impact the accuracy of recordings in children. There are, however, also substantial differences between conducting paediatric versus adult VFSS. The adults in the Omari (2006) study all had normal swallows, but for ethical reasons it is not possible to study children with normal swallows in the same way (as discussed previously in Section 3.4). The adults were all able to swallow on command and tolerate strict control of bolus size. It was not possible in the paediatric study to control for bolus size or rate of feeding during VFSS to this same precise level. As a result, bolus size was variable from one swallow to the next (i.e. a small bolus may not have connected the impedance segments, especially if it was a small bolus of low conductivity), and as children do not always tolerate the same positioning throughout the study, this also often varied (e.g. side to side movements of body, resistance to further boluses, head back for swallows, bolus drooled from mouth etc.). Such factors could also have played a part in the accuracy of recordings, but it is also reasonable to conclude that the main feature relating to complicated pharyngeal impedance recordings is the complex structure of the pharynx, which requires a different approach for calculating meaningful impedance assessment recordings in this region.

In impedance studies with patients in Group A, agreement between impedance detected bolus flow and videofluoroscopy detected bolus flow was fair (K=0.3). It was then necessary to also determine agreement between raters of bolus flow. While agreement between the two independent raters was better than between videofluoroscopy and impedance, the agreement was still only moderate (K=0.57). Reasons for this may be that judgment of bolus presence or absence at two impedance electrodes was at times subjective. Shadows on fluoroscopy may have complicated this form of detailed analysis. There may also have been confusion as to whether to include trace amounts present at impedance segments, with the possibility that such quantities were not detected by the impedance electrodes. Additionally, positioning of the child during videofluoroscopy was not always optimal due to child movement/non-compliance with radiology procedure. This at times distorted the videofluoroscopic view of the moving bolus. It is also likely that the impact of the mucosa and secretions in the pharynx would affect baseline impedance recordings through the PE segment, raising the baseline impedance (Omari, et al., 2006b; Szczesniak, et al., 2008; Szczesniak, et al., 2009). Despite these difficulties, this result (i.e. moderate agreement) is similar to the observer K agreement for videofluoroscopic analysis in normal adult swallowing studies including impedance (Kappa = 0.483) and for VFSS studies involving patients with dysphagia (Kappa = 0.553) (Szczesniak, et al., 2009). The agreement between raters of VFSS has been reported as variable in the literature. McCullough et al. (2001) reported on inter-rater agreement for frame by frame analysis of videofluoroscopy images (the method also used in this study). In their study agreement for signs of residue in the valleculae was fair (K=0.35 to 0.41), however, agreement for residue in the pyriforms was poor to slight (K=-0.16 to 0.16). Detection of residue in the hypopharynx was also poor to slight (K = -0.01 to 0.15). Other studies have shown more favourable results, but only when judging whether or not aspiration was present (Hind et al., 2009; Kuhlemeier, Palmer, & Rosenberg, 2001). Hind et al. (2009) reported up to 76% accuracy and Kuhlemeier, Palmer and Rosenberg (2001) did not use frame by frame analysis, but also found that inter-rater reliability was high (greater than 90%) for identification of aspiration. Training of judges was recommended to improve inter-rater reliability scores (Hind, et al., 2009; McCullough, et al., 2001). There have been reports of moderate agreement for identification of bolus residue on VFSS (K=0.56) (Stoeckli, et al., 2003), but this is still not close to an ideal result of almost perfect agreement. Therefore, when examining the inter-rater reliability scores for the present study in light of the current inter-rater reliability scores for VFSS analysis, fair agreement between VFSS and impedance is not being compared with a perfect score, but rather moderate (K=0.56) inter-rater agreement at best when assessing for pharyngeal residue (Stoeckli, et al., 2003). Impedance has the potential to provide objective recordings of residue in the pharynx. While identification of aspiration is of course also extremely important, valuable additional information from combined manometry and impedance could highlight more causal factors behind the dysphagia and aspiration.

Overall, use of raters analysing presence or absence of bolus at each impedance segment was tedious and yielded poor results. Therefore, interpreting impedance recordings relative to baseline appears problematic. Despite attempts at direct correlation between VFSS and impedance and also the use of two observers to rate bolus presence or absence at impedance segments, visual analysis by reviewers remains subjective. An alternative method again to remove this subjectivity would enable the interpretation of the most objective impedance recordings.

The need identified by Omari and others (2006) for a new analysis technique for results of pharyngeal impedance has been highlighted again during this study. Impedance *is* measuring features of bolus transit through the pharynx, but how can these recordings be interpreted in order to provide clinically relevant information about the patient's swallowing? This question was answered with the development of the Flow Interval.

The Flow Interval

The Flow Interval is a novel method of objective assessment of bolus flow through the pharynx based on average impedance drop and recovery across multiple impedance segments from the tongue base to the proximal margin of the UOS, the results of which are correlated with evidence of bolus residue and aspiration on VFSS. As stated earlier, this method was loosely based on the algorithm used by Ghosh, Pandolfino, Zhang, Jarosz and Kahrilas (2006) to describe the measurement of UOS relaxation interval from pressure in their study using solid-state high resolution manometry in normal adults. The Flow Interval method works through standardising the impedance recordings across all segments of the catheter and then using an automated algorithm to derive the Flow Interval, which is influenced by the shape of the impedance drop/recovery curve. This results in an objective analysis rather than one based on the observations of external raters for presence or absence of bolus at the impedance segments. The results from patients who took part in Group B of the impedance plus VFSS were reanalysed using the Flow Interval method. As this method was designed to be an indicator of bolus clearance time, it was expected that the Flow Interval would be a strong indicator of bolus residue in the pharynx (indicated by delayed impedance recovery and, therefore, longer Flow Interval). This would be useful in assessment of dysphagia as failed clearance in the pharynx is a sign of reduced pharyngeal propulsion of the bolus, or reduced tongue propulsion. Impedance results did indicate a longer Flow Interval for failed bolus clearance ($p= 0.338$), however, it was in fact found to be a more reliable indicator of penetration and aspiration (p=0.05). This result was not anticipated and is novel to this study.

The benefits of a non-radiological indicator of aspiration risk in children, such as provided by these preliminary results using the Flow Interval would be substantial. It would have a positive impact on mealtime programs, swallowing therapy and quality of life for these patients. Currently, children with severe and multiple disabilities have difficulty being positioned in the radiological suite as they are required to be still while seated, and also ensure that their head and neck is in a precise field of x-ray. Additionally, once positioning is finalised it does not necessarily match the child's mealtime seating (e.g. some are fed in arms at home, or may be seated in a different chair to that available in radiology) and may not be optimal for mealtime. Custom designed wheelchairs contain head and back support not available in the radiology seating.

Another important consideration in the use of instrumental swallowing assessments is the frequency with which they can be used. Children undergoing VFSS studies often require other assessment x-rays, the treating doctor, therefore, wanting to limit any "non-essential" studies (such as VFSS) due to the cumulative radiation exposure. This means that reviews of initial VFSS assessments may only occur at the earliest after 3 months, but more likely at six month intervals – a long wait to review a swallowing program, which may or may not be meeting the needs of the patient. Changes to diet consistency, commencement of increased oral intake and review of oral fluids for those with histories of aspiration related illnesses often hinge on assessment via videofluoroscopy. Therefore, there may be occasions where a patient's rehabilitation needs or quality of life around mealtime decisions depend on the timing of a VFSS appointment.

The development and confirmation of the accuracy of impedance assessments utilising the Flow Interval as a predictor of aspiration risk would enable assessment in the child's familiar environment (potentially even at home), avoiding the need for the use of a foreign room with multiple staff present and large specialised equipment – all daunting features for the child who may already find the task of eating safely quite challenging. It would also allow for the child's usual individualised seating position and avoid the need for radiation exposure. A treatment plan could, therefore, be readily reviewed at whatever time interval the medical officer, family and/or treating speech pathologist decided on. This is of significant benefit as it meets the immediate needs of the patient.

Had combined manometry and impedance been successful, it would have been possible to determine the points of the range of interest (required to calculate the Flow Interval) in the pharynx manometrically, therefore, excluding the need for radiology to locate these points visually. Therefore, with further development of this technique and the catheter configuration required to combine manometry and impedance, reduction in the number of VFSS assessments, and exclusion of VFSS use for some patients would be possible. As well as limiting radiation exposure there are other benefits of using assessments alternative to that conducted in a radiology suite. Patients living in regional or remote areas often have delays in assessments due to the need to travel to major centres to access the necessary VFSS equipment. The use of an impedance/manometry assessment would require only the catheter and computer system and limited personnel, therefore, making it cost-effective and more portable and readily available than the VFSS assessment. Again, this would enable more timely assessments and not delay the child's dysphagia program or need for nutrition via supplementary means if swallowing was to be assessed as unsafe. Table 6-1 lists the time and resources required for VFSS versus impedance studies.

Table 6- 1: A comparison of time and resources required for VFSS versus Impedance assessments of swallowing

	VFSS	Impedance
Staff	• 2 x Speech Pathologists • Radiographer • Radiologist • Nurse	• 1 Speech Pathologist • Nurse/technician to place catheter
Specific Training Required	• VFSS clinical training and experience • Experience in rating/assuring intra-rater reliability	• Speech Pathology interpretation of results and ability to relate this to clinical findings
Equipment	• Radiology Suite with fluoroscopy (generally only available in major hospitals) • Customised videofluoroscopy chair • Patient's own foods • Radiopaque contrast required for each patient	• Portable catheter and computer • Catheter - $30,000 • Computer Software - $70,000 • Can be used in hospital, clinic or home setting. • Patient's own foods • Catheter sterilisation for reuse
Procedure	• Food preparation – 10 minutes • 30 minutes for procedure, but 2 minutes of swallows.	• 30 minutes/duration of a meal • Swallows can be recorded throughout entire meal, not just in 'snapshots' of 2-3 swallows.
Results and Analysis	• 1-2 Speech Pathologists • 1 Radiologist • Frame by frame analysis, approximately an additional 30 minutes.	• Computer generated results • Interpretation by Speech Pathologist

The technique of combined impedance and manometry may also be a useful indicator in determining aspiration risk in patients showing pulmonary complications, where the suspected cause is aspiration. In this way the technique could be used as a screening tool in place of another x-ray in a battery of tests required to exclude 'top-end' aspiration.

Combined impedance and manometry as an assessment of swallow function is likely to be most beneficial for those with disorders in the severe to profound range [DDS (Sheppard, 2003)]. In such patients, frequent assessments and monitoring of their swallowing across the week or even throughout a day (similar to a pH probe and impedance test) would be useful due to the variable nature of swallowing performance in these children. VFSS assessments run for a maximum of 2 minutes, and only short runs of consecutive swallows can be viewed. The impact of fatigue or performance across a day cannot be assessed, yet through clinical experience it is known that these factors do have an impact on swallow performance. Calculating Flow Interval for different consistencies during different time periods across the day, and at the beginning of meals versus the end of meals could provide particularly valuable information for those whose oral intake is significantly limited. Characteristics of the 'best' feeding times could be generated from an objective assessment such as this.

Therefore, the use of the Flow Interval in impedance assessment with the potential for combined manometry to define the region of interest would enable assessment in the child's own environment (potentially even at home), allow for the child's individualised seating position and avoid the need for radiology. This method would also be more cost effective than the use of VFSS and would enable reviews at whatever time interval family, doctor or therapist decided on. All these factors would contribute to improved patient outcomes and quality of life.

Limitations and Future Directions

The use of manometry in combination with VFSS and impedance would have added value to the recordings in Stage 2 of this study, however, it was not feasible to use such a method with either a single catheter or two individual catheters. The use of manometry is valuable as it is able to indicate swallow onset and the proximal margin of the UOS as markers during the swallow. This could remove the need for VFSS as a marker of these regions for comparison with impedance recordings. Such a method could be used without VFSS to screen patients for aspiration risk, removing the concern for radiation exposure and enabling more frequent assessments and evaluations of a longer duration.

Since the completion of this study, it has proven possible that alteration to catheter configuration could improve results further and enable combined manometry together with impedance recordings in children. The impedance electrodes on the catheter used in this study were quite small (each 1cm on a catheter of only 1.9mm diameter). Preliminary data from a new catheter measuring 3.2mm in diameter, containing electrodes 4mm long by 3.2mm wide spaced at 2cm intervals, have indicated that larger impedance segments and a more rigid catheter improve the reliability of results (Noll, et al., 2011). This is effective because of the greater chance of continuous contact of the catheter with the mucosa and with bolus, resulting in greater accuracy. Impedance drops when pharyngeal contractions and/or bolus passage connects the electrodes in an impedance segment. High impedance is recorded when air surrounds the segments or the catheter moves away from the pharyngeal wall. This study by Noll et al. (2011) has shown that reliability of catheter impedance recordings could be improved with a catheter of greater diameter and rigidity, but this requires further validation. The comfort of the patient would also need to be taken into account, as the catheters used in previous adult manometry and impedance assessments were only 2.5mm in diameter (Omari, et al., 2006b; Szczesniak, et al., 2009). The study conducted by Noll et al (2011) is the first to report on the tolerance of catheters of this diameter in children, and supports the use of manometry as the marker to define ROI in combined impedance and manometry assessments in children.

Another factor to consider in addition to catheter size is the invasiveness of transnasal catheter placement itself. While this may seem significant, for those living with severe dysphagia and their families, the transnasal positioning of a tube is not unfamiliar, and in a number of participants' cases had been required for nasogastric tube feedings or 24 hour pH probe assessments in the past. The parents of the participating children with chronic swallowing disorders were found to be interested in the research being undertaken and were agreeable to using new techniques to evaluate their child's swallow. This parental interest in the development of new techniques to help other children in the future is similar to the altruistic findings reported by Morgan and others (2009). Previous studies using manometry in children have reported on minimal discomfort during placement of the catheter, and sedation has not been required (Rommel, et al., 2006). It could also be posed that the placement of a catheter in the pharynx could impact on the mechanics of the swallow and hence the results. Frequently dysphagic patients require nasogastric tube insertion for complementary feeding and so the impact of nasogastric tubes on swallowing has had some evaluation. Huggins and others (1999) studied the impact of nasogastric tubes on swallowing in young normal adults and reported that wide and fine bore nasogastric tubes did not affect the coordination of swallow function, but did slow it. The impact was less significant for fine bore tubes. An additional finding was that tube placement may in fact prevent aspiration by promoting earlier closure of the airway during the swallow. This, however, required further investigation (Huggins, et al., 1999). A more recent study investigating the impact of nasogastric tubes on swallowing in dysphagic adults indicated that the tubes did not significantly impact swallow trigger times (Wang, Wu, Chang, Hsiao, & Lien, 2006). The impedance catheter used in this study was small in diameter and so hypothetically should have limited impact on swallow function. Swallow evaluation using FEES also requires transnasal placement of a fine tube and has been conducted in paediatric patients yielding useful complementary data for clinical decision making around management of the child's swallowing difficulties (Hartnick, et al., 2000). Use of assessment techniques using transnasal insertion of testing devices requires further evaluation in terms of the device's impact on the swallow versus the benefit gained from such an assessment. Further investigations of impedance use in normal and dysphagic adults could evaluate the swallow with and without catheter presence to assess this possible impact further. The children in this study tolerated presence of the impedance catheter well and its presence did not appear to impact on their cooperation in the VFSS.

It is possible that the lack of standardisation of bolus size could have had an impact on results of impedance recordings. In comparison to adult studies, some patients swallowed only small boluses during the VFSS manometry or impedance studies. A validation study of pharyngeal impedance in normal adults showed that bolus volume did not have a significant impact on the impedance drop recorded during swallowing (Omari, et al., 2006b). It was, therefore, considered that small bolus size swallowed by some participants should not have significantly impacted the results. Only two patients were omitted from the results analysis because of poor compliance with the VFSS procedure and insufficient amounts swallowed to make an assessment on VFSS. Bolus size does have an effect on the mechanics of the swallow. When comparing a bolus of 1ml versus a 20ml bolus, extended UOS opening and a longer period of airway closure occurs for the larger bolus (Cichero & Halley, 2006; Kahrilas, et al., 1988). It is, therefore, important that an appropriately sized bolus for the age/size of the child is evaluated wherever possible during VFSS to ensure accurate and clinically applicable assessment. Bolus volume was not able to be standardised in this study, however, those participants excluded were judged to not be swallowing amounts significant enough to make informed decisions regarding their swallowing safety on VFSS.

The proposed technique for impedance assessment of swallowing using the Flow Interval has limitations for some patient groups due to the potential complication of tube placement. In such groups, it is probable that at the current time, assessment using videofluoroscopy is the most suitable and appropriate. Some patients with craniofacial anomalies may have structural features which make placement of a tube transnasally impossible. In the case of the proposed future technique of combined impedance and manometry, palatal defects would impact on pressure recordings throughout the oral and pharyngeal regions, therefore distorting recordings. Similarly, pressure recordings would also be impacted significantly in patients with tracheostomy. Further research into the impedance assessment technique as well as the combined impedance and manometry technique, and their use within a population such as exclusively cleft palate patients may yield suitable normative data for patient groups with additional complex features impacting swallowing. Until such time, this technique is unsuitable for use in gaining information about the swallow safety of patients whose presentation includes tracheostomy, palatal anomalies or complex craniofacial surgery.

Hospital patients who are particularly unwell at the time of swallowing assessment are an additional group who are unlikely to tolerate unnecessary tube placement. Children or infants with significant respiratory distress were excluded from this study for this reason. In these patients, any further compromise of respiratory status would result in further negative impact on swallow function and general health. However, VFSS is also withheld from such patients until they are stable, in order to ensure the swallow is evaluated in the most clinically useful situation where recommendations can be made for the greatest long term benefit and rehabilitation of swallow function.

Behavioural compliance issues also need to be considered in the case of any instrumental assessment of swallowing. The videofluoroscopy clinic is daunting with its unfamiliar equipment and number of staff present, and the requirement for the child to be seated in a specific chair in a particular position for the duration of the study. Similarly, a child who is unlikely to comply with VFSS is also unlikely to tolerate being positioned for placement of a transnasal catheter. If, however, a catheter was able to be placed, it has been found throughout the course of this study that children tend to be calm and ignore the presence of the catheter once it is positioned. It is then likely that eating and drinking would be able to be assessed in whatever position the child was most comfortable. Additionally, impedance assessment does not require that the child's food/drink be coated in, or mixed with radiopaque contrast, thereby avoiding issues of food/drink refusal during the study.

SUMMARY

This study has contributed information towards another step in the complex area of assessing paediatric dysphagia. With further assessment and development, the devised method will serve as another complementary assessment technique that, similarly to FEES, is able to provide clinically relevant information regarding the swallow. While it is not possible to replace VFSS and its valuable role in assessment of children's swallowing disorders and identification of aspiration, combined impedance and manometry has the benefits of objectively characterising bolus transit and transit time through the pharynx and can possibly highlight those patients at risk of significant aspiration without the use of radiological assessment. This is important for health outcomes, especially nutrition and chest health and will inform therapy approaches and diet modification for safe swallowing. Further development and standardisation of a catheter combining both manometry and impedance is required and could remove the need for VFSS in cases involving screening assessments and/or frequent reviews of swallow function. Clearly it would be important to prescribe a protocol for such an assessment in order to standardise it as much as possible and to improve its objectivity even further.

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Appendix 1

DYSPHAGIA DISORDER SURVEY Pediatric Edition
TEST FORM
Justine Joan Sheppard, Ph.D.

NAME:	D.O.B:	CA:	M F
ADDRESS/CENTER:	D.O.E:	I.D.#	
EXAMINER:		DIAGNOSIS	

SCORES:	Raw Score	Disability Percentile
PART 1. Related Factors	______	
PART 2. Feeding Competency	______	
TOTAL	______	________
LEVEL OF EATING AND SWALLOWING COMPETENCY		
1. No Disorder	______	________
2. Mild Disorder	______	________
3. Moderate Disorder	______	________
4. Severe Disorder	______	________
5. Profound Disorder	______	________

GENERAL COMMENTS: (medications, respiratory health, etc.)________________________________

WEIGHT LOSS or FTT: YES / NO Low 1-yr. Weight: _____High 1-yr. Weight:______
Comment: ____________________

GASTRO-ESOPHAGEAL DISORDER: YES / NO Satisfactory management Disorder Persists
Comment: ____________________

POSITIONING: Appropriate Inappropriate
Comment: ____________________

DIET: Appropriate Inappropriate
Comment: ____________________

FEEDING TECHNIQUE: Appropriate Inappropriate
Comment: ____________________

SUPERVISION/ASSISTANCE Appropriate for age Inappropriate for age
Comment: ____________________

EVALUATION SERVICES NEEDED:

DYSPHAGIA____________________
POSITIONING____________________
ADAPTIVE FUNCTION____________________
MEDICAL/DENTAL____________________
DIETARY____________________
BEHAVIOR MODIFICATION____________________
STAFF IN-SERVICE____________________
OTHER____________________

DDS FORM PAGE 1 of 2
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DYSPHAGIA DISORDER SURVEY Pediatric Edition

Justine Joan Sheppard, Ph.D.

NAME:____ **AGE**__________

INSTRUCTION: Score item subsections: 0=normal/unrestricted 1=deficient/restricted
See User's Manual for scoring instructions for each item.

PART 1. RELATED FACTORS

	Item Score
1. **BODY MASS INDEX:** ____ WNL < 10th %ile <5th %ile HT______ HT/WT: WNL <25 %ile <10%ile WT______	
2. **DIET:** cut up/whole ground puree tube Liquid unrestricted restricted	
3. **INDEPENDENCE:** self-feeder assisted self-feeder dependent feeder tube feeder	
4. **ADAPTIVE UTENSILS USED:** none spoon cup tube	
5. **POSITIONING:** upright independent upright assisted reclining	
6. **POSTURAL CONTROL:** trunk stable unstable head/neck stable unstable	
7. **FEEDING TECHNIQUE/SUPERVISION:** normal adaptive mal-adaptive	

PART 1. SUB SCORE	

PART 2. FEEDING & SWALLOWING COMPETENCY :
TEST FOODS: ____

	Non Chewable	Chewable	Liquid	Item Score
8. **ORIENTING** (alerting to food, moving toward food, mouth opening)				
9. **RECEPTION** (stripping spoon, biting, sipping from cup, taking appropriate bolus size, timing)				
10. **CONTAINMENT** (no dribbling or ejecting food or liquid)				
11. **ORAL TRANSPORT** (no residual in mouth after swallow, efficient bolus transit)				
12. **CHEWING** (chew adequate for bolus, no special placement required)				
13. **ORAL-PHARYNGEAL SWALLOW** (prompt, sequential liquid swallow, no gagging or multiple swallows)				
14. **POST SWALLOW** (absent coughing, wet breath sounds or wet voice) rpt/obs				
15. **GASTRO-ESOPHAGEAL FUNCTION** (absent vomiting or rumination) rpt/obs				

PART 2. SUB SCORES				

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DYSPHAGIA MANAGEMENT STAGING SCALE (DMSS)

Justine Joan Sheppard, Ph.D.

Name____Date________________

Dysphagia Disorder Survey Score_____________ Date of Survey_____________

Level 1. No Disorder

No symptoms of feeding or swallowing disorder in oral preparation, oral initiation, pharyngeal or esophageal stages of swallowing. Swallowing capabilities are functional for all bolus types. No symptoms of related unsafe or anorexic behaviors. May be dependent for intake.

Level 2. Mild Disorder

Feeding and swallowing disorder and unsafe or anorectic behaviors can be managed with either diet restrictions, or medications, or adaptive, feeding/swallowing strategies. Person maintains satisfactory nutrition and hydration with no secondary respiratory complications.

Level 3. Moderate Disorder

Feeding and swallowing disorder and unsafe or anorectic behaviors can be managed with a combination of diet restrictions, adaptive feeding/swallowing strategies and medications. Person maintains satisfactory nutrition and hydration with no secondary respiratory complications.

Level 4. Severe Disorder

Management of feeding and swallowing disorder and unsafe or anorectic behaviors includes a combination of diet restrictions, adaptive feeding/swallowing strategies and/or medications. Related nutritional, hydration or respiratory problems persist in spite of the management program.

Level 5. Profound Disorder

Disorder is managed with non-oral feeding for supplemental or total nourishment. Related nutritional, hydration and/or respiratory problems may persist or condition may be satisfactory.

Dysphagia Disorders Survey and Dysphagia Management Staging Scale Percentile Ranking

Percentile Rank	5	10	15	25	50	75	85	90	95
Total DDS Score	0.0	1.0	2.0	4.0	9.0	17.0	21.3	25.0	31.0
DMSS Level				DDS Score					
No Disorder	0.0	0.0	0.0	0.0	2.0	2.0	4.0	4.0	4.7
Mild Disorder	3.7	4.0	4.6	5.0	7.0	8.0	9.5	10.3	12.9
Moderate Disorder	8.5	9.0	9.5	11.0	13.0	17.0	18.5	20.0	21.5
Severe Disorder	15.6	15.6	18.0	20.0	24.0	27.0	27.4	30.6	34.4
Profound Disorder	30.0	30.0	30.5	31.0	34.0	38.0	38.0	38.0	38.0

Sheppard, J.J. (2002) Dysphagia Disorders Survey and Dysphagia Management Staging Scale User's Manual and Test Forms, revised. Ryde,NSW: Centre for Developmental Disability Studies.

Appendix 2

Assessment of swallowing in children with feeding difficulties

What is swallowing?

Safe swallowing means that food and liquid move from the mouth into the oesophagus and then into the stomach without entering the airway. Most of us have experienced occasional coughing or choking during swallowing. We recover quickly and fortunately this doesn't happen too often. When it happens we cough right away and clear the liquid or food out of the airway. Some children do not swallow safely on a regular basis. They get food or liquid in their airway and damage their lungs. This is called aspiration. Children who aspirate thin liquids may also aspirate liquids that move backwards from the stomach or oesophagus into the throat. This upward and backward movement of food from the stomach to into the oesophagus, throat or mouth is called gastro-oesophageal reflux. The children may not be ready to swallow when material comes back up rather than going down.

Some children do not cough when the food gets into the airway. This is called 'silent' aspiration. We have special concerns for children who do not cough when food or liquid is in the airway. Therefore, we want to examine what causes the swallowing and feeding problem.

Why is my child suitable to participate?

Your child has been invited to participate in this study as he/she has symptoms of feeding and swallowing problems.

What is involved?

In this study you will be asked to bring your child to the Gastroenterology Unit at 1.00pm (Rieger Building, 8th Floor). During the visit your child will be cared for by a registered nurse, but if you like you can stay with your child during the whole study. You will be asked to bring your child's normal formulae/drink, semi-solids and solids as specified by the speech pathologist, and his/her normal drinking bottle, cup, spoon and pacifier. Of course you can bring your child's favourite toy!

A small flexible tube will be passed through your child's nostril into the oesophagus. Once positioned, the tube will be taped to your child's cheek. This tube will enable us to measure the movements of the food in the throat and oesophagus during and after swallowing via a connection to a computer program.

This trial will use a special measuring tube (catheter). This tube measures both food movements and pressures generated by the throat during swallowing. We will then visit the Radiology Department with the tube still in place, where we perform the videofluoroscopy. Your child will be placed in an infant chair, specially designed for swallow studies. First, we will assess the position of the catheter by a few seconds of radiological exposure and adjust in when needed. Secondly, your child will be asked to drink some of his/her normal formula or other drink, and swallow a range of his/her current foods. The formula and foods will be mixed with a tasteless and colourless contrast medium, which shows up on X-ray. The contrast used (Omnipaque®) is safe and harmless. It will take probably two minutes of X-ray time to capture a sufficient number of swallows for assessment. After finishing the videofluoroscopy the catheter will be removed. The total time of the study should be around 1 hour.

What are the risks?

There are no known risks or side effects of this study. The placement of the tube causes discomfort equivalent to the insertion of a naso-gastric tube. Patients are usually settled and comfortable within 30 minutes of intubation. We have performed in excess of 250 similar procedures in infants and children per year with no side effects. The risk involved due to the radiation exposure is minimal.

Are there any benefits?

Your child may not directly benefit from participating in this study, however, we hope to be able to provide a more thorough assessment of his/her swallow problem by using state of the art diagnosis techniques. Our experience indicates that the techniques can pinpoint the cause of severe feeding problems and may provide a guide for future therapy. However, this is not the case in all patients. We will provide you with the results of the oral feeding and swallowing evaluation. If this study is successful, it will provide information that will aid in the development of better techniques to diagnose children with feeding and swallowing problems.

Withdrawal and confidentiality

While your child's participation in this study is welcomed, you are under no obligation to participate and are free to withdraw at any stage. Any follow up by phone after your visit will be done with your consent and you should not feed pressured to commit to anything you do not feel comfortable with. The results of the study will be published, but the anonymity of the participants is assured.

This study has been approved by the Women's and Children's Hospital Research Ethics Committee. In case you wish to discuss the approval process or have any complaint or concern, you can contact Ms Brenda Penny (08 8161 6521), Secretary of the Committee.

Thank you for taking time to learn about this study. We are hopeful of a positive outcome, which will assist in the diagnosis and management of feeding problems in children. If now or in the future you wish to discuss the study further please feel free to contact:

Professor Geoffrey Davidson
Director
Centre for Paediatric and
Adolescent Gastroenterology
(08) 8161 7352

Mrs Larissa Noll
Speech Pathologist
(08) 8161 7381

Ms Lisa McCall
Research Nurse
(08) 8161 7188

THIS TRIAL HAS THE APPROVAL OF THE WCH RESEARCH ETHICS COMMITTEE. IF YOU WISH TO DISCUSS THE APPROVAL PROCESS, OR HAVE ANY OTHER CONCERN OR COMPLAINT PLEASE FEEL FREE TO CONTACT:

MS BRENDA PENNY

SECRETARY, WCH RESEARCH ETHICS COMMITTEE (08) 8161 6521

Appendix 3

WOMEN'S & CHILDREN'S HOSPITAL RESEARCH ETHICS COMMITTEE

CONSENT FORM

I ____

hereby consent to my child's involvement in the research project entitled:

'ASSESSMENT OF SWALLOWING AND REFLUX IN CHILDREN WITH FEEDING DIFFICULTIES'

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it, and agree to my child taking part.
2. I understand that my child may not directly benefit by taking part in this study.
3. I acknowledge that the possible risks and/or side effects, discomforts and inconveniences, as outlined in the Information Sheet, have been explained to me.
4. I understand that while information gained in the study may be published, my child will not be identified and information will be confidential.
5. I understand that I can withdraw my child from the study at any stage and that this will not affect medical care or any other aspects of my child's relationship with this hospital.
6. I understand that there will be no payment to my child for taking part in this study.
7. I have had the opportunity to discuss taking part in this research project with a family member or friend and/or have had the opportunity to have a family member or friend present whilst the research project was being explained by the researcher.
8. I am aware that I should retain a copy of the Consent Form, when completed, and the Information Sheet.

Signed: ....

Relationship to Patient: ....

Full name of patient: ....

Dated:.............................

I certify that I have explained the study to the parent and/or child and consider that he/she understands what is involved.

Signed: .... Title: ....

Dated: ....

Appendix 4

Women's & Children's Hospital ADELAIDE

ORAL FEEDING ASSESSMENT

PATIENT LABEL

UR Number: ....

Surname: ....

Given Names: ....

D.O.B. .... Sex: ....

Date : .... Reporting Speech Pathologist : (Printed name) ....

Referred by : .... (Signature) ....

Complaint: ....

....

HISTORY

....

....

....

....

Medication : ....

Birthweight : .... GA : ....

Growth : Weight :......... (pc......) Length : .... (pc......) Head Circumference :........ (pc......)

Route for nutrition: ☐ oral ☐ oral + tube ☐ tube ☐ IV

☐ If tube fed : total volume : ....

Tube : ☐ NG ☐ GT ☐ NJ

Administration : ☐ continuous drip : ml/hour, hours/day

daytime / night time, from till

☐ bolus feeds : ml , x/day

☐ weaning to oral feeding started : ☐ yes ☐ not yet ☐ currently not a priority

Oral feeding therapy : ☐ yes by : ....

☐ no

Videofluoroscopy : ☐ no ☐ yes : date : ....

result : ....

....

ORAL FEEDING SCHEDULE

Infant : Bottle : Frequency : .... hourly feeds Amount : .... Formula : ....

Enriched / thickened : ....

Baby : Solid : Frequency : .... x /day Amount : .... Type of food : ....

....

....

Liquid : Frequency : .... x /day Amount : .... Type of liquid : ....

....

ORAL FEEDING ASSESSMENT IN 85.3

ORAL SKILLS

1) ORAL **STRUCTURES**

Tongue ....

Lips ....

Jaw ....

Palate ....

2) ORAL **MOTOR** FUNCTION

ORAL REFLEX	PRESENT	ABSENT	NOT OBSERVED	PERMANET Present at	TEMPORARY Present at	TEMPORARY Extinction	OUTCOME Normal	OUTCOME Pathologic
Gag				32 wks GA	/	/		
Cough				birth	/	/		
Swallow				14 wks GA	/	/		
Transverse tongue				28 wks GA	/	/		
Phasic bite				/	28 wks GA	9-12 months		
Tongue protrusion				/	birth	4-6 months		
Sandmyer				/	34 wks GA	1-2 years		
Palmomental				/	birth	3-4 months		
Roothing				/	32 wks GA	3-6 months		
Suck				/	17 wks GA	3-4 months		

Aged under 3 months : Neonatal Oral Motor Assessment Scale : ☐ normal ☐ disorganised ☐ dysfunctional

Aged over 3 months :

Tongue : ....

Lips :..

Jaw : ....

Palate : ....

Conclusion : ☐ normal ☐ abnormal ☐ delayed

3) ORAL **SENSORY** RESPONSE

Clinical symptoms : ....

Baseline : ....

Conclusion : ☐ aversion ☐ hypersensibility ☐ normal ☐ hyposensibility ☐ absence

FEEDING OBSERVATION

FLUID : ....

....

....

SEMI-SOLID : ....

....

....

SOLID : ....

....

CERVICAL AUSCULTATION

☐ normal

☐ abnormal : ☐ residue ☐ stridor ☐ apnea ☐ cough ☐ other

CONCLUSION

Type of feeding problem :

☐ oral : ☐ oral phase...

☐ pharyngeal phase...

....

☐ medical

☐ behavioural ☐ educational ☐ developmental

Severity : Aspiration Risk

☐ normal or no suspicion	(0)
☐ minimal impairment with minimal influence on oral intake	(1)
☐ often present and intermittent influence on oral intake	(2)
☐ constantly present and continued influence on oral intake	(3)

Suspicion of silent aspiration ☐ yes ☐ no

Feeding Skills

☐ normal or no suspicion	(0)
☐ minimal impairment with influence on oral intake	(1)
☐ often present and intermittent influence on oral intake	(2)
☐ constantly present, continued influence on oral intake	(3)

RECOMMENDATIONS

Oral feeding : ☐ started ☐ to be continued ☐ temporarily stopped until : .... ☐ stopped

Feeds to be given by ☐ nursing staff ☐ speech pathologist ☐ caregiver ☐ other

Written feeding advice given to feeder : ☐ yes ☐ no

☐ Position : ☐ on lap ☐ in Tumble form seat ☐ in babyseat ☐ in high chair

☐ Head position : ☐ chin tuck (flexed) ☐ neutral (neck elongated)

☐ midline ☐ head tilt

☐ head supported with rolled up towel

☐ Body posture : ☐ upright (90°) ☐ semi reclined (60°)

☐ Food characteristics :

☐ Taste : ☐ introduce a variety of tastes ☐ strong flavoured ☐ bland flavoured ☐ add lemon

☐ Texture : ☐ thin liq ☐ thickened liq ☐ smooth ☐ mashed ☐ lumps ☐ crunchy ☐ soluable solids

☐ Temperature : ☐ room temperature ☐ chilled ☐ warm

☐ Placement of food in mouth : ☐ lower lip ☐ cheek ☐ on tongue ☐ other :

☐ Volume : ☐ ..... ml by syringe ☐ 1/2 teaspoon ☐ heaped spoon ☐ other :

☐ Utensils :

☐ syringe : ....ml

☐ teat : ☐ flow rate ☐ premie ☐ other :

☐ bottle : ☐ angled bottle ☐ squeeze bottle ☐ other :

☐ spoon : ☐ hard plastic ☐ soft plastic ☐ metal ☐ other :

☐ cup ☐ rim ☐ cut out cup ☐ spout ☐ other :

☐ Timing of food presentation

☐ count .... sucks – withdraw milk while leaving bottle in mouth, wait for ....seconds – reintroduce bottle for .... sucks, repeat.

☐ alternate liquids and solids

☐ wait to introduce food until swallow has occurred and mouth is emptied

☐ let rim of cup rest on lower lip and give one sip at the time

☐ consecutive swallows

☐ Duration of feed : no longer than ☐ 30 minutes ☐ 20 minutes ☐ 10 minutes ☐ other :

FOLLOW UP

Type of follow up :

☐ Not needed

☐ Therapy: ☐ feeding therapy ☐ oral stimulation therapy

☐ in WCH ☐ closer to home :

☐ Further diagnostic assessment :

☐ palatogram ☐ videomanometry ☐ medical ☐ behavioural ☐ developmental

Scheduled on :

Appendix 5

8-Point Penetration-Aspiration Scale

Score	Description of Events
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 into the larynx or out of the airway.
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.

Rosenbek, J. C., Robbins, J., Roecker, E. B., Coyle, J. L., & Wood, J. L. (1996). A penetration-aspiration scale. *Dysphagia*, *11*, 93-98.

Appendix 6

6 Point Bolus Residue Scale (After the swallow)

Score		*Description of Events*
1	=	No bolus residue
2	=	Bolus residue in the valleculae
3	=	Bolus residue on posterior pharyngeal wall OR piriform sinus only
4	=	2 locations of bolus residue. Bolus residue in the valleculae AND posterior pharyngeal wall OR piriform sinus.
5	=	Bolus residue on the posterior pharyngeal wall AND piriform sinus.
6	=	Bolus residue at valleculae, posterior pharyngeal wall AND piriform sinus.