

## Research Article

# Developing a Protocol for Quantitative Analysis of Liquid Swallowing in Children

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## ABSTRACT

**Purpose:** Objective measures in videofluoroscopic swallow studies (VFSSs) can quantify swallow biomechanics. There are a wide array of validated measures studied in infants, children, and adults. There is a need for a pediatric VFSS protocol that consists of a small number of vital, time efficient, and clinically relevant measures. In this study, we aimed to establish a standard protocol for quantitative VFSS analysis in children.

**Method:** Protocol development began with a systematic literature review, which identified 22 quantitative and eight descriptive measures available in the literature. A pediatric VFSS database of 553 children was collected using a standardized VFSS protocol. Studies were evaluated using the 30 previously reported measures covering displacement and timing parameters as well as penetration–aspiration and residue. Measures were tested for rater reliability and internal consistency. Measures meeting acceptable values for protocol inclusion were included in the final protocol (Cronbach’s alpha > .53).

**Results:** Interrater and intrarater reliability of 17 measures met acceptable reliability levels. During internal consistency testing, we removed six further measures based on Cronbach’s alpha levels indicating that two or more measures were equivalent in measuring the same aspect of swallow biomechanics in children. A VFSS protocol of reliable, valid, and obtainable objective quantitative ( $n = 6$ ) and descriptive measures ( $n = 3$ ) with separate protocols for young infants ( $\leq 9$  months) and older children was established.

**Conclusions:** A standardized quantitative VFSS protocol for children has been developed to suit two age groups ( $\leq 9$  and  $> 9$  months old). Consistent VFSS administration and reporting support assessment over time and across disease groups. Future research should focus on how this information can be used by clinicians to produce individualized treatment plans for children with swallowing impairment.

The videofluoroscopic swallow study (VFSS) is the most common instrumental assessment used to visualize the dynamic mechanism of swallowing in children (Arvedson, 2008). Possibly due to the absence of normative data across the life span and poor utilization of standardized measures, interpretation of VFSS remains largely subjective (Henderson et al., 2016; Leonard et al., 2004). Reliability of subjective observations is often found to be low

(Gibson et al., 1995; Lee et al., 2017; Scott et al., 1998), reducing the quality of information gathered.

To improve objective interpretation, clinicians need quantifiable and reproducible measures (Lee et al., 2017). MBSImP (Martin-Harris et al., 2008) uses criterion-based ratings of VFSS observations in adults to provide a level of quantification to swallowing biomechanics across phases of swallowing from mouth through to esophagus. Recently, BaByVFSSImP, a pediatric prototype of MBSImP for bottle-fed infants, with features unique to bottle-feeding, has been validated (Martin-Harris et al., 2020). These tools improve interrater reliability through raters using the same structure and terminology. However, the BaByVFSSImP

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still utilizes criterion-based observation ratings of VFSS to select each rating value by the clinician.

Objective, quantitative timing and displacement VFSS measures for adults have been established and validated over decades (Kendall et al., 2000; Leonard et al., 2004). However, validated quantitative measures for children are in their infancy. A normative data set of quantitative VFSS measures for children is challenging to obtain due to ethical concerns with exposing healthy children to radiation. There are a few recently published studies that expand our understanding of obtaining quantitative VFSS measures in children (Dharmarathna et al., 2020a, 2021a, 2021b; Gosa et al., 2015; Henderson et al., 2016; McGrattan et al., 2019; Riley et al., 2018; Sales et al., 2017; Weckmueller et al., 2011).

In 2015, our lab conducted a systematic review of quantitative VFSS swallow measures available in the literature (Dharmarathna et al., 2018, 2020b). A panel of three researchers and three clinicians reviewed the list for clinical relevance and repetition/replication. We found 22 quantitative swallow measures and eight descriptive measures of swallowing. We found that penetration–aspiration scale (PAS; Rosenbek et al., 1996), postswallow residue, nasopharyngeal reflux, and esophagopharyngeal reflux were the most commonly reported descriptive measures of swallow impairments in pediatric VFSS studies (Gosa et al., 2015; Henderson et al., 2016; McGrattan et al., 2019; Riley et al., 2018; Sales et al., 2017; Weckmueller et al., 2011).

In our previously published work, we established preliminary construct–content validity and criterion validity for these measures (Henderson et al., 2016). In 146 infants (0–9 months old), we found that infants with more than three sucks per swallow and significantly longer total pharyngeal transit times (TPTs) were at higher risk of aspiration compared to infants with only one to three sucks per swallow and shorter TPT (Dharmarathna et al., 2020a). In a larger follow-on study, bolus clearance ratio (BCR), pharyngeal constriction ratio (PCR), TPT, and duration of maximum hyoid elevation (Hdur) were predictive of penetration–aspiration in 533 children aged 0–21 years (Dharmarathna et al., 2021a). We studied postswallow residue in relation to swallow biomechanics in the same 533 children using the BCR (Leonard, 2017). BCR was correlated with PCR, TPT, pharyngoesophageal segment maximum opening (PESmax), and PAS (Dharmarathna et al., 2021b). These studies establish predictive and construct–content validity, demonstrating that quantitative measures are capable of measuring swallow biomechanics in children.

Due to time constraints in clinical settings and the large number of quantitative measures available in the literature, it is challenging for clinicians to decide which quantitative measures should be prioritized, if any. A

standardized protocol with a feasible and valid set of selected quantitative measures would assist uptake in busy clinical settings. A quantitative assessment tool has merit, but tool development takes time and needs to be conducted with care (Schoenfeldt, 1984). Building on our foundational validity work, the overall aim of this study was to create a feasible and reliable quantitative measure protocol with acceptable rater reliability and established internal consistency.

## Method

Ethical approval for this study was received from the University of Auckland, New Zealand (University of Auckland Human Participants Ethics Committee: 9263).

### Standardized VFSS Administration

In 2015, we designed and validated a standardized pediatric fluoroscopic methodology to obtain 20-s video loops of stable feeding using continuous fluoroscopy to achieve a recording at 30 frames per second to optimize reliable, quantitative VFSS measurement ensuring no increase in radiation dose or exposure time (Henderson et al., 2016). The mean total radiation time recorded for the full clinical procedure was 1.58 min (range: 0.15–3.47 min,  $SD = 0.66$  min), and the mean radiation exposure dose was 30.1 cGy $cm^2$  (range: 6.5–85,  $SD = 15.3$ ). In this study, VFSS was conducted in the radiology suite on a Siemens Sireskop radiographic unit. Children were placed in lateral view in their usual or recommended feeding posture with or without the support of a caregiver capturing the oral cavity, pharynx, larynx, and cervical esophagus. Either a radiopaque ring of a known diameter was placed in the child's chin with tape, or a ruler-like tool (in pixels) was present in digitalized VFSS images to allow displacement measures to be made. An in-house speech pathologist was present to guide the caregiver and to cue older children to swallow when required. A radiologist activated the fluoroscope.

As described in our previous work (Dharmarathna et al., 2020a, 2021a, 2021b), all the children were administered Varibar barium sulfate contrast (40% w/v; E-Z-EM Canada, Inc.) in a concentration of 50:50 with water/preferred milk/juice:barium to create Level 0 thin fluids using the International Dysphagia Diet Standardisation Initiative (2016) flow test. Infants were fed in their usual feeding position by their usual feeder wherever possible. A 20-s video loop of “midfeed sucking” was obtained in bottle-fed infants using the infant's usual nipple and either breast milk or the infant's usual formula combined with barium contrast. *Midfeed* was defined as “midway through the feed,” ensuring that children have established

their stable, typical feeding pattern (Henderson et al., 2016). Midfeed cup drinking of sequential swallowing from a sipper cup was recorded for younger children who had grown out of bottle drinking but had not yet established open cup drinking skills. For children with open cup drinking skills, swallowing of two Level 0 bolus sizes (5 and 10 ml) by an open cup was observed. Only the smallest bolus volumes were obtained from children to follow the standard procedure of safe and manageable bolus for administration (Martin-Harris et al., 2000). The in-house speech pathologist used their clinical judgment in continuing the study with exploration of compensatory strategies and other texture trials. These recordings were kept in the hospital internal clinical records and were not included in analyses. The mid-feed 20-s loop was recorded on a USB external drive in .avi file format at 30 frames per second rate for frame-by-frame analysis.

## Pediatric VFSS Database

Our database holds VFSS data, demographic data, and medical history information on 533 children consecutively referred for VFSS due to concerns related to feeding and/ or swallowing from 2016 to early 2020. The American Academy of Pediatrics has identified the upper limit of pediatrics as 21 years (Hardin & Hackell, 2017), and the children's hospital adheres to this classification to care for children and adolescents with complex disabilities until a developmentally appropriate transition to adult care. From a total of 572 fluoroscopic videos of children obtained during this period, 553 videos of children were included. Children who refused the standardized VFSS procedure or did not swallow thin liquids were excluded from the database.

Primary medical diagnoses were categorized as neurological (e.g., cerebral palsy and stroke), chromosomal (e.g., Prader-Willi syndrome and trisomy 21), anatomical (e.g., tracheomalacia and tracheoesophageal fistula), respiratory (e.g., chronic lung disease and bronchiolitis), cardiac (e.g., Tetralogy of Fallot and congenital heart disease), gastrointestinal (e.g., toxic ingestion-related injuries and gastroenteritis), multiple (a combination of medical etiologies), and unknown (no known medical etiology). Pulmonary dysfunction has been previously identified as a significant cofactor in children with swallowing difficulties (Tutor et al., 2015). Therefore, children were grouped according to the presence or absence of respiratory complications for statistical analysis. Respiratory complications were defined as any respiratory sign that can result in morbidity and/ or mortality of children (Carroll & Agarwal, 2010; von Ungern-Sternberg, 2014). Laryngospasm, bronchospasm, severe persistent cough, partial/complete airway obstruction, apnea, oxygen desaturation, bronchiectasis, and stridor were common respiratory complications identified.

Demographic data of the cohort of children studied are displayed in Table 1.

## VFSS Image Analysis

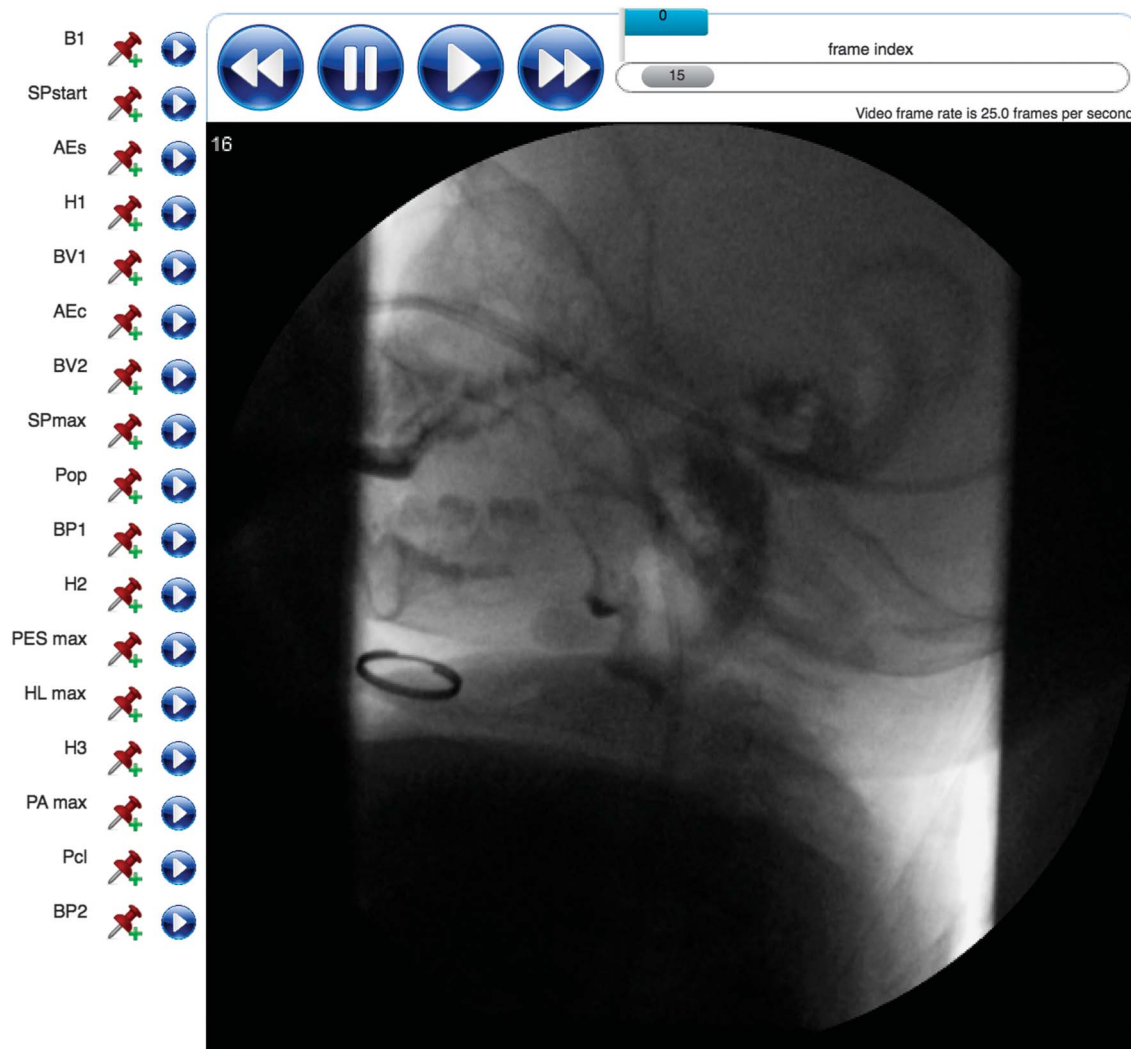
All videofluoroscopic data were analyzed using a software program specifically designed for quantitative analysis of VFSS (Swallowtail, Beldev Medical). This software application allows frame-by-frame analysis and uses integrated tools to obtain objective timing and displacement measures of the swallow. Swallowtail extracts mechanical measures from VFSS data accurately and expediently (Leonard & Kendall, 2019) and was developed based on quantitative measures described by Leonard and Kendall (Kendall et al., 2000; Leonard, 2017; Leonard et al., 2004, 2011). Swallow gesture times can be marked in the software allowing frame-by-frame analysis of the VFSS data (see Figure 1). Calibration is used to allow displacement measures, and timing and displacement measures can be calculated by the software. We understood that

**Table 1.** Demographics/clinical information (Dharmarathna et al., 2021a, 2021b).

Demographic		<i>n</i>	%
Sex	Female	212	38.3
	Male	341	61.7
Age <sup>a</sup>	0–9 months	146	27.5
	9.1–12 months	38	7.2
	1.1–3 years	183	34.5
	3.1–5 years	61	11.5
	5.1–12 years	72	13.6
	12.1–18 years	29	5.5
	18–21 years	1	0.2
Volume of contrast	Midfeed cup drinking	214	38.7
	Midfeed bottle-feeding	210	38.0
	Thin liquid–5 ml	99	17.9
	Thin liquid–10 ml	30	5.4
Primary medical etiology	Respiratory	114	20.6
	Neurological	165	29.8
	Anatomical	71	12.8
	Cardiac	25	4.5
	Chromosomal	62	11.2
	Multiple	32	5.8
	Other	13	2.4
	Unknown	71	12.8
Respiratory complications at present	Yes	217	39.2
	No	336	60.8
Tracheostomy	Yes	35	6.3
	No	518	93.7
Alternative feeding at time of procedure	NGT	107	19.4
	PEG	51	9.2
	None	395	71.4
Penetration–aspiration	No penetration/aspiration (PAS 1–2)	326	58.9
	Penetration (PAS 3–5)	69	12.5
	Aspiration (PAS 6–8)	158	28.6

<sup>a</sup>Classification of age recognized by the American Academy of Pediatrics (Hardin & Hackell, 2017).

**Figure 1.** Frame-by-frame viewing pane of Swallowtail to record swallow gesture times. Child aged 9 years. Printed with permission from Swallowtail.



not all selected measures could be obtained from every child. In particular, measuring timing and displacement measures of the hyoid bone in children younger than 9 months is not reliable, as visibility of hyoid movements is poor (Riley et al., 2018). Due to the unique mechanism of suck–swallow–breathe in bottle-feeding milk-sucking infants (Matsuo & Palmer, 2008; Morris, 1990; O’Hare et al., 1995), a set of suck–swallow–timing measures was additionally obtained from bottle-fed infants. Operational definitions of all the selected measures that were extracted from published literature are described in Table 2.

For each infant, one swallow was selected from their 20-s loop. If the infant aspirated, their swallow with the highest PAS scale score was selected. This supported the objective of the research program, which was to develop a VFSS protocol that could predict swallow risk factors such as aspiration and residue. If the infant did not aspirate, the

researcher analyzed the first swallow in the 20-s loop. For children who took measured bolus volumes, their largest volume was measured. The frame that the swallow chosen commenced (B1) was collected for interrater reliability purposes. Analysis took < 20 min per child in line with our previous work in adults (Nordin et al., 2017).

### Rater Reliability Testing

Rater reliability was used to determine whether the selected measures were replicable (Shiple & McAfee, 2020). Selected quantitative measures were tested for reliability, except for sucks per swallow (SSw ratio) and the number of sucks within a 20-s loop, as they require no specialized training and are commonly calculated measures. Three raters were trained to obtain the measures to achieve satisfactory reliability. All three raters (I.D., L.F., and M.J.) were speech

**Table 2.** Operational definitions of all the selected measures extracted from the literature.

Objective quantitative measure	Definition
Timing(s)/coordination	
Total pharyngeal transit time (TPT) <sup>a</sup>	Represents the total time of the bolus passage through the pharynx, from when the bolus head passes the posterior nasal spine (B1) to the time at which the bolus tail completely clears the PES (BP2). TPT = BP2 – B1
Time to airway closure (Airwaycl) <sup>a</sup>	Time taken to total arytenoid-epiglottis approximation to close the supraglottic airway. Airway start (AEs) – airway close (Acl)
Airway closure duration (ACD) <sup>a</sup>	The duration of total airway closure, from the approximation of the elevated arytenoids with the down folding epiglottis (AEc) to the first frame in which the epiglottis has returned to its preswallow position (Em). Airway closure time = Em – AEc
PES opening duration (PESdur) <sup>a</sup>	The duration of PES opening from the first frame in which it opens (Pop) to when it closes behind the bolus tail (Pcl). PES opening time = Pcl – Pop
Coordination of airway closure with bolus transit (BP1AEcl) <sup>a</sup>	Airway closure time (AEcl) in relation to bolus reaching PES (BP1). Coordination of airway closure with bolus transit = BP1 – AEcl
Stage transition duration (STD) <sup>b,c</sup>	First upward movement of the hyoid (H1) in relation to bolus head passes the posterior nasal spine (B1).
Laryngeal elevation (LE) <sup>a,c</sup>	First upward movement of the hyoid (H1) in relation to the first upward movement of the arytenoids.
Duration to hyoid maximum elevation (Hdur) <sup>a,c</sup>	The duration from the first upward movement of the hyoid (H1) to its maximum anterior–superior displacement (H2). Hdur = H2 – H1
Duration of maximum hyoid displacement (Hm) <sup>a,c</sup>	The duration hyoid bone remains in its maximum elevation. From the first frame of maximum elevation (H2) to the first frame hyoid begins to retract from its maximum elevation (H3). Hm = H3 – H2
Suck time <sup>d,e</sup>	Begins with the frame at the initiation of downward mandibular movement and ends with the frame at the initiation of the base of tongue propulsion. The difference between these two measures is the time spent sucking.
Tongue and soft palate cycle (T-SP) <sup>e,f</sup>	The first contact of the soft palate with tongue (SP) in relation to the first downward motion of the back of the tongue (BT). T-SP = SP – BT
Duration of velopharyngeal closure (VCD)	The number of video frames exhibiting contact of the velum to the posterior pharyngeal wall multiplied by the duration of one video frame.
Number of sucks per swallow (SSw ratio) <sup>d,e</sup>	Downward motion of mandible to mandible returning to the neutral position is counted as one suck. The total number of sucks per swallow is counted.
Number of swallows in the 20-s segment (Sucks20) <sup>e,g</sup>	Count number of swallowing in the 20-s midfeed loop.
Oropharyngeal swallow efficiency (OPSE) <sup>h,i</sup>	Represents a global measure of swallow function, taking into account all the aspects or effects of oropharyngeal dysphagia. OPSE = percentage of bolus transported into the esophagus / oral transit time + pharyngeal transit time (oropharyngeal transit time)
Displacement measures (cm)	
Maximum pharyngeal area at rest (PAhold or PAs) <sup>a</sup>	Measured when the pharynx is at rest, either prior to or following a swallow. The pharyngeal area is outlined by the posterior pharyngeal wall extending from the midportion of the tubercle of the atlas to the top of the arytenoid cartilages anteriorly over the arytenoids to outline the epiglottis, valleculae, and tongue base up to the soft palate (Yip et al., 2006).
Pharyngeal area at maximum constriction (PAMax) <sup>a</sup>	The same pharyngeal area, as outlined in the maximum pharyngeal area, is measured again, but at the point of maximum constriction during a swallow.
Pharyngeal constriction ratio (PCR) <sup>a,j</sup>	The ratio of pharyngeal area at its maximum constriction to the area of the pharynx at rest. PCR = PAMax / PAhold
PES max opening (PESmax) <sup>a</sup>	The width of the PES is measured at the point of maximum opening during the swallow.
Bolus clearance ratio (BCR) <sup>j,k</sup>	Ratio between the bolus area in the pharynx before a swallow and the residual bolus area in the pharynx after a swallow. BA <sub>1</sub> = bolus area during a swallow immediately prior to the UES opening. BA <sub>2</sub> = bolus area/any residual material in the pharynx immediately after the UES closure. BCR = BA <sub>2</sub> / BA <sub>1</sub>
Maximum elevation of hyoid bone (Hmax) <sup>a,c</sup>	The change in hyoid position from a referent frame (hold) to its maximum anterior–superior displacement (H2).
Maximum approximation of the hyoid and larynx (HL) <sup>a,c</sup>	The difference in distance between hyoid bone and larynx at hold position and at their point of maximum approximation (HLmax) during a swallow.

(table continues)

Table 2. (Continued).

Objective quantitative measure	Definition
Descriptive/binary observations	
Penetration–aspiration scale (PAS) <sup>l</sup>	1–8 rating scale
Presence of penetration–aspiration	< 3 PAS, 3+ PAS <sup>h</sup>
Frequency of penetration–aspiration <sup>c,g</sup>	Number of times a bolus enters the airway in a 20-s loop (PAS = ≥ 3).
Time of airway violation <sup>m</sup>	1 = preswallow, 2 = midswallow, 3 = postswallow, 4 = multiple
Postswallow residue <sup>d</sup>	Yes or no in response to whether there was residue after the swallow, marked as (+) or (–).
Bolus residue scale (BRS) <sup>n</sup>	1–6 rating scale
Nasopharyngeal reflux (NPR) <sup>m</sup>	Presence or absence of NPR, marked as (+) or (–).
Esophagopharyngeal reflux (EPR) <sup>m</sup>	Presence or absence of EPR, marked as (+) or (–).
Suck/swallow bolus control <sup>d,e</sup>	Reviewer to mark yes = controlled suck/swallow or no = not controlled suck/swallow, as (+) or (–).

Note. PES = pharyngoesophageal segment; (+/–) = (present/absent); UES = upper esophageal sphincter.

<sup>a</sup>Leonard and Kendall (2019). <sup>b</sup>Byeon and Koh (2016). <sup>c</sup>Measured in children above 9 months old only. <sup>d</sup>Gosa et al. (2015). <sup>e</sup>Measured during midfeed sucking of bottle-fed infants only. <sup>f</sup>Goldfield et al. (2013). <sup>g</sup>Henderson et al. (2016). <sup>h</sup>Rademaker et al. (1994). <sup>i</sup>Consists of a subjective variable. <sup>j</sup>Unitless measures. <sup>k</sup>Leonard (2017). <sup>l</sup>Rosenbek et al. (1996). <sup>m</sup>Dodds et al. (1990). <sup>n</sup>Rommel et al. (2015).

pathologists with a minimum of 3 years of work experience. They completed a comprehensive 3-hr face-to-face training on quantitative swallow measures and use of the specialized software from the lead researcher (A.M.). The raters completed weekly 1-hr peer supervision sessions for 4 weeks to develop precision, consistency (intrarater reliability), and agreement (interrater reliability). In-house manual and video tutorials were available.

Due to significant differences in visibility of anatomical locations on fluoroscopy between young infants (≤ 9 months old) and older children, reliability was tested separately. One investigator (I.D.) completed the analysis of all videofluoroscopic data ( $n = 533$ ). VFSS data of 50 infants (≤ 9 months old) and 124 children (> 9 months old) were randomly selected for interrater and intrarater reliability, which was 30% of the database. Measures for interrater reliability were obtained from two further raters (L.F. and M.J.) for infant and older children groups, respectively. The raters were blinded to each other's scores and to medical history and clinical characteristics of the children. One investigator (I.D.) measured the same data set of 50 infants (≤ 9 months old) and 124 children (> 9 months old) twice, with at least 10 months between repeat analyses to calculate intrarater reliability. Intraclass correlation coefficient (ICC) was used to determine reliability. An ICC of ≥ .7 was considered a satisfactory agreement for interrater and intrarater reliability for ratings (Koo & Li, 2016).

## Internal Consistency

Internal consistency “reflects the extent to which items within an instrument measures various aspects of the same characteristic or construct” (Revecki, 2014). To examine the internal consistency of the protocol, we used two statistical methods: average interitem correlation and Cronbach's alpha (Glen, 2016). Average interitem correlations

were used in deciding which measures should be removed when more than one variable was capable of describing a particular phenomenon. When two or more measures were found to have strong interitem correlation, we selected the measures that offered construct–content and criterion validity. We performed Pearson product–moment correlation coefficient test to determine the interitem correlation of the protocol. A Pearson correlation coefficient ( $r$ ) between .3 and .5 is considered a moderately strong correlation, and a Pearson correlation coefficient between .5 and .1 is considered a strong correlation (Hinkle et al., 2003; Mukaka, 2012).

Cronbach's alpha was used to identify how closely related the list of measures were as a group (Glen, 2016). In conventional subjective questionnaire development, Cronbach's alpha above .7 is considered acceptable internal consistency (Tavakol & Dennick, 2011). However, the purpose of using Cronbach's alpha here was to identify whether more than one variable measured the same aspect of swallow biomechanics in children. We did not expect the list of measures to achieve a higher Cronbach's alpha if the measures represented distinct and unique phenomena in the swallowing mechanism. We aimed to reduce the total number of measures included to make the protocol time efficient.

## Results

Raw descriptive statistics of the quantitative swallow measures obtained from the children are reported in Appendix A.

## Rater Reliability

For both young infants and older children, all timing measures had absolute agreement (ICC = 1), whereas

**Table 3.** Interrater reliability of quantitative swallow measures.

Objective quantitative swallow measure	Infants (0–9 months)				Other children (9 months–21 years)			
	ICC	95% CI		Sig. ( <i>p</i> ) <sup>a</sup>	ICC	95% CI		Sig. ( <i>p</i> ) <sup>a</sup>
		Lower bound	Upper bound			Lower bound	Upper bound	
TPT	.845	.733	.901	.001	.928	.794	.993	.032
Airwaycl	.726	.824	.901	.005	.899	.808	.967	< .001
ACD	—	—	—	—	.832	.702	.954	< .001
PESdur	.828	.756	.900	< .001	.771	.685	.834	.012
BP1AEcl	.757	.664	.912	.045	.805	.712	.908	< .001
STD	—	—	—	—	.810	.608	.900	.005
LE	—	—	—	—	.774	.698	.885	< .001
Hdur	—	—	—	—	.890	.784	.913	.010
Hm	—	—	—	—	.875	.756	.950	< .001
VCD	.821	.687	.914	.032	.920	.758	.959	.015
PCR	.764	.567	.868	.033	.890	.781	.942	.010
BCR	—	—	—	—	.860	.740	.961	< .001
PESmax	.805	.688	.899	< .001	.910	.875	.955	.011
Hmax	—	—	—	—	.859	.754	.911	.003
HL	—	—	—	—	.798	.688	.898	< .001
Suck time	.720	.608	.774	.002	—	—	—	—
T-SP	.856	.724	.911	< .001	—	—	—	—

Note. Em dashes indicate data not completed. ICC = intraclass correlation coefficient; CI = confidence interval; TPT = total pharyngeal transit time; Airwaycl = time to airway closure; ACD = airway closure duration; PESdur = pharyngoesophageal segment opening duration; BP1AEcl = coordination of airway closure with bolus transit; STD = stage transition duration; LE = laryngeal elevation; Hdur = duration to hyoid maximum elevation; Hm = duration of maximum hyoid displacement; VCD = duration of velopharyngeal closure; PCR = pharyngeal constriction ratio; BCR = bolus clearance ratio; PESmax = pharyngoesophageal segment maximum opening; Hmax = maximum elevation of hyoid bone; HL = maximum approximation of the hyoid and larynx; T-SP = tongue and soft palate cycle.

<sup>a</sup>A *p* value (significance) of < .05 is considered statistically significant (95% confidence interval).

displacement measures had excellent agreement (ICC ≥ .98, 95% confidence interval [.98, 1.00], *p* < .001). Interrater reliability was greater in older children compared to infants (ICC range in infants: .72–.84 vs. ICC range in older children: .77–.92; see Table 3). Oropharyngeal swallow efficiency (OPSE; Rademaker et al., 1994) was removed from the proposed VFSS protocol due to early concerns in achieving satisfactory intrarater reliability during the training. Out of 100 videos in which OPSE was measured, intrarater reliability was tested for the first 20, with poor agreement (ICC = .24). Even though this measure is considered to offer a global measure of oropharyngeal swallowing (Logemann et al., 2005), it requires subjective VFSS observation to assume the percentage of bolus passed down to the esophagus, resulting in poor agreement between our raters.

### Internal Consistency

As the list of statistically significant interitem correlations was lengthy, only the associations with strong correlations are reported. The list of all statistically significant correlations can be found in Appendix B. Duration of PES opening significantly correlated with PESmax,  $r(552) = .28, p < .001$ . PESmax was significantly larger in children with a larger pharyngeal area at rest,  $r(552) = .386, p < .001$ . Time to airway closure,  $r(552) = .176, p <$

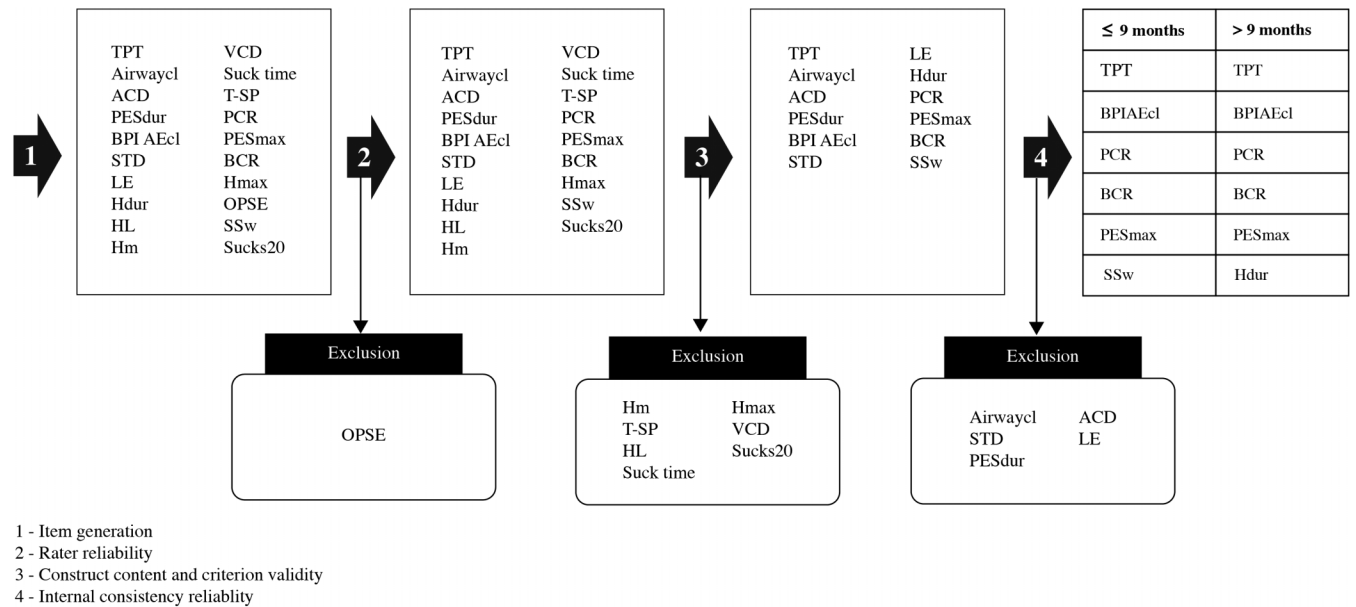
.001, and coordination of airway closure with bolus transit (BP1AEcl),  $r(552) = .451, p < .001$ , were significantly longer in children with longer TPT. A strong positive correlation was observed between two timing measures of the airway, where airway closure duration was significantly longer in children with longer stage transition duration (first movement of hyoid in relation to the position of the bolus head),  $r(552) = .974, p < .001$ .

We removed items that did not contribute a unique weighting to the model, and this left six items in the final model with a Cronbach's alpha of .531. In older children (> 9 months old), the following measures were included in the model: BCR, PCR, TPT, Hdur, BP1AEcl, and PESmax. For infants (≤ 9 months old), SSw ratio replaced the Hdur in the model. The list of measures was not reduced further due to the uniqueness of the six measures, which were found to be worthy of retention in the final protocol, resulting in lowering the alpha if deleted.

### Establishing the Protocol

The final protocol included 12 swallow measures (see Figure 2). We removed suck time, the number of sucks within 20-s loop, maximum hyoid elevation (Hmax), velopharyngeal closure duration (VCD), maximum approximation of hyoid bone and larynx (HL), tongue–soft palate cycle, and Hdur, as these measures did not

**Figure 2.** Developing a protocol of objective quantitative measures of videofluoroscopic swallow studies for children. TPT = total pharyngeal transit time; Airwaycl = time to airway closure; ACD = airway closure duration; PESdur = pharyngoesophageal segment opening duration; BP1AEcl = coordination of airway closure with bolus transit; STD = stage transition duration; LE = laryngeal elevation; Hdur = duration to hyoid maximum elevation; HL = maximum approximation of the hyoid and larynx; Hm = duration of maximum hyoid displacement; VCD = duration of velopharyngeal closure; T-SP = tongue and soft palate cycle; PCR = pharyngeal constriction ratio; PESmax = pharyngoesophageal segment maximum opening; BCR = bolus clearance ratio; Hmax = maximum elevation of hyoid bone; OPSE = percentage of bolus transported into the esophagus/oral transit time + pharyngeal transit time (oropharyngeal transit time); SSw = sucks-swallow ratio; Sucks20 = number of swallows in the 20-s segment.



show strong potential to describe swallow dysfunction in children in our previous validity testing (Dharmarathna et al., 2020a, 2021a, 2021b). We then reduced the number of quantitative measures to six measures each for older children (> 9 months old) and infants (≤ 9 months old) through internal consistency and reliability testing.

In addition to quantitative swallow measures, we tested eight descriptive swallow measures. These measures were not studied for validation, as they are already established and commonly used to describe swallowing symptom severity. Of these eight measures, PAS, bolus residue scale, and binary observation of presence of nasopharyngeal reflux reached clinical validity for inclusion in the final protocol due to significant associations with quantitative swallow measures ( $p < .05$ ) and a prediction accuracy of > 60% in our previous work (Dharmarathna et al., 2020a, 2021a, 2021b). Table 4 presents the finalized pediatric VFSS protocol for objective analysis in infants and older children.

## Discussion

We were able to develop a standard pediatric videofluoroscopic assessment protocol through systematic testing and validation using a large heterogeneous, cross-

sectional cohort of children referred for VFSS. In the proposed protocol, we aimed to refine the number of swallow measures while still including essential aspects of swallow biomechanics for clinical feasibility. Although our focus was on the exploration of quantitative measures, the final protocol includes both quantitative and well-known descriptive measures of swallow impairments such as aspiration. Our intention here was to provide clinicians with a benchmark minimum data set to improve the quality of the VFSS information we gather in the clinical context but to prevent overburdening a clinician with excessive measurements. As recommended by the American Psychological Association, we established the construct and content validity, criterion validity, and internal consistency for credibility of the protocol (American Psychological Association, 1995). Due to developmental differences between milk-sucking infants and children with eating and drinking skills (Matsuo & Palmer, 2008; Logemann et al., 1994; Morris, 1990; O'Hare et al., 1995), we developed two different protocols: one for bottle-fed infants/children and another for children who were cup-drinking. This protocol can be followed at the VFSS suite during administration of the fluoroscopic swallow study, and clinicians can decide what measures to report in each child depending on their chronological age and swallow abilities.



**Table 4.** Final pediatric videofluoroscopic swallow study (VFSS) protocol.

<b>VFSS administration</b>	
VFSS view	Lateral view. The boundaries of the fluoroscopic frame can be: child's lips – cervical spine (anterior–posterior) nasopharynx – cervical esophagus (superior–inferior)
Calibration	Required. Any radiopaque ring/disk of known diameter can be secured to the child's chin or to a place visible on the screen.
Frame rate	30 frames per second
Recording of swallows	Required
Swallow acts	Bottle-fed infants Midfeed sucking of bottle-feeding during 20-s midfeed loop. Bolus volume is not calculated. Other older children If able: Open cup drinking: 5, 10, 20, and 100 ml (using a straw). Measure the remaining volume in the cup to determine the swallowed bolus size. Alternative: Midfeed drinking of sequential swallowing (sipper cup/bottle) during a 20-s midfeed loop. Bolus volume is not calculated.
Bolus viscosity	Level 0, thin liquid bolus (International Dysphagia Diet Standardisation Initiative [IDDSI], 2016). Barium sulfate contrast made by different manufacturers come with specifications to meet IDDSI levels.
Selection of the swallow/s to be measured	Measuring the swallow with the highest PAS score allows clinicians to assess swallow safety (Hedström et al., 2017). If penetration/ aspiration is not present during the 20-s loop, measuring the largest bolus swallowed is recommended (Leonard & Kendall, 2019).

**Objective quantitative analysis**

<b>Age groups</b>	<b>Objective quantitative measures</b>	<b>Descriptive measures</b>
Bottle-fed infants (0–9 months old or older bottle-feeding children)	Total pharyngeal transit time (TPT) Coordination of airway closure with bolus transit (BP1AEcl) Number of sucks per swallow (SSw ratio) Bolus clearance ratio (BCR) Pharyngeal constriction ratio (PCR) Maximum opening of PES during a swallow (PESmax)	Penetration–aspiration scale (PAS) Bolus residue scale (BRS) Nasopharyngeal reflux (NPR) (+/–)
Older children <sup>a</sup> (> 9 months to 21 years)	Total pharyngeal transit time (TPT) Coordination of airway closure with bolus transit (BP1AEcl) Duration of maximum hyoid elevation (Hdur) Bolus clearance ratio (BCR) Pharyngeal constriction ratio (PCR) Maximum opening of PES during a swallow (PESmax)	Penetration–aspiration scale (PAS) Bolus residue scale (BRS) Nasopharyngeal reflux (NPR) (+/–)

**Reference values/key events of swallowing to look for, to identify swallow risk in children**

<b>In bottle-fed infants (0–9 months)</b>	<b>In all children (0–21 years)</b>
PAS ≥ 3 indicates airway violation. When the bolus arrives at the PES before airway is closed, the risk of airway violation is higher (longer BP1AEcl). Risk of penetration–aspiration is higher if TPT is > 0.5 s. Risk of penetration–aspiration is higher if more than three sucks per swallow are present. Risk of nasopharyngeal reflux is increased in children with narrower PESmax. Risk of nasopharyngeal reflux is higher if the PCR is ≥ 0.2. Risk of esophagopharyngeal reflux is higher if the BCR is ≥ 0.3.	PAS ≥ 3 indicates airway violation. When the bolus arrives at the PES before airway is closed, the risk of airway violation is higher (longer BP1AEcl). Risk of penetration–aspiration is higher if TPT is ≥ 2 s. Risk of penetration–aspiration is higher if BCR is ≥ 0.1. Risk of penetration–aspiration is higher if PCR is ≥ 0.2. Risk of penetration–aspiration is higher if Hdur is > 1 s. Nasopharyngeal reflux is more prevalent in children with elevated BCR. Nasopharyngeal reflux is more prevalent in children with narrower PESmax. Risk of penetration–aspiration is higher in children with residue in the posterior pharyngeal wall or pyriform sinuses than in children with no residue (BRS). Risk of penetration–aspiration is higher in children with residue in valleculae, posterior pharyngeal wall, and pyriform sinuses than in children with no residue (BRS).

Note. PES = pharyngoesophageal segment.

<sup>a</sup>Children from 9 months old to 21 years old.

## Reliability

We found the selected measures to have high interrater reliability. This adds to the growing literature demonstrating good reliability of objective measures in children (Dharmarathna et al., 2020a, 2021a, 2021b; Gosa et al., 2015; Henderson et al., 2016; McGrattan et al., 2019; Riley et al., 2018; Sales et al., 2017; Weckmueller et al., 2011). Previously, both Henderson et al. (2016) and Gosa et al. (2015) have reported satisfactory interrater reliability in obtaining timing and displacement measures of children through VFSS. Newman et al. (1991) reported good interrater reliability in temporal measures of swallowing in bottle-fed infants. In addition, Riley et al. (2018) reported excellent interrater reliability in measuring the displacement of the hyoid bone in children above 9 months. To our knowledge, this is the largest cohort studying the reliability of objective VFSS measures in children.

## Validity

Satisfactory reliability of measures does not necessarily mean they are valid (Tavakol & Dennick, 2011). Earlier commendable work has been done to explore the possibilities of objective analysis in children (Henderson et al., 2016; McGrattan et al., 2019; Sales et al., 2017; Weckmueller et al., 2011), studying quantitative measures to describe swallowing in different groups of children. It is noteworthy that most of these measures were previously studied in adults and have proved their ability in describing adult swallowing mechanism (Johnson & McKenzie, 1993; Kendall & Leonard, 2001; Kendall et al., 2000; Leonard, 2017, 2019; Leonard et al., 2000, 2004, 2006, 2011; Molfenter & Steele, 2013; Steele et al., 2011; Yip et al., 2006). Our recent work aided us in identifying key quantitative measures that are beneficial in describing or identifying signs of swallow impairment such as penetration–aspiration and residue in children (Dharmarathna et al., 2020a, 2021a, 2021b).

## Internal Consistency Reliability

Although a typically acceptable Cronbach alpha score is  $> .7$ , we accepted a lower rate at .531 because each valid item contributed uniquely to describing a different aspect of swallowing. The internal consistency testing indicates the individual value of each of these measures in a battery of VFSS assessment. Interestingly, some key measures in adult swallow evaluation, such as Hmax and HL, did not show significant impact in describing pediatric swallow biomechanics or aspiration (Leonard, 2019). In neurotypical adults, the influence of bolus volume on hyoid displacement has been well documented (Dodds

et al., 1988; Nagy et al., 2014; Ueda et al., 2013). It could be that lack of control of bolus volume in this pediatric cohort may have led to poor statistical power, resulting in statistical insignificance. This may be because the hyoid bone sits elevated in children already due to incomplete laryngeal descent; therefore, the range of motion may be constricted, and thus, variation in range may have less clinical impact. It is possible that hyoid movement has a lesser part to play in swallowing in infants in comparison to adults and older children. This highlights the uniqueness of pediatric feeding biomechanics in comparison to adults. With the exception of SSw ratio, additional measures of SSw coordination such as suck time and tongue–soft palate cycle did not have strong interitem correlation and were removed from the final protocol. These findings question the use of obtaining these measures, as they show poor ability in describing infant swallow biomechanics, even though they are feasible and reliable.

## Feasibility

As the final step to protocol development, we considered clinical feasibility of obtaining objective quantitative VFSS measures under four sections; technical resources, economic, logistical, and operational aspects (Rajadhyaksha, 2010).

### Technical

A specialized commercial software was used in this study for the quantitative analysis of VFSS. However, there are many no- or low-cost tools available for obtaining quantitative timing and displacement measures. Appendix C includes a list of options available for measurements at the time of writing. Frame rate and pulse rate of the videofluoroscopic data have a significant influence on the precision of objective quantitative swallow measures. Thirty frames per second is recommended for best detection of pharyngeal changes during VFSS analysis, particularly given the swallow rate in sucking children (Azpeitia Armán, 2017; Belafsky & Kuhn, 2014; Bonilha et al., 2013; Cohen, 2009; Mulheren et al., 2019). Clinicians should ensure they understand the screening and recording equipment in their radiology suite and understand the pulse rate they are recording at. A recommended rate for pharyngeal measures is 30 frames per second due to the total oropharyngeal swallow duration being less than 1 s. For some suites, screening in continuous rather than pulsed mode is required to achieve recording at 30 frames per second. This frame rate avoids missing airway violation and optimizes information that may be obtained from the 20-s loops. Moreover, reducing the overall recording time ensures minimal radiation exposure in developing children (Henderson et al., 2016; Hiorns & Ryan, 2006; Weir et al., 2007).

## Economic

VFSS is a commonly used instrumental swallowing assessment tool, and the quality of information obtained through VFSS can be improved by using quantitative analysis. It is extremely important that we obtain the maximum amount of information that can aid our clinical decision making to be mindful of both the radiation risk and the cost. Appendix C provides the cost of adding tools to facilitate objective analysis to an already-established VFSS suite at the time of writing.

## Logistical

Training in objective quantitative VFSS measurement and interpretation for timing and displacement measures is essential. Training and practicing of quantitative VFSS analysis may take time, as it requires precision in measuring. Expertise increases with familiarity, and the use of specific tools will aid in reducing the time spent on analysis. Nordin et al. (2017) reported improved interrater agreement and reduced measuring times in a group of novice and experienced clinicians following 8 weeks of once-weekly training in objective VFSS analysis. Appendix D provides instructions on how to obtain the key objective quantitative measures including demonstration videos.

## Operational

VFSS exposes children to ionizing radiation. VFSS administration should be done thoughtfully and only if necessary. If VFSS is selected, clinicians and researchers have ethical and clinical responsibility to obtain the maximum amount of information possible from fluoroscopic studies to aid clinical decision making in treating children with swallowing difficulties. Minimizing unnecessary radiation exposure and adhering to ALARA (as low as reasonably achievable) principles must be observed at all times during VFSS performance (Tolbert et al., 1996). We followed a standard protocol for VFSS administration in this study, which is proven to limit radiation dose in children (Henderson et al., 2016) while still obtaining all needed information. This approach reduces the risk of adverse events while obtaining clinically reliable and useful information on swallow biomechanics compared to subjective VFSS evaluation.

## Limitations

We acknowledge a number of limitations to this study. We are observing one swallow from videofluoroscopic recordings of limited time portions (20-s loops and volume-based single bolus swallows) to limit radiation exposure of children. Therefore, some signs/ observations of swallow impairments may not have been identified. Volume control in bottle-feeding infants was not possible,

and this should be taken into consideration in view of the volume effect on biomechanics reported in the literature (Lau et al., 2003). Fatigue testing and texture evaluation is not part of this protocol, and it is expected that clinicians use their clinical judgment to add these after the protocol as required for each child. Full medical history and details of preterm births were unavailable, and we do not know the potential impact of this on our interpretations. As we are unable to study healthy swallowing in children through VFSS, all our interpretations are based on swallow biomechanics observed in children with suspected swallowing difficulties, and conclusions on normal biomechanics should be guarded.

## Conclusions

This study addresses the need for a clinically validated, standardized VFSS protocol that provides objective findings, quantification, and interpretation of swallow biomechanics in children. By following an evidence-directed, comprehensive process, we have established rater reliability and internal consistency of a VFSS protocol for objective interpretation of swallowing in children. We anticipate that clinicians may use these valid and reliable swallow measures in their decision-making process. Implementation of such a protocol will allow for meaningful comparisons of swallowing skills of children across time, clinics, laboratories, and therapeutic strategies. Future research should focus on how this information can be used by clinicians to produce individualized treatment plans for children with swallowing impairment.

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## References

- American Psychological Association.** (1995). *The standards for educational and psychological testing.*
- Arvedson, J. C.** (2008). Assessment of pediatric dysphagia and feeding disorders: Clinical and instrumental approaches. *Developmental Disabilities Research Reviews, 14*(2), 118–127. <https://doi.org/10.1002/ddrr.17>
- Azpeitia Armán, F. J.** (2017). *Oropharyngeal videofluoroscopic swallow study. A how-to pictorial review.* Paper presented at the European Society of Radiology. <https://doi.org/10.1594/ecr2017/c-0995>
- Belafsky, P. C., & Kuhn, M. A.** (2014). *The clinician's guide to swallowing fluoroscopy.* Springer. <https://doi.org/10.1007/978-1-4939-1109-7>

- Bonilha, H. S., Humphries, K., Blair, J., Hill, E. G., McGrattan, K., Carnes, B., Huda, W., & Martin-Harris, B. (2013). Radiation exposure time during MBSS: Influence of swallowing impairment severity, medical diagnosis, clinician experience, and standardized protocol use. *Dysphagia*, 28(1), 77–85. <https://doi.org/10.1007/s00455-012-9415-z>
- Byeon, H., & Koh, H. W. (2016). The duration of stage transition during pharyngeal swallowing among young-elderly, and mid-elderly individuals. *Journal of Physical Therapy Science*, 28(5), 1505–1507. <https://doi.org/10.1589/jpts.28.1505>
- Carroll, J. L., & Agarwal, A. (2010). Development of ventilatory control in infants. *Paediatric Respiratory Reviews*, 11(4), 199–207. <https://doi.org/10.1016/j.prrv.2010.06.002>
- Cohen, M. D. (2009). Can we use pulsed fluoroscopy to decrease the radiation dose during video fluoroscopic feeding studies in children? *Clinical Radiology*, 64(1), 70–73. <https://doi.org/10.1016/j.crad.2008.07.011>
- Dharmarathna, I., Miles, A., & Allen, J. (2018). Current approaches to instrumental assessment of swallowing in children. *Current Opinion in Otolaryngology and Head & Neck Surgery*, 26(6), 349–355. <https://doi.org/10.1097/MOO.0000000000000492>
- Dharmarathna, I., Miles, A., & Allen, J. (2020a). Quantitative video-fluoroscopic analysis of swallowing in infants. *International Journal of Pediatric Otorhinolaryngology*, 138, 110315. <https://doi.org/10.1016/j.ijporl.2020.110315>
- Dharmarathna, I., Miles, A., & Allen, J. (2020b). Twenty years of quantitative instrumental measures of swallowing in children: A systematic review. *European Journal of Pediatrics*, 179(2), 203–223. <https://doi.org/10.1007/s00431-019-03546-x>
- Dharmarathna, I., Miles, A., & Allen, J. (2021a). Predicting penetration–aspiration through quantitative swallow measures of children: A videofluoroscopic study. *European Archives of Oto-Rhino-Laryngology*, 278(6), 1907–1916. <https://doi.org/10.1007/s00405-021-06629-4>
- Dharmarathna, I., Miles, A., & Allen, J. (2021b). Quantifying bolus residue and its risks in children: A videofluoroscopic study. *American Journal of Speech-Language Pathology*, 30(2), 687–696. [https://doi.org/10.1044/2020\\_AJSLP-20-00275](https://doi.org/10.1044/2020_AJSLP-20-00275)
- Dodds, W. J., Logemann, J. A., & Stewart, E. T. (1990). Radiologic assessment of abnormal oral and pharyngeal phases of swallowing. *American Journal of Roentgenology*, 154(5), 965–974. <https://doi.org/10.2214/ajr.154.5.2108570>
- Dodds, W. J., Man, K. M., Cook, I. J., Kahrilas, P. J., Stewart, E. T., & Kern, M. K. (1988). Caudate lobe of the liver: Anatomy, embryology, and pathology. *American Journal of Roentgenology*, 154(1), 87–93. <https://doi.org/10.2214/AJR.20.23034>
- Gibson, E., Phyland, D., & Marschner, I. (1995). Rater reliability of the modified barium swallow. *Australian Journal of Human Communication Disorders*, 23(2), 54–60. <https://doi.org/10.3109/asl2.1995.23.issue-2.05>
- Glenn, S. (2016). *Internal consistency reliability: Definition, examples*. <https://www.statisticshowto.com/internal-consistency>
- Goldfield, E. C., Smith, V., Buonomo, C., Perez, J., & Larson, K. (2013). Preterm infant swallowing of thin and nectar-thick liquids: Changes in lingual–palatal coordination and relation to bolus transit. *Dysphagia*, 28(2), 234–244. <https://doi.org/10.1007/s00455-012-9440-y>
- Gosa, M. M., Suiter, D. M., & Kahane, J. C. (2015). Reliability for identification of a select set of temporal and physiologic features of infant swallows. *Dysphagia*, 30(3), 365–372. <https://doi.org/10.1007/s00455-015-9610-9>
- Hardin, A. P., & Hackell, J. M. (2017). Age limit of pediatrics. *Pediatrics*, 140(3), e20172151. <https://doi.org/10.1542/peds.2017-2151>
- Hedström, J., Tuomi, L., Andersson, M., Dotevall, H., Osbeck, H., & Finizia, C. (2017). Within-bolus variability of the penetration–aspiration scale across two subsequent swallows in patients with head and neck cancer. *Dysphagia*, 32(5), 683–690. <https://doi.org/10.1007/s00455-017-9814-2>
- Henderson, M., Miles, A., Holgate, V., Peryman, S., & Allen, J. (2016). Application and verification of quantitative objective videofluoroscopic swallowing measures in a pediatric population with dysphagia. *Journal of Pediatrics*, 178, 200–205.e1. <https://doi.org/10.1016/j.jpeds.2016.07.050>
- Hinkle, D. E., Wiersma, W., & Jurs, S. G. (2003). *Applied statistics for the behavioral sciences* (5th ed.). Houghton Mifflin.
- Hiorns, M., & Ryan, M. (2006). Current practice in paediatric videofluoroscopy. *Pediatric Radiology*, 36(9), 911–919. <https://doi.org/10.1007/s00247-006-0124-3>
- International Dysphagia Diet Standardisation Initiative. (2016). *Drink testing methods: IDDSI flow test*. <https://iddsi.org/framework/>
- Johnson, E. R., & McKenzie, S. W. (1993). Kinematic pharyngeal transit times in myopathy: Evaluation for dysphagia. *Dysphagia*, 8(1), 35–40. <https://doi.org/10.1007/BF01351476>
- Kendall, K. A., & Leonard, R. J. (2001). Pharyngeal constriction in elderly dysphagic patients compared with young and elderly nondysphagic controls. *Dysphagia*, 16(4), 272–278. <https://doi.org/10.1007/s00455-001-0086-4>
- Kendall, K. A., McKenzie, S., Leonard, R., Gonçalves, M., & Walker, A. (2000). Timing of events in normal swallowing: A videofluoroscopic study. *Dysphagia*, 15(2), 74–83. <https://doi.org/10.1007/s004550010004>
- Koo, T. K., & Li, M. Y. (2016). A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *Journal of Chiropractic Medicine*, 15(2), 155–163. <https://doi.org/10.1016/j.jcm.2016.02.0>
- Lau, C., Smith, E. O., & Schanler, R. J. (2003). Coordination of suck–swallow and swallow respiration in preterm infants. *Acta Paediatrica*, 92(6), 721–727. <https://doi.org/10.1111/j.1651-2227.2003.tb00607.x>
- Lee, J. W., Randall, D. R., Evangelista, L. M., Kuhn, M. A., & Belafsky, P. C. (2017). Subjective assessment of videofluoroscopic swallow studies. *Otolaryngology—Head & Neck Surgery*, 156(5), 901–905. <https://doi.org/10.1177/0194599817691276>
- Leonard, R. (2017). Two methods for quantifying pharyngeal residue on fluoroscopic swallow studies: Reliability assessment. *Annals of Otolaryngology and Rhinology*, 4(3), 1168.
- Leonard, R. (2019). Dynamic swallow study: Objective measures and normative data in adults. In R. Leonard & K. Kendall (Eds.), *Dysphagia assessment and treatment planning: A team approach* (4th ed.). Plural.
- Leonard, R., Belafsky, P. C., & Rees, C. J. (2006). Relationship between fluoroscopic and manometric measures of pharyngeal constriction: The pharyngeal constriction ratio. *Annals of Otolaryngology & Rhinology*, 115(12), 897–901. <https://doi.org/10.1177/000348940611501207>
- Leonard, R., & Kendall, K. (Eds.). (2019). *Dysphagia assessment and treatment planning: A team approach* (4th ed.). Plural.
- Leonard, R., Kendall, K., & McKenzie, S. (2004). Structural displacements affecting pharyngeal constriction in nondysphagic elderly and nonelderly adults. *Dysphagia*, 19(2), 133–141. <https://doi.org/10.1007/s00455-003-0508-6>
- Leonard, R., Kendall, K., McKenzie, S., Gonçalves, M., & Walker, A. (2000). Structural displacements in normal swallowing: A video fluoroscopic study. *Dysphagia*, 15(3), 146–152. <https://doi.org/10.1007/s004550010017>
- Leonard, R., Rees, C., Belafsky, P., & Allen, J. (2011). Fluoroscopic surrogate for pharyngeal strength: The pharyngeal

- constriction ratio (PCR). *Dysphagia*, 26(1), 13–17. <https://doi.org/10.1007/s00455-009-9258-4>
- Logemann, J., Shaker, R., & Dodds, W.** (1994). Coordination between respiration and swallowing: Respiratory phase relationships and temporal integration. *Journal of Applied Physiology*, 76(2), 714–723. <https://doi.org/10.1152/jappl.1994.76.2.714>
- Logemann, J., Williams, R., Rademaker, A., Pauloski, B., Lazarus, C., & Cook, I.** (2005). The relationship between observations and measures of oral and pharyngeal residue from videofluorography and scintigraphy. *Dysphagia*, 20(3), 226–231. <https://doi.org/10.1007/s00455-005-0019-8>
- Martin-Harris, B., Brodsky, M., Michel, Y., Castell, D., Schleicher, M., Sandidge, J., Maxwell, R., & Blair, J.** (2008). MBS measurement tool for swallow impairment—MBSImp: Establishing a standard. *Dysphagia*, 23(4), 392–405. <https://doi.org/10.1007/s00455-008-9185-9>
- Martin-Harris, B., Carson, K. A., Pinto, J. M., & Lefton-Greif, M. A.** (2020). BaByVFSSImP. A novel measurement tool for videofluoroscopic assessment of swallowing impairment in bottle-fed babies: Establishing a standard. *Dysphagia*, 35(1), 90–98. <https://doi.org/10.1007/s00455-019-10008-x>
- Martin-Harris, B., Logemann, J. A., McMahan, S., Schleicher, M., & Sandidge, J.** (2000). Clinical utility of the modified barium swallow. *Dysphagia*, 15(3), 136–141. <https://doi.org/10.1007/s004550010015>
- Matsuo, K., & Palmer, J.** (2008). Anatomy and physiology of feeding and swallowing: Normal and abnormal. *Physical Medicine and Rehabilitation Clinics of North America*, 19(4), 691–707. <https://doi.org/10.1016/j.pmr.2008.06.001>
- McGrattan, K. E., McGhee, H. C., McKelvey, K. L., Clemmens, C. S., Hill, E. G., DeToma, A., Hill, J. G., Simmons, C. E., & Martin-Harris, B.** (2019). Capturing infant swallow impairment on videofluoroscopy: Timing matters. *Pediatric Radiology*, 50(2), 199–206. <https://doi.org/10.1007/s00247-019-04527-w>
- Molfenter, S., & Steele, C.** (2013). The relationship between residue and aspiration on the subsequent swallow: An application of the normalized residue ratio scale. *Dysphagia*, 28(4), 494–500. <https://doi.org/10.1007/s00455-013-9459-8>
- Morris, S. E.** (1990). *Issues in anatomy and physiology of swallowing: Impact on assessment and treatment of children with dysphagia*. New Visions.
- Mukaka, M.** (2012). Statistics corner: A guide to appropriate use of correlation coefficient in medical research. *The Journal of Medical Association of Malawi*, 24(3), 69–71. <https://doi.org/10.4000/books.cidehus.4589>
- Mulheren, R. W., Azola, A., & González-Fernández, M.** (2019). Do ratings of swallowing function differ by videofluoroscopic rate? An exploratory analysis in patients after acute stroke. *Archives of Physical Medicine and Rehabilitation*, 100(6), 1085–1090. <https://doi.org/10.1016/j.apmr.2018.10.015>
- Nagy, A., Molfenter, S. M., Péladeau-Pigeon, M., Stokely, S., & Steele, C. M.** (2014). The effect of bolus volume on hyoid kinematics in healthy swallowing. *BioMed Research International*, 2014, 1–6. <https://doi.org/10.1155/2014/738971>
- Newman, L., Cleveland, R., Blickman, J., Hillman, R., & Jaramillo, D.** (1991). Videofluoroscopic analysis of the infant swallow. *Investigative Radiology*, 26(10), 870–873. <https://doi.org/10.1097/00004424-199110000-00005>
- Nordin, N. A., Miles, A., & Allen, J.** (2017). Measuring competency development in objective evaluation of videofluoroscopic swallowing studies. *Dysphagia*, 32(3), 427–436. <https://doi.org/10.1007/s00455-016-9776-9>
- O'Hare, B., Nakagawa, S., & Cox, P.** (1995). The paediatric airway. *Bailliere's Clinical Anaesthesiology*, 9(2), 359–377. [https://doi.org/10.1016/S0950-3501\(95\)80010-7](https://doi.org/10.1016/S0950-3501(95)80010-7)
- Rademaker, A. W., Pauloski, B. R., Logemann, J. A., & Shanahan, T. K.** (1994). Oropharyngeal swallow efficiency as a representative measure of swallowing function. *Journal of Speech and Hearing Research*, 37(2), 314–325. <https://doi.org/10.1044/jshr.3702.314>
- Rajadhyaksha, V.** (2010). Conducting feasibilities in clinical trials: An investment to ensure a good study. *Perspectives in Clinical Research*, 1(3), 106–109.
- Revicki, D.** (2014). Internal consistency reliability. *Encyclopedia of Quality of Life and Well-Being Research*, 33.0. [https://doi.org/10.1007/978-94-007-0753-5\\_1494](https://doi.org/10.1007/978-94-007-0753-5_1494)
- Riley, A., Miles, A., & Steele, C. M.** (2018). An exploratory study of hyoid visibility, position, and swallowing-related displacement in a pediatric population. *Dysphagia*, 34(2), 248–256. <https://doi.org/10.1007/s00455-018-9942-3>
- Rommel, N., Borgers, C., Van Beckevoort, D., Goeleven, A., Dejaeger, E., & Omari, T.** (2015). Bolus residue scale: An easy-to-use and reliable videofluoroscopic analysis tool to score bolus residue in patients with dysphagia. *International Journal of Otolaryngology*, 2015, 780197–7. <https://doi.org/10.1155/2015/780197>
- Rosenbek, J. C., Robbins, J. A., Roecker, E. B., Coyle, J. L., & Wood, J. L.** (1996). A penetration–aspiration scale. *Dysphagia*, 11(2), 93–98. <https://doi.org/10.1007/BF00417897>
- Sales, A., Giacheti, C., Cola, P., & da Silva, R.** (2017). Qualitative and quantitative analysis of oropharyngeal swallowing in Down syndrome. *Codas*, 29(6). <https://doi.org/10.1590/2317-1782/20172017005>
- Schoenfeldt, L. F.** (1984). Psychometric properties of organizational research instruments. In T. S. Bateman & G. R. Ferris (Eds.), *Methods and analysis in organizational research* (pp. 68–80). Reston.
- Scott, A., Perry, A., & Bench, J.** (1998). A study of interrater reliability when using videofluoroscopy as an assessment of swallowing. *Dysphagia*, 13(4), 223–227. <https://doi.org/10.1007/PL00009576>
- Shipley, K., & McAfee, J.** (2020). Foundations of assessment. In K. Shipley & J. McAfee (Eds.), *Assessment in speech-language pathology: A resource manual* (6th ed.). Plural.
- Steele, C. M., Bailey, G. L., Chau, T., Molfenter, S. M., Oshalla, M., Waito, A. A., & Zoratto, D. C.** (2011). The relationship between hyoid and laryngeal displacement and swallowing impairment. *Clinical Otolaryngology*, 36(1), 30–36. <https://doi.org/10.1111/j.1749-4486.2010.02219.x>
- Tavakol, M., & Dennick, R.** (2011). Making sense of Cronbach's alpha. *International Journal of Medical Education*, 2, 53–55. <https://doi.org/10.5116/ijme.4dfb.8dfd>
- Tolbert, D., Janower, M. L., & Linton, O. W.** (1996). Sources of radiation exposure. In *ACR* (pp. 3–4). American College of Radiology.
- Tutor, J. D., Srinivasan, S., Gosa, M. M., Spentzas, T., & Stokes, D. C.** (2015). Pulmonary function in infants with swallowing dysfunction. *PLOS ONE*, 10(5), e0123125. <https://doi.org/10.1371/journal.pone.0123125>
- Ueda, N., Nohara, K., Kotani, Y., Tanaka, N., Okuno, K., & Sakai, T.** (2013). Effects of the bolus volume on hyoid movements in normal individuals. *Journal of Oral Rehabilitation*, 40(7), 491–499. <https://doi.org/10.1111/joor.12060>
- von Ungern-Sternberg, B.** (2014). Respiratory complications in the pediatric postanesthesia care unit. *Anesthesiology Clinics*, 32(1), 45–61. <https://doi.org/10.1016/j.anclin.2013.10.004>
- Weckmueller, J., Easterling, C., & Arvedson, J.** (2011). Preliminary temporal measurement analysis of normal oropharyngeal swallowing in infants and young children. *Dysphagia*, 26(2), 135–143. <https://doi.org/10.1007/s00455-010-9283-3>

Weir, K., McMahon, S., Long, G., Bunch, J., Pandeya, N., Coakley, K., & Chang, A. (2007). Radiation doses to children during modified barium swallow studies. *Pediatric Radiology*, 37(3), 283–290. <https://doi.org/10.1007/s00247-006-0397-6>

Yip, H., Leonard, R., & Belafsky, P. C. (2006). Can a fluoroscopic estimation of pharyngeal constriction predict aspiration? *Otolaryngology—Head & Neck Surgery*, 135(2), 215–217. <https://doi.org/10.1016/j.otohns.2006.03.016>

## Appendix A

### Descriptive Statistics

Objective measure	<i>M</i>		<i>SD</i>		Minimum		Maximum	
	Bottle-fed	Cup	Bottle-fed	Cup	Bottle-fed	Cup	Bottle-fed	Cup
Timing (s)								
TPT	1.283	1.246	1.006	1.106	0.0200	0.240	8.160	10.500
Airwaycl	0.110	0.126	0.986	0.153	0.0200	0	0.900	1.500
ACD	—	0.476	—	0.224	—	−0.030	—	1.870
PESdur	0.381	0.405	0.214	0.159	0.040	0.020	2.000	1.867
BP1AEcl	0.065	0.067	0.410	0.588	−0.840	−0.600	4.400	9.467
STD	—	−0.479	—	1.077	—	−0.960	—	0.020
LE	—	−0.119	—	0.175	—	−0.120	—	0.240
Hdur	—	0.302	—	0.128	—	9.9	—	0.640
Hm	—	0.063	—	0.078	—	0.001	—	0.060
VCD	0.215	0.196	0.138	0.149	0.030	0	1.000	1.500
Suck time	0.568	—	0.254	—	0.06	—	1.34	—
T-SP	0.146	—	0.122	—	0.03	—	0.7	—
Displacement								
PCR	0.214	0.192	0.199	0.190	0	0	0.986	0.998
BCR	0.026	0.036	0.115	0.143	0	0	0.728	0.973
PESmax (cm)	0.440	0.545	0.206	0.244	0.011	0.118	1.415	1.641
Hmax (cm)	—	1.134	—	0.718	—	0.12	—	3.886
HL (cm)	—	0.495	—	0.242	—	0.011	—	1.618

Note. Em dashes indicate data not completed. TPT = total pharyngeal transit time; Airwaycl = time to airway closure; ACD = airway closure duration; PESdur = pharyngoesophageal segment opening duration; BP1AEcl = coordination of airway closure with bolus transit; STD = stage transition duration; LE = laryngeal elevation; Hdur = duration to hyoid maximum elevation; Hm = duration of maximum hyoid displacement; VCD = duration of velopharyngeal closure; T-SP = tongue and soft palate cycle; PCR = pharyngeal constriction ratio; BCR = bolus clearance ratio; PESmax = pharyngoesophageal segment maximum opening; Hmax = maximum elevation of hyoid bone; HL = maximum approximation of the hyoid and larynx.

## Appendix B

### Interitem Correlations Between Timing and Displacement Swallow Measures

Measure		<i>r</i> (Pearson correlation)	<i>p</i>
PESdur	BCR	-.100	.023
	HPT	.183	< .001
	TPT	.101	.022
	PESmax	.280	< .001
	VCD	.105	.018
Airwaycl	Hdur	.194	.004
	BRS	.144	.001
	Hm	.174	.010
	HPT	.188	< .001
	TPT	.176	< .001
	BP1AEcl	.197	< .001
	STD	-.148	.029
	ACD	-.231	< .001
	VCD	.399	< .001
	Hdur	.476	< .001
OPT	Hm	.155	.022
	PESmax	-.116	.015
	STD	-.305	< .001
HPT	ACD	-.330	< .001
	VCD	.110	.013
TPT	Hdur	.168	.013
	BCR	.174	< .001
HL	BRS	.196	< .001
	BP1AEcl	.451	< .001
	STD	-.683	< .001
	ACD	-.621	< .001
	Hdur	.187	.005
PESmax	Hm	-.267	.002
	Hdur	-.238	.007
PCR	BCR	-.109	.023
	PAs	.386	< .001
	VCD	.135	.005
STD	BCR	.219	< .001
	BRS	.220	< .001
	PAMax	.626	< .001
	BCR	-.263	< .001
LE	BRS	-.244	< .001
	LE	.148	.029
	ACD	.974	< .001
	BCR	-.139	.039
ACD	Hm	.201	.003
	Hdur	.169	.012
	BCR	-.153	.001
	BRS	-.180	< .001
VCD	VCD	-.099	.026
	Hdur	-.165	.015
	Hm	.182	.007
Hdur	Hdur	.416	< .001
	Hm	.503	< .001

*Note.* Degree of freedom is 552 ( $n - 1$ ). PESdur = pharyngoesophageal segment opening duration; BCR = bolus clearance ratio; HPT = hypopharyngeal transit time; TPT = total pharyngeal transit time; PESmax = pharyngoesophageal segment maximum opening; VCD = duration of velopharyngeal closure; Hdur = duration to hyoid maximum elevation; Airwaycl = time to airway closure; BRS = bolus residue scale; Hm = duration of maximum hyoid displacement; OPT = oropharyngeal transit time; BP1AEcl = coordination of airway closure with bolus transit; STD = stage transition duration; ACD = airway closure duration; HL = maximum approximation of the hyoid and larynx; PAs = pharyngeal area at rest; PCR = pharyngeal constriction ratio; PAMax = pharyngeal area at maximum constriction; LE = laryngeal elevation.

## Appendix C

Range and Cost of Instruments Available for Quantitative Videofluoroscopic Swallow Study (VFSS) Analysis, Sourced July 2021

Instrument/equipment	Purpose	Approximate price (USD)	Source
Radiology setup			
Equipped videofluoroscopic suite, including fluoroscopic machine, camera, and recording	For radiographic visualization or oral, pharyngeal, and esophageal phases of swallowing	600,545 <sup>a</sup> excluding room hire and personnel	American College of Radiology
Protective equipment package for personnel	Lead aprons, gloves, goggles, screen for administration procedures	500	American College of Radiology
Videofluoroscopy viewing			
PACS professional workstation	Data archiving and reviewing system	15,255	American College of Radiology
TIMS workstation	Recording and reviewing VFSS data Has in-built timing and displacement measurement tools	22,000–26,000	<a href="https://inline.com.au/shop/medical/software-archiving/tims-recording-editing-solution-msa/">https://inline.com.au/shop/medical/software-archiving/tims-recording-editing-solution-msa/</a>
PharyDoc workstation <sup>b</sup>	Recording and reviewing VFSS data Including in-built timing and displacement measurement tools	35,500–39,500	<a href="https://www.bildtechnik.com/pharydoc/">https://www.bildtechnik.com/pharydoc/</a>
Objective timing and displacement measurement equipment			
ImageJ	Allows line measurements for displacement swallow measures	Free	Download at <a href="https://imagej.nih.gov/ij/docs/install/index.html">https://imagej.nih.gov/ij/docs/install/index.html</a>
Universal desktop ruler (Universal On-Screen Digitizer)	Allows line measurements for displacement swallow measures	24	Purchase at <a href="https://avpsoft.com/products/udruler/">https://avpsoft.com/products/udruler/</a>
Swallowtail	Specialized software for objective VFSS analysis	1200 <sup>c</sup>	<a href="http://www.belldevmedical.com/swallowtail#TOC-WHAT-IS-SWALLOWTAIL-">http://www.belldevmedical.com/swallowtail#TOC-WHAT-IS-SWALLOWTAIL-</a>
Quintic biomechanics software	Analyzes timing measures of swallowing	390–4,550	<a href="https://www.quinticsports.com/">https://www.quinticsports.com/</a>
Horita VS-50 Video Stopwatch	Online time display for timing measures of swallowing that can be attached to the recording equipment in the radiology suite	650–750	<a href="https://horita.com/vs-50">https://horita.com/vs-50</a>

<sup>a</sup>Annual subscription for research use and clinical use (only in New Zealand and Australia). <sup>b</sup>Clinically used in Sweden and Middle Eastern countries. <sup>c</sup>May need to replace after 8–10 years.



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**Appendix D** (p. 1 of 4)

Manual for Obtaining Objective Quantitative Swallow Measures

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All operational definitions are as described by Leonard (2019).

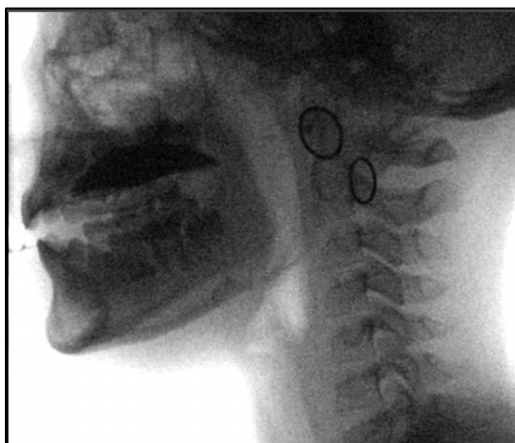
**Total pharyngeal transit time (TPT)**

**Instructional video demonstrating TPT in an 8-year-old child in Quintic, Swallowtail, and TIMS** <https://youtu.be/OJusaNdSDEg>

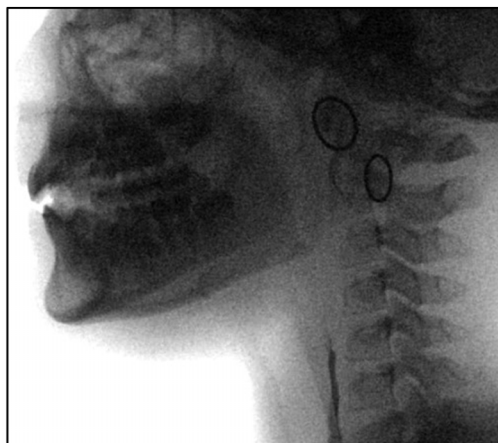
**Instructions:**

- Select the frame in which the bolus head passes the posterior nasal spine (B1) and mark the time.
- Move the video forward and select the frame in which the bolus tail clears the pharyngoesophageal segment (PES) completely (BP2) to mark the time.
- Calculate the time difference between B1 and BP2, which is the total pharyngeal transit time (TPT).

*Note.* In case of premature spillage, still use it to mark B1.



Bolus head passing posterior nasal spine (B1)



Bolus tail clearing the PES (BP2)

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**Appendix D** (p. 2 of 4)

Manual for Obtaining Objective Quantitative Swallow Measures

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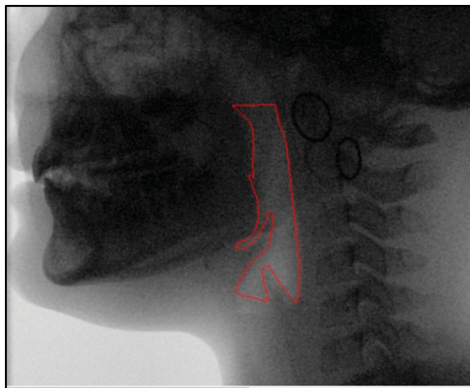
**Pharyngeal constriction ratio (PCR)**

**Instructional video demonstrating PCR in an infant using universal desktop ruler:** <https://youtu.be/IWssICKISFc>

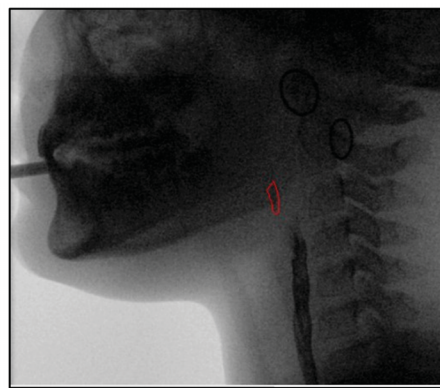
**Instructions:**

- Select a frame when the pharynx is wholly relaxed at rest or when a 1-cc bolus is held in the oral cavity.
- Measure the pharyngeal area of this frame (PA<sub>hold</sub>).
- Move forward and observe pharyngeal constriction during the swallow.
- Select the frame in which the pharynx is maximally constricted in order to push the bolus down. Move the frames back and forth to compare the pharyngeal relaxation.
- Measure the area of the pharynx, including pharyngeal bolus residue, in its maximally constricted position (PA<sub>max</sub>).
- Calculate PCR = PA<sub>max</sub> / PA<sub>hold</sub>.

*Note.* When there is no bolus residue/air cavity in the frame of maximum pharyngeal constriction, the pharyngeal area is considered “0” in the calculation.



Pharyngeal area at rest



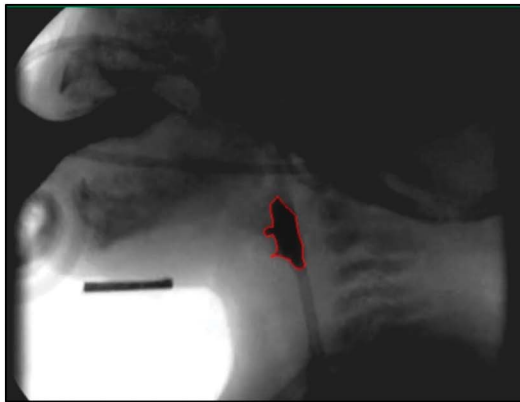
Pharyngeal area at maximum constriction

**Bolus clearance ratio (BCR)**

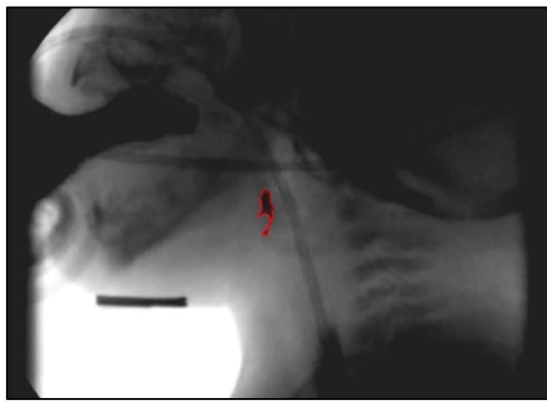
**Instructions:**

- Select the frame just before the PES opening for bolus entrance.
- Measure the bolus area in that frame (bolus area preswallow).
- Move the frames forward to select the frame just before the PES closure after the swallow.
- Measure the bolus area in that frame (bolus area postswallow).
- Calculate the BCR using the two area measures,  $BCR = \text{bolus area postswallow} / \text{bolus area preswallow}$ .

*Note.* When there is no bolus residue after a swallow, the bolus area is considered “0” in the calculation.



Bolus area preswallow



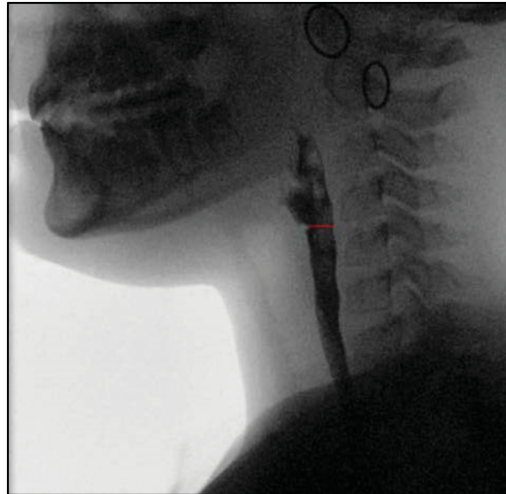
Bolus area postswallow

**Maximum opening of PES during a swallow (PESmax)**

**Instructional video demonstrating PESMax in an infant using universal desktop ruler:** <https://youtu.be/lfjhtB7v6QA>

**Instructions:**

- PES is defined as the narrowest point in the opening between C3 and C6 (commonly C4–C6) when the PES is maximally distended during the swallow.
- Move the bolus forward to identify the frame in which the PES achieves its maximum displacement.
- Measure the distance between the anterior and posterior borders of the lumen, not the tissue area.
- Measurement should be taken perpendicular to the bolus flow. This distance is PESmax.



Maximum opening of the PES during a swallow (PESmax)

**Coordination of airway closure with bolus transit (BP1AEcl)**

**Instructional video demonstrating BP1AEcl in 4-yr-old child:**

In Swallowtail <https://youtu.be/6UkxQzelNtM>

**Instructions:**

- Identify the frame in which the bolus enters the PES and mark the timing (BP1).
- Select the first frame in which arytenoids and epiglottis close the supraglottic airway and mark the timing (AEcl).
- BP1AEcl = BP1 – AEcl.

**Reference**

**Leonard, R.** (2019). Dynamic swallow study: Objective measures and normative data in adults. In R. Leonard & K. Kendall (Eds.), *Dysphagia assessment and treatment planning: A team approach* (4th ed.). Plural.

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