Research Article

Real-Time Analyses of Sucking Waveforms to Drive Oral Feeding Practice and Improve Patient Care Outcomes

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Abstract

Objective measurement of nutritive sucking could improve outcomes for preterm and sick term infants experiencing difficulty with oral feeding. Using a matched case series design, an oral feeding quality improvement project was initiated in a Level IV Neonatal Intensive Care Unit (NICU). Participants included a heterogenous group of infants matched for gestational age, diagnoses and comorbidities. Infants in the control group received standard of care for oral feeding transition and infants in the experimental group received standard of care plus nfant® Feeding Solution; a technology that captured and displayed the sucking signal in real-time. Infants in the experimental group achieved full oral feeding 1-week sooner, had an overall feeding stay of 11 days shorter and were discharged 3 days earlier, compared to matched controls. Biofeedback of the infant sucking signal may moderate variability in feeding care practice, lessening the time to full oral feeding and reducing length of stay.

Keywords: Dysphagia; Neonatal neuromotor behavior; Neonatal feeding; Nutritive sucking; Technology-aided assessment

Introduction

Safe and efficient oral feeding is an important achievement for full term and preterm infants and one criterion for hospital discharge set by the American Academy of Pediatrics [1]. Oral feeding requires precise coordination of sucking, swallowing and breathing [2] involving multiple sensory-motor systems [3]. Published work focused on quantifying the physiological signal of sucking first appeared in 1865 when Herz measured negative intraoral pressure using a mercury manometer attached to a nipple [4]. Since then, interest in studying infant nutritive sucking has crossed multiple disciplines to enhance our understanding of personality formation [4], maturation of sucking skills [5], the role of sucking in early infant weight gain [6] and sucking as a biomarker for neonatal brain injury [7].

Work in our lab has focused on capturing the physiological signal of sucking as a way to better understand the challenges facing infants in the Neonatal Intensive Care Unit (NICU) who exhibit difficulty transitioning to oral feeding. Research has shown that 40-70% of infants in the NICU exhibit both immature and atypical feeding ability. Infants requiring respiratory support [8] and those whose comorbidities delay the beginning of oral feeding are most often affected [9]. Additionally, recent research has demonstrated that poor oral feeding is the most common barrier to discharge for even moderately preterm infants [10]. As a result, a substantial number of preterm infants and sick term infants demonstrate feeding difficulties after leaving the hospital [11] and are at greater risk of rehospitalization as compared to healthy term infants [12]. An estimated 16% of rehospitalizations are attributable solely to oral feeding difficulty [13]. Accurate and reliable measurements of the physiological signal of nutritive sucking have the potential to reduce the time to transition to oral feeding and improve feeding outcomes for fragile infants.

Our methods for capturing the physiological signal of sucking represent a departure from measurement of intraoral pressures as a proxy for sucking ability and focus instead on the

role of the lingual musculature in driving safe and efficient oral feeding. Our approach is grounded in animal models of muscle disuse atrophy documenting multiple changes in tongue musculature of dam reared versus intravenously fed rat pups from the same litter [14-17]. IV fed rat pups had significantly fewer tongue muscle fibers, smaller muscle fibers and fewer motoneurons driving the muscle. Researchers speculated the same thing might be happening with preterm or sick term infants are non-orally fed for an extended period of time.

In human infants, the tongue contributes significantly to the coordinative actions that occur during the oral and pharyngeal phases of the swallow (Figure 1) [18,19]. During the oral phase, the tongue drives the necessary nipple compression, expression of fluid and transport of the fluid toward the valleculae to initiate the swallow [18]. The pharyngeal phase involves propulsion of fluid via the posterior tongue and the contraction of the pharyngeal constructor muscle [20]. To investigate the role of the lingual musculature in driving safe and efficient oral feeding, we developed noninvasive instrumentation using sonomicrometry [21]. A standard pacifier and flow through nipple were instrumented with piezoelectric crystals strategically located to enable direct measurement of nipple deformation kinematics in response to forces of the tongue. Controlling for weight and post menstrual age, we found a statistically significant difference in tongue force during nutritive sucking and a clinically significant difference in posterior tongue thickness between full term and preterm infants beginning oral feeding. Full term infants demonstrated greater tongue force and greater posterior tongue thickness as compared to healthy preterm infants [21,22].
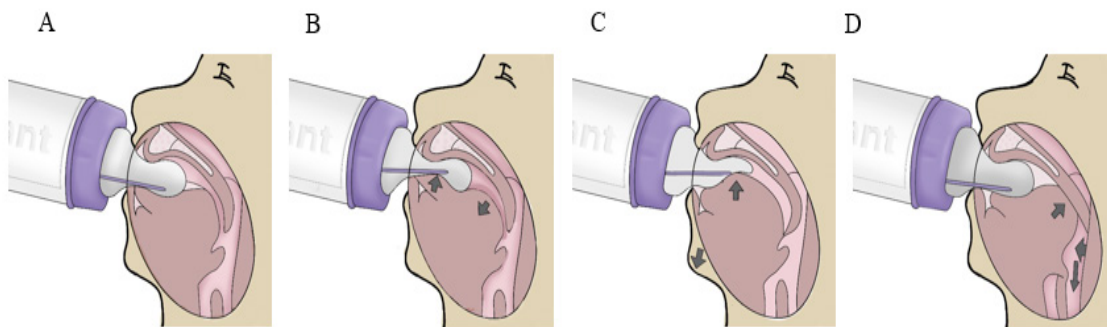
Figure 1: Role of the lingula musculature in safe and efficient sucking and swallowing. The nipple rests on the anterior portion of the tongue (A) followed by compression of the nipple via forces of the tongue against the palate (B). While the mid portion of the tongue maintains contact with the palate, the jaw simultaneous drops to create negative intraoral pressure which permits expression of fluid from the nipple (C). Finally, the fluid is carried via the tongue and is propelled to the posterior pharyngal wall to initiate the swallow (D). The lips maintain a seal around the nipple throughout.

The use of sonomicrometry for capturing the sucking signal required multiple people at bedside and a cumbersome amount of computer equipment. The unsustainability of this approach for ongoing study prompted development of methods with a smaller NICU footprint and easily incorporated into routine clinical care. The result was nfant® Feeding Solution (nFS; NFANT Labs, Marietta GA, USA), a patented, noninvasive device for quantifying neonatal and infant sucking signals and cleared by the FDA for use in the NICU. We have demonstrated the utility of our approach for characterizing sucking ability between full-term and preterm infants at hospital discharge [23] and as a method for quantifying the impact of feeding interventions on nutritive sucking performance [24]. The technology has also been used successfully by independent researchers interested in the feeding performance of specific neonatal populations such as: infants with Neonatal Abstinence Syndrome, micropremies, infants with neonatal brain injury and infants pre- and post- tethered tissue release. The use of the system is contraindicated for infant populations with congenital oral abnormalities such as cleft lip and cleft palate as the ability to create both negative and positive intraoral pressure is required to produce the waveform data and ensuing metrics.

Objective

The aim of the current manuscript is to: (1) provide a description of the instrumentation we have developed for capturing the sucking signal during actual liquid swallow; and (2) report how this signal can be used clinically to drive oral feeding care practice for preterm and sick term infants that decreases the time to transition to oral feeding and, consequently, reduces hospital length of stay.

Methods and Materials

The Quality Improvement (QI) project was performed using a matched case series design involving a heterogenous

group of infants matched for gestational age, diagnoses and comorbidities. Infants were receiving care in a Level IV Neonatal Intensive Care Unit (NICU). The QI project was approved by the NICU Medical Director, the NICU Nursing Director and the Inpatient Rehabilitation Director. To be included in the QI project, participants met the following criteria: (1) > 32 weeks Post Menstrual Age (PMA); (2) demonstrated autonomic stability; (3) on room air, or high-flow nasal cannula (or Nasal Cannula), 2 L or less; and (4) exhibited feeding readiness behaviors. Once criteria were met, infants were included in the QI project on a rolling basis.

Mothers had the option to breastfeed or gavage feed for the first 72 hours. If mothers were not present and if their infants were demonstrating cueing behaviors during the 72 hours of breastfeeding or gavage feeds, the infants were presented with a pacifier dipped in expressed breastmilk (Control Group) or the nfant No Flow nipple attached to a volufeeder filled with warm water to simulate the sensation of expressed breastmilk (Experimental Group). Unit therapists (PTs, OTs & SLPs) and nurses were trained per the QI protocol prior to initiating the QI project.

Participants included micropremies (N = 12), late and moderate preterm infants (N = 4), term infants with hypoxic ischemic encephalopathy, post cooling protocol (N = 2) and term infants with Down syndrome (N = 2) (Table 1). Infants in the control group (CG; N = 10) received the unit's current gold standard of care for feeding transition in the NICU (SOC): Infant Driven Feeding® [25-27]. In this approach, feeding specialists and nurses are systematically trained to the interpret infant physiological responses and behavioral distress responses during oral feeding as a way of assessing infant stability and instability. When signs of instability are observed, the feeder hypothesizes how best to optimize feeding and help the infant regain stability. The readiness of the infant to initiate and maintain the feeding are also monitored and scored in this approach along with the quality of the feeding and any interventions that were used. Common interventions include providing rest breaks, pacing the number of sucks per burst, altering the flow rate of the bottle nipple and altering the feeding position [28]. The experimental group (NFS; N = 10) received the unit's SOC + nfant® Feeding Solution (NFANT Labs LLC, Marietta, GA) which provided objective sucking signal data in real-time. The primary outcome measures of interest were days to reach full oral feeding and hospital length of stay.

	NFS	CG
	AP	LJ
Gender	F	M
GA at Birth (Weeks)	22.2	23.3
PMA (Weeks) @ 1st Oral Feeding	36.4	34.6
PMA (Weeks) @ Full Oral Feeding	42.4	41.4

PMA (weeks) at Discharge	43.2	42.5
	CA	SD
Gender	M	M
GA at Birth (Weeks)	23.5	23.3
PMA (Weeks) @ 1st Oral Feeding	34.5	35.2
PMA (Weeks) @ Full Oral Feeding	40.6	42.1
PMA (Weeks) at Discharge	41.3	42.3
	ML	DC
Gender	F	M
GA at Birth (Weeks)	24.1	26.4
PMA (Weeks) @ 1st Oral Feeding	39.3	39.4
PMA (Weeks) @ Full Oral Feeding	45.6	44.6
PMA (Weeks) at Discharge	46.6	45.1
	RH	HE
Gender	F	M
GA at Birth (Weeks)	24.5	26.5
PMA (Weeks) @ 1st Oral Feeding	41.2	34
PMA (Weeks) @ Full Oral Feeding	43.4	36.6
PMA (Weeks) at Discharge	44.4	37.1
	KaA	HG
Gender	F	M
GA at Birth (Weeks)	27.7	27.6
PMA Weeks) @ 1st Oral Feeding	33.3	33
PMA (Weeks) @ Full Oral Feeding	35.4	38.2
PMA (Weeks) at Discharge	35.6	38.5
	KeA	SN
Gender	M	M
GA at Birth (Weeks)	27.6	28
PMA (Weeks) @ 1st Oral Feeding	33.3	36.1
PMA (Weeks) @ Full Oral Feeding	36.6	40.3
PMA (Weeks) at Discharge	37.3	40.5
	DD	DG
Gender	M	F
GA at Birth (Weeks)	32.6	32.5
PMA (Weeks) @ 1st Oral Feeding	33.6	34.1
PMA (Weeks) @ Full Oral Feeding	36.5	38.4
PMA (Weeks) at Discharge	37	38.4
	RV	BD
Gender	F	M
GA at Birth (Weeks)	36.1	36.3
PMA (Weeks) @ 1st Oral Feeding	36.6	36.6
PMA (Weeks) @ Full Oral Feeding	38.5	39.3

PMA (Weeks) at Discharge	39	39.5
	EC*	HB*
Gender	F	M
GA at Birth (Weeks)	38.6	38.1
PMA (Weeks) @ 1st Oral Feeding	38.6	38.6
PMA (Weeks) @ Full Oral Feeding	40.3	47.6
PMA (Weeks) at Discharge	40.5	48.4
	AnP^	MF^
Gender	M	M
GA at Birth (Weeks)	39.5	38.6
PMA (Weeks) @ 1st Oral Feeding	40.3	39.6
PMA (Weeks) @ Full Oral Feeding	41.2	41.6
PMA (Weeks) at Discharge	41.4	42.2

Table 1: Description of the population.

Nfant® Feeding Solution (nFS) is a noninvasive, patented and FDA cleared Class II medical device that measures tongue movement on a nipple during nonnutritive (NNS; pacifier) and nutritive (NS; liquid intake) sucking. nFS consists of an a disposable nfant Coupling (A) that connects a standard bottle (B) to a standard nipple (C) (Figure 2). The coupling houses a cantilever mechanism for measuring tongue movement on the nipple. The nfant Sensor (D) connects to the coupling and wirelessly transmits real-time data on nipple movement to a tablet via the nfant Mobile App (E). nFS addresses a significant limitation of subjective observation alone, as the real-time feedback of the sucking waveform allows the healthcare team to see the immediate impact of an intervention on the sucking signal [29]. Following a feeding, waveforms of NNS and NS nipple movement are transmitted to the HIPAA protected nfant Cloud Database and the signals converted via custom algorithms to identify key features and measures that describe sucking performance [30]. We define a sucking burst as a minimum of three sequential sucking events with intervals < 2 seconds [31]. Suck amplitude is defined as the displacement of the nipple during the compression phase of a single suck, normalized to the maximum observed peak during the entire feeding (0% to 100%). Suck duration is the time, in seconds, from the onset of the suck to the end of the suck and frequency is the rate, in Hertz, of consecutive sucks.
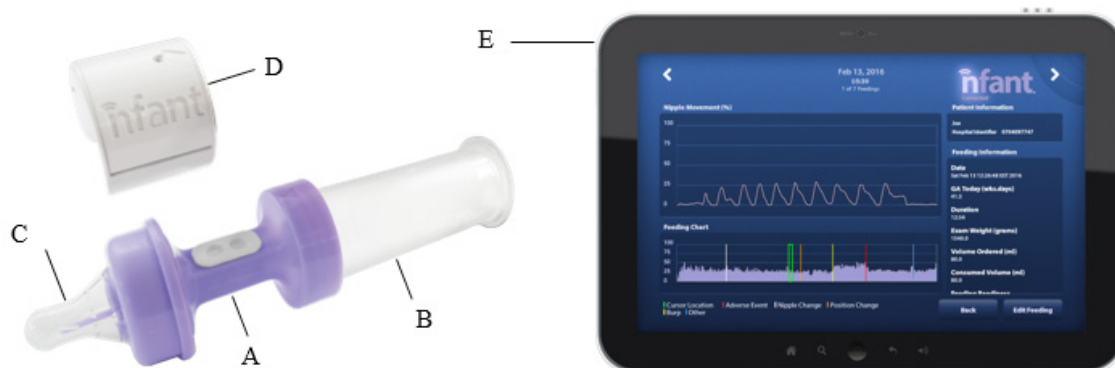
Figure 2: nfantÒ Feeding Solution consists of an a disposable nfant Coupling (A) that connects a standard bottle (B) to a standard nipple (C). The coupling houses a cantilever mechanism for measuring tongue movement on the nipple. The nfant Sensor (D) connects to the coupling and wirelessly transmits real-time data on nipple movement to a tablet via the nfant Mobile App (E).

Movement smoothness was quantified by noting the number of changes in the speed profile (accelerations and decelerations) of the movement. In the case of the sucking signal, smoothness is conceptualized as the number of velocity changes one would expect to see with skilled sucking: (1) compression of the nipple, (2) expression of the fluid and (3) propulsion of the fluid to the posterior pharyngeal wall for swallow initiation.

All infants entering the protocol received family-centered care; unit nurses and clinicians worked with parents to teach them swaddled bathing, infant massage and range of motion and strengthening exercises. The QI population also received prefeeding oral stimulation per unit protocol including stroking perioral and intraoral structures in specific ways with a gloved finger and stroking the cheeks [32,33]. The method of oral stimulation was contingent on the infant's autonomic stability at any given time. Additionally, for the experimental group, QI project personnel used nfant Analytics related to suck amplitude, duration, frequency and smoothness to determine when to transition from NNS to NS and how best to advance the transition to full oral feeding For example, using our metrics, the team differentiated sucking patterns as coordinated, disorganized or dysfunctional to assist in the determination of dysphagia, the need for prophylactic

fluid thickening or referral for instrumental swallow assessment (i.e., videofluoroscopy). With respect to the control group, these decisions were made subjectively via visual observation alone.

Infants in both groups were seen by the feeding specialists a minimum of 2 times weekly and up to 5 times weekly, based on the unit's feeding pathway and at the discretion of the healthcare team. Breastfeeding was never preempted for the collection of data. The feeding specialists were also available on weekends to come in and see infants who, according to progression on the feeding pathway, continued to demonstrate difficulty transitioning to oral feeding.

Results and Discussion

The primary aim of this QI project was to determine whether the addition of objective measures of the physiological sucking signal would result in reducing the time to full oral feeding as well as hospital length of stay for preterm and sick terms infants in a Level IV NICU. A Wilcoxon Signed-Rank test (one-tailed; significance set at <.05) was used to compare days to full oral feeding and hospital length of stay between groups. Length of feeding transition (number of days to full oral feeds) for the NFS group was shorter than matched controls by eleven days and this difference was statistically significant (p <.05). Infants in the nFS group had a reduced hospital length of stay of three days, on average. This difference was not statistically significant (p = .30); however, the economic impact and psychosocial advantages would be considered clinically important. As would be expected in a matched pairs design, analysis of variance indicated no significant differences between groups with respect to gestational age at birth (p = .882) or post menstrual age at 1st oral feeding (p = .632). Additionally, there was no statistically significant difference between groups with respect to post menstrual age at full oral feeding (p = .521) or post-menstrual age at discharge (p = .603). However, of clinical importance was the finding that infants in the NFS group reached full oral feeding at a younger age by 1 week, as compared to matched controls.

The current gold standard for determining adequate tongue strength and coordination for oral feeding is via subjective visual feedback of the oral facial musculature, along with tactile feedback of rhythmicity and direction of tongue movement using a gloved finger [34]. The validity of these subjective measures has been called into question by a number of researchers [35,36]. Moreover, as with any subjective assessment, the quality of the assessment is highly dependent on the level of education and personal experience of the assessor. Consequently, the need for a simple tool that provides objective fundamental measures of the sucking signal is necessary to advance the field of neonatal oral feeding and improve outcomes [5,18,19].

Historically, instruments that collect sucking data have routinely collected the data for analyses off-line [2,37]. Such an approach eliminates the ability to interpret the sucking signal during actual liquid intake. Our method for capturing the sucking signal allows the clinical team to interpret the nature of the sucking signal in real time, and, when appropriate, provide interventions that could improve sucking performance [38]. Moreover, the efficacy of an intervention can also be observed in real-time and objectively measured. The ability to review a feeding and document events important to care (e.g., nipple flow rate, feeder, stress cues, interventions) contributes significantly to collaborative care practice and reduces variability in feeding care; two factors which we believe contributed to the positive feeding outcomes observed for the NFS group as compared to controls.

Safe, efficient oral feeding is a motor skill; and like other motor skills, it is dependent on CNS maturation and learning [39]. Researchers have shown that a reduction in errors in the early stages of motor learning results in motor skills that are stable against physiological fatigue, are retained longer and result in better performance [40]. The concept of 'errorless learning' has particular importance for the development of oral feeding skill as a single adverse event (i.e., liquid aspiration, apnea, & bradycardia) can lead to a long-term feeding aversion [41]. Consequently, the more consistent and supportive the feeding experience is for the infant early on, the fewer 'errors' or adverse events the baby will experience. For the NFS group, it is possible that the ability to measure the physiological sucking signal at cribside informed the optimal way(s) to support the infants' feeding skill development which resulted in accelerated learning and consequently, reduced time to reach full oral feeding and an earlier hospital discharge.

Conclusion

Safe and efficient infant feeding is complex and requires integration of physiological function and neurobehavioral ability. Results suggest that measurement and display of the sucking signal in real-time provides objective information that can be used to guide bedside care, help avoid feeding complications and navigate infants to earlier full oral feeds and safer hospital discharge. The findings from the QI project are encouraging but there were limitations. The sample size was relatively small; however, the heterogeneity of the population suggests that the addition of objective measures of the sucking signal can improve feeding outcomes for a number of different infant populations commonly admitted to the NICU. Results reflect the real-world capabilities of measuring the physiological sucking signal to determine impact on clinical outcomes. Given these findings, the unit is navigating toward the incorporation of these objective measures as standard of care for all infants admitted to the NICU.

Acknowledgement

Conflict of Interest

The first and second authors have a financial interest in NFANT Labs, LLC. The 3rd and 4th authors have no financial, commercial or other relationships that could be construed as a potential conflict of interest.

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