Early Feeding Skills Assessment in Preterm Infants

BY

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ABSTRACT

The objective of this study was to examine oral feeding skill attainment among four different preterm infant groups within the neonatal intensive care unit (NICU) using the Early Feeding Skills (EFS) assessment checklist. The newborn groups included preterm infants with respiratory distress syndrome (RDS) or chronic lung disease (CLD), preterm infants of diabetic mothers (IDM), and healthy preterm controls (HI), randomized to a pacifier (SHAM) or pulsatile orocutaneous (PULSED) condition during gavage feeds. Differences in suck-swallow-breathe patterns revealed by the EFS assessment tool were analyzed using mixed modeling and linear regression techniques as a function of orosensory condition. Significant changes in EFS score, adjusted for gestational age and birthweight, were found for EFS days and preterm group. No treatment effect was observed in the EFS score. In general, sicker preterm infants (e.g., RDS, CLD) manifest lower EFS scores as a function of post-menstrual age.

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Introduction/Aim:

For infants born preterm, one of the greatest concerns for discharge from the NICU to the home is the maturation of oral feeding skills. The risk for developing feeding complications in preterm infancy is high due to weak oral and laryngeal musculature needed for suck and safe swallow, as well as immature neural substrate to coordinate the suck-swallow-breathe (Gewolb, Vice, Schweitzer-Kenney, Taciak, & Bosma, 2001b; Amaizu, Schulman, Schanler, & Lau, 2008; Barlow, 2009; Goldfield, Buonomo, Fletcher, Perez, Margetts, Hansen, Smith, Ringer, Richardson, & Wolff, 2010). Medical diagnoses such as chronic lung disease (CLD) and respiratory distress syndrome (RDS) exacerbate feeding problems due to an underdeveloped or damaged respiratory system. The preterm infant of a diabetic mother (IDM) is often born with macrosomia and is at higher risk for hypoglycemia, hypocalcemia, hyperbilirubinemia, RDS, congenital anomalies, cardiomyopathy, and postnatal problems later in life such as late childhood and/or adult obesity and poor neurological development (Nold & Georfieff, 2004; Weindling, 2009). These infants appear to be 'large' but also somewhat lethargic when it comes to early neonatal oromotor skills such as sucking and feeding (deRegnier, Long, Georgieff, & Nelson, 2007). This delay often results in IDM infants remaining in the NICU for extended periods until they achieve these life-essential skills (Weindling, 2009). Therefore, it appears that this group would derive significant benefit from assessment of their sucking and feeding skills. Without adequate oral feeding skills during infancy, overall nutritional status and growth can be negatively affected with the possibility for disordered feeding to continue through the transition into solid feeding. A longitudinal study found that preterm infants at a corrected age of 24 months had significantly lower weight, length, and head circumference, along with significantly delayed attainment of motor milestones, such as use of feeding utensils and walking (Bucher, Killer, Ochsner, Vaihinger, & Fauchére, 2002). It has been estimated that more than 40% of patients treated for feeding disorders later in life were born preterm (Lau, 2006).

The cost of treating feeding disorders in infancy has become an even greater concern in recent years due to the rise in premature births since 2000. In 2010, 12% (478,790) of infants were born preterm in the United States (March of Dimes, 2013). The average cost of preterm birth in 2005 was estimated to be $32,325 per preterm infant, which was ten times the average cost of a term birth in 2005 ($3,325) (March of Dimes, 2013). For extremely low birthweight preterm infants (<1000g, and typically born <27 weeks gestation), the costs of hospitalization in the NICU can approach $1 million since these infants often sustain insults to their nervous system and present complex feeding disorders. Depending upon insurance coverage and parental salary, the cost of having a preterm infant with additional feeding concerns can cause extreme financial and care burdens for the family of that infant.

The evaluation of oral feeding skills aids the clinician in assigning a prognosis of oral feeding outcomes in preterm infants, especially high-risk populations diagnosed with RDS, IDM, or CLD. While knowledge regarding suck-swallow-breathe patterns among healthy term and preterm infants has been well developed in the literature, less is known regarding developmental trajectories within special populations. Therefore, the objective of this study focuses on using the Early Feeding Skills (EFS) assessment tool to map the developmental differences in suck-swallow-breathe as perceived by the neonatal nurse among RDS, CLD, IDM, and healthy preterm controls. Differences in suck-swallow-breathe patterns revealed by the EFS assessment tool will also be analyzed as a function of oral somatosensory stimulation, *SHAM* pacifier versus pulsatile orocutaneous stimulation via the NTrainer System® (Innara Health, Inc., Shawnee, KS).

Background:

Anatomy of the suck and swallow. Swallowing in infants is an extremely complex sensorimotor behavior involving the sequenced and coordinated activity of the oral, pharyngeal, and esophageal phases. During the oral phase of swallowing, the infant lowers the jaw to open the oral cavity and a latch is created onto a nipple, either bottle or breast. A pressure gradient is then created by approximation of the base of the tongue to the soft palate, referred to as the lingual-palatal seal (Goldfield et al., 2010; Miller, Sonies, & Macedonia, 2003). In addition, an infant's tongue fills the majority of the oral cavity, an efficient anatomy for generating positive and negative pressures needed for sucking (Geddes, Kent, Mitoulas, & Hartmann, 2008). During sucking, anterior-posterior movement of the tongue decreases oral cavity pressure, which in turn draws nutrient from the nipple. The lingual-palatal seal then allows the liquid bolus to pool in the posterior oropharynx without risk of early spillage (Goldfield et al., 2010; Geddes et al., 2008).

With a large enough bolus, stimulation of the surrounding pharynx triggers the pharyngeal swallow. Stimulation of mechano-, chemo-, and thermoreceptors generates afferent activity in the oropharynx, which is transmitted to primary sensory relay nuclei and central pattern generators (CPGs) in the brainstem (da Costa, van den Engel-Hoek, & Bos, 2008; Barlow, 2009; Jadcherla, Gupta, Wang, Coley, Fernandez, & Shaker, 2009). Initiation of the swallow includes concurrent glottal closure and laryngeal elevation that provides airway protection (Jadcherla et al., 2009; Geddes, Chadwick, Kent, Garbin, & Hartmann, 2010). Laryngeal elevation is followed closely with propulsion of the bolus by the tongue and by contractions in the pharyngeal walls (Geddes et al., 2010). Epiglottic inversion may result in additional protection of the airway during bolus propulsion and may allow the bolus to pass safely over the laryngeal opening. However, in neonates little is known regarding epiglottic activity during swallowing.

During the esophageal phase in adults, the bolus passes through the pharynx and relaxation of the upper-esophageal sphincter occurs followed by peristalsis of the esophagus (Ertekin & Aydogdu, 2003). These events allow the bolus to pass from the pharynx into the esophagus and eventually the stomach. In neonates relaxation of the upper-esophageal sphincter has been shown to occur, but not at the pressure magnitude that is seen in an adult swallow which is hypothesized to be the reason for high occurrence of gastro-intestinal-reflux in infants (Jadcherla, Gupta, Stoner, Fernandez, & Shaker, 2007).

In order to gain the adequate amount of nutrition needed to maintain healthy growth and maturation an infant must coordinate oral, pharyngeal, and esophageal phases of swallowing. In addition, overall efficiency of oral feeding requires the coordination of the respiratory system into the suck and swallow pattern, known collectively as the suck-swallow-breathe pattern. Sensorimotor control and coordination of the suck-swallow-breathe is accomplished by networks of interneurons within CPGs in the medullar reticular formation of the brainstem (da Costa et al., 2008; Barlow, 2009; Barlow, Lund, Estep, & Kolta, 2010). A mature suck-swallow-breathe pattern is characterized by complex activity in the CPGs to coordinate motor output in a 1:1:1 or 2:2:1 ratio (Lau, 2006).

Typical development of the *swallow* in preterm infancy. The earliest skill to mature in the suck-swallow-breathe pattern is the swallow. The occurrence of a fetal pharyngeal swallow has been observed via ultrasound at as early as 15 weeks gestational age (GA) (Miller et al., 2003). However, a study on rhythmicity of suck and swallow reveals that healthy preterm infants do not develop a mature and rhythmic swallow until approximately 32-33 weeks postmenstrual age (PMA) (Gewolb et al., 2001b; Amaizu et al., 2008).

Typical development of the *suck* in preterm infancy. There are two fundamental types of suck. The first is nutritive suck (NS) in which the infant acquires nutrient through either bottle or breast and the second is non-nutritive suck (NNS) in which an infant is provided a pacifier or finger and no nutrient is consumed. NNS can also be identified *in utero* as mouthing movements that are not associated with swallowing of the amniotic fluid (Miller et al., 2003). Inconsistent NNS movements have been observed with ultrasound in *fetuses* at as early as 14-16 weeks GA, with a more consistent pattern of anterior-posterior movement observed at 28-32 weeks GA (Miller et al., 2003; Mizuno & Ueda, 2005). By use of fetal magnetometry, intra-uterine NNS at 34 and 38 weeks gestation was observed at a frequency of about 3 sucks per second (E. Popescu, M. Popescu, Wang, Barlow, & Gustafson, 2008). Extra-uterine NNS patterning in infants is typically modulated at a rate ranging from 1.5 to 3.0 sucks per second, whereas a typical NS pattern is reduced to a fundamental rate of 1 suck per second (Barlow, Lee, Wang, Oder, Hall, Knox, Weatherstone, & Thompson, 2013a). The physiological make-up of NNS also shares many features with NS and therefore can be regarded as a precursor to NS. The primary difference between the two is that NS requires additional coordination with bolus control, along with swallowing and respiration (Figure 1). Due to this difference, an infant may show fully developed and coordinated NNS, however their NS may still be underdeveloped and uncoordinated with swallowing and breathing (Lau, 2006).

Research on sucking in *preterm* infants usually includes a description of suck parameters, including duration of bursts, number of sucks per burst, number of bursts per minute, number of sucks per minute, as well as rhythmicity, amplitude, and coordination of suction and expression. Mature suck is characterized by alternating burst-pause patterning, in which a *burst* of multiple sucks occurs followed by a 2-3 second respiratory *pause* wherein the cycle then repeats (Figure 1). At 34 and 38 weeks gestation, Popescu and colleagues observed *in utero* NNS parameters of 3.5-4.5 bursts per minute, a mean burst duration between 2.5 and 3, with 7-8 sucks per burst (Popescu et al., 2008). Whereas, the first oral feeding trial of 186 preterm infants demonstrated an average NS burst duration of 7 seconds with 4 burst per minute when born between 33-34 weeks GA (Medoff-Cooper, Bilker, & Kaplan, 2001). The same study showed an increase in burst duration to 15 seconds with a decrease in bursts per minute to 2.5 for infants born between 35-40 weeks GA. This evidence demonstrates that around 35 weeks GA, the healthy infant transitions to a more controlled NS burst-pause pattern and shows increased endurance to support longer burst durations.

The number of sucks per burst varies greatly from infant to infant and depends upon GA, PMA, and the infant's level of suck development. At 30 weeks PMA, NS is rapid, mostly arrhythmic, and does not occur in burst-pause cycles (Gewolb et al., 2001b). As mentioned above fetal NNS at 34 and 38 weeks gestation was comprised of 7-8 sucks per burst (Popescu et al., 2008). When measuring NS, infants born 33-35 weeks GA had an estimated 11-12 sucks per burst, which increased to 20 sucks per burst for infants born at 40 weeks GA (Medoff-Cooper et al., 2001). For neurotypical preterm infants that were less than 35 weeks PMA, only 73.6% of nutritive sucking occurred in bursts. Whereas infants that were older than 35 weeks PMA showed 85.4% of nutritive sucks occurring in bursts with a burst duration that was also found to be relatively longer (Gewolb et al., 2001b). This reinforces Medoff-Cooper and colleagues' findings that NS burst-pause patterning matures at around 35 weeks of age. It can therefore be assumed that the ability to coordinate sucking into bursts is, to some extent, an innate behavior (Gewolb et al., 2001b) that is modifiable by local sensory experience.

Once an infant's suck shows developed and rhythmic burst-pause cycles, further improvements occur in strength and oromotor coordination. In a mature NS, an infant uses both suction (S) and expression (E) to draw nutrient from the nipple. Expression is the anterior-posterior movement of the tongue compressing the nipple against the hard palate to extract nutrient (Lau, 2006; Lau, Alagugurusamy, Schanler, Smith, & Shulman, 2000). Suction is the creation of negative intraoral pressure to generate a pressure gradient that draws nutrient into the oral cavity (Lau, 2006; Lau et al., 2000). Lau and colleagues described five-stages of suck based upon S and E development (Lau et al., 2000; Lau, 2006). Infants between 33.5-34.5 weeks PMA fell in the first stage of this model with mostly arrhythmic expression and no suction observed. At stage two the infant develops a rhythmic expression occurring in bursts with inconsistent suction beginning to emerge. Stage two was seen between 34.5 and 36.5 weeks PMA. Stage three occurred between 35-37 weeks PMA, in which rhythmic S/E begins to develop, with an S/E ratio of less than one. Once the S/E-ratio reaches one, an infant transitions to the fourth stage of suck, typically observed at ages 36-37 weeks PMA. At stage five, rhythmicity of S/E is distinct and the ability for the infant to generate higher levels of negative intraoral pressure (S) was noted with a significant increase in the S-amplitude. Stage five in development is considered to match the sucking ability of a full-term mature suck, characteristic at 36-41 weeks PMA. The 5-stage S/E trajectory in healthy preterm infants provides further evidence that coincides with Gewolb and colleagues' theory on sucking as an innate behavior. However, this theory does not explain the oral feeding difficulties that are observed in sicker infant populations such as IDM, RDS, and CLD.

While suction does not occur in the two initial stages of this model, evidence from this study showed that successful oral feeds could still be attained with use of expression only (Lau et al., 2000). The benefit of a coordinated suction and expression was demonstrated in the positive correlation found between stage of suck and rate of nutrient transfer (Lau et al., 2000). However, at stage five in development, rate of milk transfer continued to be significantly lower for preterm infants as compared to post-natal age-matched term infants (Lau et al., 2000).

Coordination of suck-swallow-breathe. The coordination of the suck-swallow-breathe pattern in preterm infants is dependent on the development of oromotor and respiratory CPG networks in the brainstem (Lau, 2006; Barlow, 2009). Without appropriate CPG development the suck-swallow-breathe is arrhythmic and lacks sufficient coordination to support safe swallows and efficient oral feeding. In healthy preterm infants swallowing matures between 32-33 weeks PMA (Gewolb et al., 2001b; Amaizu et al., 2008), this suggests that maturation of the swallow CPG occurs at that age. However, the ability for a preterm infant to coordinate sucking and breathing into a coordinated rhythm requires further development within the brainstem and reciprocal connections with sensorimotor cortex. Compared to NNS, the addition of swallowing and breathing requirements during NS causes decreased ability for infants to coordinate suction, expression, and burst cycles for sucking. Research on preterm infants demonstrates that NS requires further development through 41 weeks PMA to increase coordination of S/E to swallowing (Lau et al., 2000). This suggests that multiple CPG networks within the ponto-medullary complex are needed for suck-swallow coordination. A similar pattern is seen with the integration of respiration during oral feeding in that an infant may exhibit stable breathing at rest, but requires further CPG development to coordinate breathing with suck and swallow during oral feeds.

Fetal development of the respiratory system occurs during the third trimester and may continue through 40 weeks GA (McEvoy, Venigalla, Schilling, Clay, Spitale, & Nguyen, 2012). Depending on GA, infants born preterm often show signs of an underdeveloped respiratory system. During rest, preterm infants between 33-40 weeks GA showed no changes in resting respiratory rate and maintained an average of 54 breaths per minute (McEvoy et al., 2012). However during oral feeds, respiration can be compromised by the use of protection mechanisms that insure a safe swallow, resulting in apneic events.

There is considerable overlap in the sequencing and integration of suck, swallow, and respiratory related movements within the oral-pharyngeal and laryngeal-esophageal anatomy during oral feeds. Evidence for infants at 36 weeks PMA showed that upwards of 45 seconds per minute was dedicated to suck-swallow coordination during oral feeding (Medoff-Cooper et al., 2001; Amaizu et al., 2008) with approximately 30 seconds per minute dedicated to breathing (Mizuno & Ueda, 2003). The coordination of breathing and suck-swallow begins to develop stability at approximately 36 weeks PMA (Mathew, 1991) with further maturation of CPG activity patterns continuing past 38 weeks PMA (Amaizu et al., 2008).

Infants continue to develop swallow-breathe coordination to enhance safe swallows, minimize the risk of aspiration, and optimize respiratory efficiency during feeding. The safest and most efficient respiratory-swallow pattern is known as Inspiration-Swallow-Expiration (I-S-E), with Expiration-Swallow-Expiration (E-S-E) also considered a safe pattern but somewhat less efficient (Gewolb & Vice, 2006b; Mizuno & Ueda, 2003). For infants born at term, 55.9% of infants between ages 37-41 weeks PMA used expiration after swallowing (Gewolb & Vice, 2006b). However, only 37.8% of preterm infants at a similar age range, 35-40 weeks PMA, showed swallowing events followed by a safe respiratory phase (Gewolb & Vice, 2006b). This evidence coincides with previous knowledge that preterm infants often show developmental delays in the integration of respiratory control into the suck-swallow-breathe CPG.

Recent evidence suggests that the performance anatomy of the feeding apparatus continues to evolve post 40 weeks PMA. For example, significant changes in the shape and size of the medulla oblongata occur during the first year of infancy (Darnall, Ariagno, & Kinney, 2006). Since the occurrence of I-S-E is only observed in 55% of neurotypical infants at 41 weeks PMA, this suggests that the suck-swallow-breathe CPG network continues to develop through 1 year of age (92 weeks PMA).

Suck-swallow-breathe development in RDS, CLD, and IDM. While the evidence above shows developmental trajectories for neurotypical preterm infants, little is known regarding oral feeding development in special populations, such as RDS, CLD, and IDM. Infants with RDS require 6-28 days of supplemental oxygen treatment and often show difficulties in oral feeding development. Due to continuous application of positive airway pressures through supplement oxygen treatment, infants with RDS receive limited or maladaptive oral stimulation that is known to delay development of ororhythmic brainstem CPGs and the attainment of oral feeding skills during the first year of infancy (Stumm, Barlow, Estep, Lee, Cannon, Carlson, & Finan, 2008). A study on NNS development in infants with RDS found delays in the emergence of suck-burst structure and suck pressure amplitude both of which were strongly correlated to RDS severity (Stumm et al., 2008). Infants with RDS usually remain in the NICU 2-3 weeks longer than neurotypical preterm infants (Stumm et al., 2008).

Infants of diabetic mothers are at risk for macrosomia, hypoglycemia, hypoinsulinemia, cardiomyopathy, RDS, iron deficiency, birth at a premature age, and fetal hypoxic events (Nold & Georfieff, 2004; Weindling, 2009). These risks can result in poor neurodevelopment for an infant with IDM (Nold & Georfieff, 2004), and may negatively impact CPG control and coordination of the suck-swallow-breathe during oral feeding. An example of neurodevelopmental deficit in 6-month-old infants with IDM revealed decreased activation of event-related potentials for left medial temporal cortex and hippocampus, resulting in delays in recognition and working memory (Nelson, Wewerka, Thomas, deRegnier, Tribbey-Walbridge, & Georgieff, 2000; deRegnier et al., 2007).

Another study on 530 IDM babies resulted in 36% born preterm and 34% treated for RDS in the NICU (Cordero, Treuer, Landon, & Gabbe, 1998). The connection between IDM and RDS has been studied in animal models as well. For example, in rat pups with high glucose levels the production of surfactant and proliferation of alveolar lining cells was inhibited, causing a direct impact on the respiratory function (Gewolb & O'Brien, 1997; Gewolb, 1996). However, not all IDM infants have RDS. For IDM infants without RDS, suck-swallow-breathe development may occur similarly to that of neurotypical preterm infants.

For infants requiring more than 28 days of supplemental oxygen the diagnosis of RDS changes to chronic lung disease (CLD), also known as bronchopulmonary dysplasia (BPD). The degree of respiratory system underdevelopment in CLD is more severe and is correlated with more significant delays in suck-swallow-breathe development than the IDM and RDS populations. Research on bottle-feeding in infants with BPD confirms this prediction, with a 3-4 week delay in development of the sucking pattern when compared to age-matched neurotypical infants (Howe, Sheu, & Holzman, 2007). At 38 weeks PMA, 53% of BPD infants generated less than 10 sucks per burst and 39% generated less than 5 sucks per burst. Gewolb and colleagues found that rhythmicity of the suck-swallow in BPD infants with PMAs greater than 35 weeks did not follow the same developmental trajectory as neurotypical infants, with a decreased number of suck-swallows per burst and decreased burst duration (Gewolb, Bosma, Taciak, & Vice, 2001a; Gewolb, Bosma, Reynolds, & Vice, 2003). Another study found that infants with BPD, defined as oxygen dependency at 36 weeks PMA, demonstrated a significantly higher occurrence of "abnormal" and "incoordinated" sucking during feeding trials (da Costa, van der Schans, Zweens, Boelema, van der Meij, Boerman, & Bos, 2010). In addition, BPD infants older than 35 weeks PMA, showed significantly higher rates of deglutition apnea than neurotypical infants (Gewolb & Vice, 2006a). The rhythmicity of respiration alone was significantly delayed in the same BPD population with concomitant delays in the ability to coordinate respiration with the suck-swallow (Gewolb & Vice, 2006a).

Assessment of oral feeding skills. The importance of studying oral feeding development among neurotypical, RDS, IDM, and CLD preterm infants is significant in order to develop procedures and protocols that will reduce length of stay in the NICU and decrease cost of managing feeding disorders. Current methods utilized to measure oral feeding skills within the NICU include an overwhelming number of subjective tools (da Costa et al., 2008; Medoff-Cooper et al., 2001), which provide the clinician with descriptive observations in a checklist format. Such assessment tools are readily available, require little maintenance, are easy to administer, and are inexpensive. However, shortcomings include limited test-retest and interrater reliability due to uncontrollable variation in human judgment (da Costa et al., 2008; Howe, Lin, Fu, Su, & Hsieh, 2008). One such oral feeding measure currently in use at some NICUs is the Early Feeding Skills (EFS) assessment checklist (Thoyre, Shaker, & Pridham, 2007). Thoyre et al. suggest using the EFS in a qualitative and descriptive manner to guide treatment versus attempting to quantify data into a score-based system. Administration of the EFS provides descriptive data on the development of oromotor functioning, nutritive suck rhythmicity, and suck-swallow-breathe coordination (Thoyre et al., 2007). Certain items on the EFS assessment tool also provide descriptive information regarding secondary behaviors associated with decreased protection of the airway and events of aspiration.

Treatment of oral feeding skills. Current therapies for treatment of feeding disorders within the hospital setting focus on utilizing compensatory strategies such as pacing the infant, controlling flow rate with different nipples, and changing the position of the infant during oral feedings. However, research on these strategies does not provide evidence of benefit in their use (White & Parnell, 2013; Scheel, Schanler, & Lau, 2005; Lau, 2013). In terms of proactive therapeutic interventions, such as NNS and oral stimulation, recent studies show promising benefits for oral feeding outcomes. Previous research on the use of NNS to promote neurodevelopment shows inconsistent results that are more than likely due to methodological differences in the research. Fucile and colleagues found multiple benefits in the administration of both oral and full-body sensory stimulation (Fucile, McFarland, Gisel, & Lau, 2012). For infants receiving the combined oral and NNS stimulation, NS showed a significantly higher stage of suck development (based upon Lau's 5 suck stages) with significantly higher amplitudes of S/E as compared to controls (Fucile et al., 2012). Further benefits such as increased volume of intake and rate of milk transfer were found regardless of experimental group (full-body, oral, or combined oral+body stimulation) when compared to controls (Fucile, Gisel, McFarland, & Lau, 2011). However, the oral and NNS stimulation condition was the only group to show the specific benefits for NS that are listed above (Fucile et al., 2012).

Previous studies on the use of NNS as an oromotor stimulus found additional evidence in overall feeding outcomes such as transition time to full oral feeds (Fucile, Gisel, & Lau, 2002; Rocha, Moreira, Pimenta, Ramos, & Lucena, 2007; Harding, Law, & Pring, 2006; Boiron, da Nobrega, Roux, Henrot, Saliba, 2007) and decreased hospital stays (Harding et al., 2006). However, the evidence regarding the number of days needed to transition to oral feeds differed between studies and may have been due to differences in the experimental definitions for transition and GA of preterm infants. One study found that the administration of oral stimulation and NNS resulted in the initiation of oral feeding 8 days earlier than controls, yet there was no significant difference in the number of days required to transition from initial to full oral feeds when compared to a control group (Rocha et al., 2007). A second study found that infants who received either the full-body, oral, or combined treatment stimuli required 9-10 less days to transition from initial to full-oral feeds (Fucile et al., 2011).

Other suggested benefits of NNS include increased rate of weight gain, promotion of digestion motility, and improvement in behavioral state control, however evidence for these benefits vary greatly as well (Lau, 2006; Arvedson, Clark, Lazarus, Schooling, & Frymark, 2010). A recent study on the use of an oral stimulation protocol involving compression of the cheeks and lips with tongue and palate massage found a significantly higher rate of swallows and sucking bursts per minute as compared to a control group (Boiron, da Nobrega, Roux, & Saliba, 2009). Even with the small sample size in this study and a stimulus that was applied by hand, the benefit of somatosensory stimulation on the development of oral feeding skills was apparent.

Recent research has enhanced the range of options for oral stimulus control with use of a pneumatic amplifier called the NTrainer System® (Innara Health, Inc., Shawnee, KS). This instrument can be programmed to synthesize an orocutaneous experience through a silicone pacifier nipple (Barlow, Finan, Lee, & Chu, 2008; Poore, Zimmerman, Barlow, Wang, & Gu, 2008). The NTrainer System® stimulus mimics the spatiotemporal patterning of an NNS burst by modulating the air pressure within the pacifier which in turn results in mechanical deflections of the pacifier bulb and activation of oral mechanoreceptors (Barlow, 2009). Preterm infants that received this pneumatic orocutaneous stimulus show accelerated development of NNS, compared to untreated controls (Barlow et al., 2008; Poore et al., 2008). The use of this stimulus in at risk populations has resulted in recent preliminary data showing significant improvements in the NNS abilities of the healthy infant (HI) population, as well as CLD and IDM populations (Barlow et al., 2013a). This data provides support for the NTrainer® stimulus as an oral experience that promotes the development of suck CPG networks in healthy infants born prior to gestational development of suck (34-36 weeks), as well as in infants deprived of oral motor experiences, such as RDS, IDM, and CLD populations. Further research regarding the effect on NS development and overall oral feeding outcomes within these populations will provide information regarding pulsed orocutaneous stimulation as a therapeutic intervention.

Hypotheses:

- For preterm infants receiving the SHAM pacifier condition, it is hypothesized that healthy neurotypical infants (HI) will show an advantage in the attainment of oral feeding skills as reflected by higher EFS scores at an earlier PMA, when compared to the sicker infants, including RDS, CLD, and IDM populations.
- Overall, preterm infants randomized to receive the pulsed orocutaneous stimuli, are expected to show significantly higher EFS scores compared to the SHAM infants. Within the pulsed entrainment groups, we expect to find a similar advantage in the attainment of oral feeding skills (HI > IDM > RDS > CLD).

Experiment/Methods:

Study population. The EFS checklist scoring system was assessed for its utility among an available pool of 199 newborn infants (90F/109M) distributed across 4 subpopulations, including 56 healthy preterm infants (HI), 28 preterm infants of diabetic mothers (IDM), 44 with respiratory distress syndrome (RDS), and 71 with chronic lung disease (CLD) who were randomized to receive either the SHAM pacifier or PULSED orosensory stimulation simultaneous with gavage feedings in the neonatal intensive care unit. These participants were part of a larger ongoing randomized trial (NIH DC003311-Barlow). Participant characteristics are given in Table 1. The human subjects committee at each performance site, including the Overland Park Regional Medical Center (Overland Park, Kansas USA), and Stormont-Vail HealthCare (Topeka, Kansas USA) approved the research protocol for this study. Written informed consent was obtained from the parents at each NICU prior to the participants' enrollment into the study following consultation with the attending physician and the research nurse or study coordinator dedicated full-time to this project. Medical staff involved in nursing care of study participants was blinded to treatment condition for the duration of the 2-week intervention protocol in the NICU. The expected ethnic proportion for Kansas, based on the US Federal Census was African American 5.8%, Asian American 1.7%, Hispanic American 5.5%, Native American 0.8%, and White 86.2%.

Population 1: HI designates healthy preterm infants (N=56; 36 treatment, 20 control) with no specific diagnosis who were otherwise medically stable. Inclusion criteria: born between $23^{0/7}$-$36^{6/7}$ weeks GA, as determined by obstetric ultrasound and clinical examination, minimal or no oxygen history (≤ 5 days of ventilator, CPAP, and nasal cannula).

Population 2: IDM includes neonates born to mothers with diabetes (gestation or other forms) (N=28; 17 treatment, 11 control). Often these infants are born with macrosomia and are at higher risk for hypoglycemia, hypocalcemia, hyperbilirubinemia, RDS, congenital anomalies, cardiomyopathy, and postnatal problems later in life such as later child and/or adult obesity and poor neurological development. These infants appear to be 'large' but also somewhat lethargic when it comes to early neonatal oromotor skills such as sucking and feeding. This delay often results in IDM infants remaining in the NICU for extended periods until they achieve these life-essential skills. Therefore, it appears this group would derive significant benefit from therapy to improve their sucking and feeding skills. Inclusion criteria: born between 23 and 40 weeks GA, days on oxygen < 28 days.

Population 3: RDS infants (N=44; 18 treatment, 26 control) manifest a diagnosis of respiratory distress syndrome as confirmed by X-ray earlier in their hospital stay and required respiratory support. These infants typically have prolonged oxygen therapy due to their lungs not being fully developed and/or to surfactant deficiency. The oxygen therapies and tape that holds these O_2 devices in place can essentially reduce the amount of oral experience received by this population, therefore, making their sucking and feeding delayed. These infants often have oral aversion as well due to the negative experience associated with the extensive oxygen therapy. Inclusion criteria: born between $23^{0/7}$-$36^{6/7}$ weeks GA, as determined by obstetric ultrasound and clinical examination, documented oxygen history for treatment of RDS (days on ventilator + CPAP + nasal cannula).

Population 4: CLD includes sicker preterm infants (N=71; 41 treatment, 30 control) with chronic lung disease and occurs primarily in babies who need supplemental oxygen at 36 weeks postmenstrual age. Factors contributing to development of CLD include exposure to free radicals during oxygen therapy, damage to the developing lung related to ventilator injury, immaturity of lung structure itself, inflammatory cytokine cascades that may originate with maternal infection during pregnancy, and potential genetic factors. Lung tissue may be characterized by inflammation and scarring, areas of air trapping or collapse, excessive fluid, all of which can result in excessive mucous production, bronchospasm, and/or limited pulmonary reserve. Inclusion criteria: born between $23^{0/7}$-$30^{6/7}$ weeks GA, and days on oxygen > 28 days. Neurological examination included brain ultrasound and/or MRI to document the severity and localization of intraventricular hemorrhage (IVH) or periventricular leukomalacia (PVL) common to CLD infants.

General inclusion criteria: no functional suck and tube-fed at 34 weeks PMA, head circumference within 10-90th percentile of mean for PMA, neurological examination showing no anomalies for PMA: response to light, sound, and spontaneous movements of all extremities, and with stable vital signs (heart rate, blood pressure, age appropriate respiratory rate, and oxygen saturation >92 SpO_2) to allow for NNS.

General exclusion criteria: IVH grades III or IV, other intracranial hemorrhage, PVL, necrotizing enterocolitis, neonatal seizures and culture positive sepsis or meningitis at time of testing, chromosomal anomalies or craniofacial malformation, nervous system anomalies, cyanotic congenital heart disease, gastroschisis, omphalocele, diaphragmatic hernia and/or other major gastrointestinal anomalies, or not ready for oral feedings as determined by the health care team.

SHAM and PULSED orocutaneous stimulation conditions. Infants assigned to the PULSED condition received three 3-minute epochs of pulsed orocutaneous stimulation during gavage feeds using the NTrainer System® (Innara Health, Inc., Shawnee, Kansas USA). This orocutaneous stimulus was programmed to mimic the temporal features of a NNS burst. Precision stimulus control was achieved with a custom designed servo pneumatic amplifier operating under pressure feedback and coupled in series with a regular (green) Philips AVENT BPA-free Soothie® silicone pacifier. A total of 34 synthetic FM NNS burst-pause trains were presented to the infant during a single 3-minute stimulation period. The spatiotemporal features of this stimulus mimics the synchronous volleys of afference associated with non-nutritive suckling, and thus approximates a physiologically salient somatosensory experience encoded by the trigeminal system (Barlow et al., 2010; Barlow, Urish, Venkatesan, Harold, & Zimmerman, 2012; Barlow, Lee, Wang, Oder, Oh, Hall, Knox, Weatherstone, & Thompson, 2013b). The 3-minute orocutaneous stimulation periods were interleaved with 5.5-minute pause periods during which the stimulator will be turned off and the pneumatically-charged pacifier was removed from the mouth.

Infants assigned to the SHAM condition were offered the same type of Soothie® pacifier but without the pneumatically patterned stimulus. The stimulation regimen for both PULSED and SHAM infants was repeated 3 times per day for up to 10 days according to their 3-hour feed cycles, or until the infant successfully took 90% or greater of their daily nutrition orally at least for two consecutive days. Infants were swaddled with limbs at midline, and in a quiet-awake to drowsy state during stimulation (Als, 1995). Casual observers and staff responsible for administering gavage and oral feeds were blinded to stimulation condition. The same cribside NTrainer System® workstation was used for NNS assessment, PULSED and SHAM conditions.

EFS administration and protocol. The Early Feeding Skills assessment checklist was part of a larger protocol in an ongoing NIH study (DC003311 – Barlow) and was included for comparison to physiological measures of non-nutritive suck dynamics along with feeding and growth metrics. The EFS checklist was periodically completed by a research neonatal nurse following an oral feeding trial, clinical conditions permitting in the NICU. Therefore, the number of EFS checklists administered to each participant varied ranging from two to seven. Administration of the EFS occurred separately from NNS treatment sessions (SHAM, PULSED). Research neonatal nurses at each NICU were trained by Dr. Suzanne Thoyre regarding administration and scoring of the EFS. The EFS is a 36-item observational checklist designed to measure preterm infant feeding skills (Appendix A). The checklist format aims to identify specific strengths and weaknesses in the physiological stability, oral-motor functioning, and swallow coordination of an infant during an oral feeding trial. Each item on the checklist contains 2, 3, or 4 descriptive-style choices arranged along an ordinal ranking scale. Examples of choices include i) *no event observed* versus *at least one event observed*; ii) *none of the onsets, some of the onsets,* or *all of the onsets*; and iii) *fuss/cry, sleep, drowsy,* or *quiet alert*.

For the purposes of this study, only the first 33 items of the EFS checklist were utilized based upon the suggestions of Susan Thoyre. This includes the *Oral Feeding Readiness* and *Oral Feeding Skill* sections. These sections contain 5-items designated to the assessment of oral feeding readiness, 5-items assessing physiological stability and control, 3-items assessing oromotor preparation, 5-items assessing suck abilities, 5-items assessing swallow abilities, and 10-items assessing coordination of respiration. A scoring system specific to this study was designed by Susan Thoyre and used to assign a digit ranging from 0-4 to the descriptive choices, 0 represents the lowest possible score. For example, if an infant opens their mouth promptly at every onset of feeding (item 4) then the infant would receive a score of 2-*all of the onsets*, instead of a 1-*some of the onsets* or 0-*none of the onsets* (Figure 2). Once the checklist is completed the scores for each item was totaled for an overall EFS score. Possible EFS scores ranged from 0-63, 0 representing the lowest possible score associated with underdeveloped feeding skills. A score of 63 was the highest possible score and therefore representative of more adequate feeding skills.

Statistical analysis. Longitudinal comparison of EFS performance between the two treatments (SHAM, PULSED), each consisting of four preterm infant groups (HI, IDM, RDS, CLD). Mixed modeling was used to test for interdependency among repeated measures within subjects. After checking for interdependency the data sample was adjusted according to GA and birthweight. The mixed models were then used to estimate linear growths of EFS days as well as treatment group, infant population, and any interaction effects for each outcome. The restricted maximum likelihood estimator was also utilized to prevent any possible bias due to any unbalanced sample sizes or incomplete data that could have occurred in the generated estimates. Type 1 statistical error was controlled using Bonferroni's pairwise comparison of adjusted means. The error covariance structure that best fit this studies model according to Akaike Information Criterion and Baysesian Information Criterion was a compound symmetric error covariance structure and therefore was the framework for the resulting mixed models. All of the previously mentioned analyses were completed with SAS v9.3 (SAS Institute, 2011).

Simple linear regression techniques (MINITAB *v*16, 2013) and test of difference between regression functions were used to characterize the growth and variance in EFS scores as a function of PMA days among the 4 preterm groups for both SHAM and PULSED stimulation conditions. PMA days at EFS score onset and termination were calculated and subjected to an

ANOVA to determine the relative timing and duration of perceptual oral feed growth trajectories among HI, RDS, CLD, and IDM preterm infant groups.

Results:

Statistical analysis included 739 completed EFS checklists across 199 preterm infants with an average EFS score of 50.8 (SD = 7.32). Preterm infant performance on the EFS scale, adjusted for GA and birthweight, differed significantly between the four clinical populations but did not differ significantly by oral stimulation condition.

Mixed model analysis on EFS scores. A significant main effect for EFS days was found among preterm participants. EFS scores significantly increased in a linear pattern as EFS day increased ($p<.001$, Table 2). A significant main effect for preterm group also was found ($p=.01$, Table 2). EFS scores were significantly different among the four preterm populations (HI, IDM, RDS, and CLD; Table 3). For the combined CLD infant group (SHAM + PULSED) EFS scores were significantly lower than the combined HI infant group ($p<.01$, $d=0.28$) and combined RDS infant group ($p<.05$, $d=0.23$; see Figure 3). No oral stimulation treatment effect was observed.

Regression analysis for EFS scores versus PMA. Simple linear regression modeling revealed significant positive growth in EFS scores as a function of PMA as reflected in the slope of all infant groups and treatments with the exception of the SHAM condition for IDM preterm infants (Figure 4). A test of difference between SHAM and PULSED regressions for each clinical infant group revealed a significant difference in slope ($p=.004$) and intercept (p=.005) for HI infants (see Table 4). No significant differences were found in the slopes and intercepts between the SHAM and PULSED conditions for the other three clinical populations (IDM, RDS, CLD).

Distribution of PMA_{start} and PMA_{stop} across infant populations. Two-way ANOVA using a General Linear Model for unbalanced design found significant differences in the PMA at the initiation (PMA_{start}) of EFS scoring among the clinical populations ($F=3.3$, $p=.022$), and at termination of EFS scoring (PMA_{stop}) ($F=3.3$, $p=.001$).

For the SHAM regression model (Figure 4), RDS infants initiated treatment first (mean PMA_{start} = 241.62 days), followed by HI, IDM, and CLD infants (mean PMA_{start} = 244.45; 246.27; and 247.23 days). However, the SHAM regression model shows HI infants completing treatment (mean PMA_{stop} = 254.10 days) a little over 2 days before RDS infants (mean PMA_{stop} = 256.23) followed by IDM and CLD infants (mean PMA_{stop} = 256.55; and 267.53 days).

In the PULSED regression model (Figure 4) the HI infants have the earliest PMA_{start} (237.86 days), followed by RDS, CLD, and IDM infants (mean PMA = 246.33; 248.73; and 248.82 days). PMA_{stop} within the same regression model shows HI infants finishing treatment at an average PMA of 250.14 days, followed by IDM, RDS, and CLD infants (mean PMA = 258.59; 262.44; and 264.02 days). No significant differences in PMA_{start} and PMA_{stop} were found between treatment conditions in any of the four clinical populations.

Length of stay. For all infants combined, EFS score significantly decreased as length-of-stay (LOS) increased ($p<.001$). No significant group, treatment, or interaction effects for LOS were present in the mixed model analysis.

Discussion:

Measuring oral feeding success in infants born preterm is a major concern when preparing for discharge to the home environment. Within the NICU professionals are often limited to assessing oral feeding skills through subjective methods. An issue in using subjective data to make conclusions regarding oral feeding diagnosis is whether these assessments can accurately measure or quantify dysfunctions that occur past what is visually observable by the nurse. Another frequently discussed issue regarding subjective-based assessments, is in their statistical reliability and validity measures, which are often unknown and go unreported by the authors (Costa et al., 2008; Howe et al., 2008). In terms of the EFS checklist used for this study, reliability and validity values were also unknown.

The aim of this study was to measure the oral feeding trajectories of HI, IDM, RDS, and CLD infants using the EFS checklist. It was hypothesized that HI infants would show an advantage in oral feeding attainment reflected by higher EFS scores when compared to the RDS, CLD, and IDM populations. However, the HI infant's EFS scores were not found to be significantly different from that of the RDS and IDM infants. CLD infants were the only group to show significantly lower EFS scores than the HI infants. However, the effect size was relatively small indicating minimal clinical significance (d= 0.28). The lack of statistically significant findings when comparing the HI group to the IDM group may be explained by the IDM group's small sample size and relatively high variability in EFS scores. In addition, the lack of evidence differentiating between the HI and RDS populations may suggest that the EFS assessment has limited capability in measuring minute differences in oral feeding skills between the two groups.

The second focus of this study was to compare differences in oral feeding skills as a function of oral somatosensory stimulus among the HI, IDM, RDS, and CLD groups. The EFS checklist was expected to show significantly higher scores for infants receiving the pulsed orocutaneous stimuli when compared to the SHAM condition. Previous studies found that pulsed orocutaneous stimuli resulted in significant improvements in NNS for HI, IDM, and CLD populations (Barlow et al., 2008; Poore et al., 2008; Barlow et al., 2013a; Barlow et al., 2013b). This treatment was also found to result in reduced length of stay for CLD infants (Barlow et al., 2013a; Barlow et al., 2013b). It is assumed that oral feeding was successful in order for the CLD infants to be discharged and therefore suggests that pulsed orocutaneous stimulation may have resulted in accelerated NS development as well.

In this study, differences in the EFS scores of infants that received the PULSED orocutaneous stimulation versus the SHAM condition were found only to be significant for the slope and intercepts of the HI infants. For the HI infants receiving the PULSED condition, the slope and intercept were significantly larger and indicated faster growth in EFS scores. This suggests that HI infants receiving the orocutaneous stimuli may show quicker development in oral feeding skills. Furthermore, while the regression models of the IDM-SHAM group versus the IDM-PULSED group seem to represent large differences in EFS performance, the difference was not statistically significant. Similar to the lack of evidence found in the mixed model analysis, this can be explained by the IDM group's small sample size and high statistical variability. However, the lack of evidence found between the SHAM and PULSED conditions for the RDS and CLD populations questions the validity of the EFS checklist to be able to measure possible improvements in oral feeding skills resulting from pulsed orocutaneous stimulation.

Research on a similar subjective checklist also questions the accuracy in reported validity and reliability values for subjective-based assessments. For example, the Neonatal Oral Motor Assessment Scale (NOMAS) has been claimed by the authors to be a valid tool, but was found in a recent study to have poor validity and no correlations to well-established predictors of oral feeding outcomes that are currently used within the NICU (Bingham, Ashikaga, & Abbasi, 2012). The predictors utilized to measure concurrent validity within this study included feeding efficiency (measured by the amount by volume consumed in the first 5 minutes of feeding), birthweight, GA at birth, duration of respiratory support, GA at initiation of oral feeding, GA at full oral feeds, and the total number of days between initiation and attainment of oral feeding.

Similar to Bingham's findings the mixed model results of the present study found no correlations between the EFS checklist and two of the predictors listed above including, GA at birth and birthweight (Table 2). Two of the other currently suggested predictors of oral feeding outcomes were GA at initiation of oral feeding and GA at full oral feeds (Bingham et al., 2012), which can be comparable to the terms PMA_{start} and PMA_{stop} that were used in this study. The values for both PMA_{start} and PMA_{stop} for HI, IDM, RDS, and CLD infants were found to be significantly different. However, as previously mentioned EFS scores were only significantly different between HI and CLD infants, and between RDS and CLD infants.

There is, however, an issue with the oral feeding predictors listed above in that none of the included parameters include specific components of suck development that have also been suggestive of positive oral feeding outcome (e.g., percentage of sucks that occur within bursts)

(Gewolb et al., 2001b). This point has been argued previously, stating that until an agreement is made regarding optimal suck-swallow-breathe parameters that best predict successful oral feeds, generating a measure that accurately evaluates successful oral feeding will be difficult (Howe et al., 2008). Therefore, further research is needed comparing measures such as the NOMAS and EFS assessments to a variety of predictors for oral feeding outcomes. Furthermore, while the two research neonatal nurses went through training for the administration of the EFS, inter-rater and intra-rater reliability data was not collected and may be a limitation of this study. Another possible limitation was found in consistently administering the same number of EFS checklists to each participating infant. This varied greatly between infants due to differences in length of stay and clinically permitting conditions.

Current research is transitioning into developing tools that measure the suck-swallow-breathe system directly which provides reliable and quantitative data. With the use of pressure transducers, components of NS have been directly measured by placing a closed-end pressure sensor on the superior side of a bottle nipple for expression of suck, while placement of an open-ended pressure sensor within the nipple has measured the suction component of NS (Lau & Kusnierczyk, 2001). Use of pressure transducers may also provide a non-invasive way to measure deficits in swallowing that may arise after the oral phase. The method is called Pharyngo-UES-esophageal manometry, in which a flexible catheter is inserted through the nasal cavity, pharynx, and into the esophagus (Jadcherla et al., 2007). Researchers have been able to record activity of the pharynx, larynx, upper-esophageal sphincter, and esophagus with use of this technology (Jadcherla et al., 2007). This same catheter is also equipped with a water perfusion system that can apply enough water or air to safely trigger a swallow without placing the infant at risk for aspiration during oral feeding trials (Jadcherla et al., 2007).

As a subjective clinical assessment tool, the EFS scores for preterm infants (pooled among groups) showed a significant linear relationship with EFS days, and a significant main effect among individual groups. While the EFS checklist may provide a general indication of progress in oral feeding development, the EFS may lack the sensitivity and specificity to generate more detailed insights into the oral feeding dynamics of preterm infants with wide-ranging diagnoses and complex histories. Future studies will need to correlate daily oral feed intake and safe swallows using micromanometry to the EFS checklist to determine if subjective measures are sensitive to detect the complex features of feeding and swallow dynamics in the NICU.

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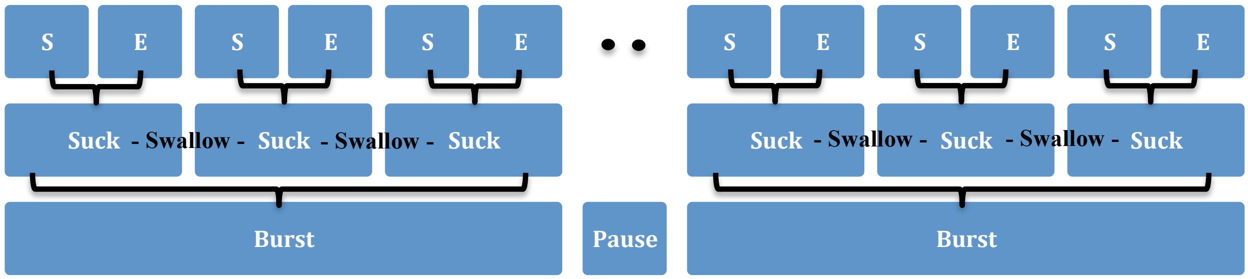


Figure 1. Nutritive Suck Schema. This diagram shows mature nutritive suck (NS), in that a single suck contains a suction (S) and expression (E) component, demonstrating rhythmic S/E (suction/expression) that occurs at a 1:1 ratio. Fully developed nutritive sucking bursts are 12-15 seconds in duration and consist of approximately 20 sucks followed by a 2-second pause which designates the completion of one burst-pause cycle. This NS cycle typically repeats at a rate of three per minute.

Ability to Organize Oral-Motor Functioning	Score = 2	Score = 1	Score = 0
4. Opens mouth promptly when lips are stroked at feeding onsets.	All of the onsets	Some of the onsets	Never
5. Tongue descends to receive the nipple at feeding onsets.	All of the onsets	Some of the onsets	Never
6. Immediately after the nipple is introduced, infant's sucking is organized, rhythmic, and smooth. (Organized sucking has a burst-pause pattern, dysfunctional sucking is demonstrated when the infant bites or clenches jaw, retracts tongue, or shows tongue thrusting)	All of the onsets begin with organized sucking	Some of the onsets	No organized sucking at the onsets
7. Once feeding is underway, maintains an organized, rhythmical, and smooth pattern of sucking. (see above item for further description)	Stable, consistently observed	Some disorganized sucking once feeding is underway	Unable to maintain organized sucking
8. Sucking pressure is steady and strong (i.e., sucks with steady and strong suction).	Stable, consistently observed	Some weak sucking	Frequent weak sucking

Figure 2. Example of EFS scoring. Items 4-8 on the EFS checklist scored as a 0, 1, or 2, with 0 being the lowest possible score, seen as green responses, and 2 being the highest score possible per item, the blue-colored responses.

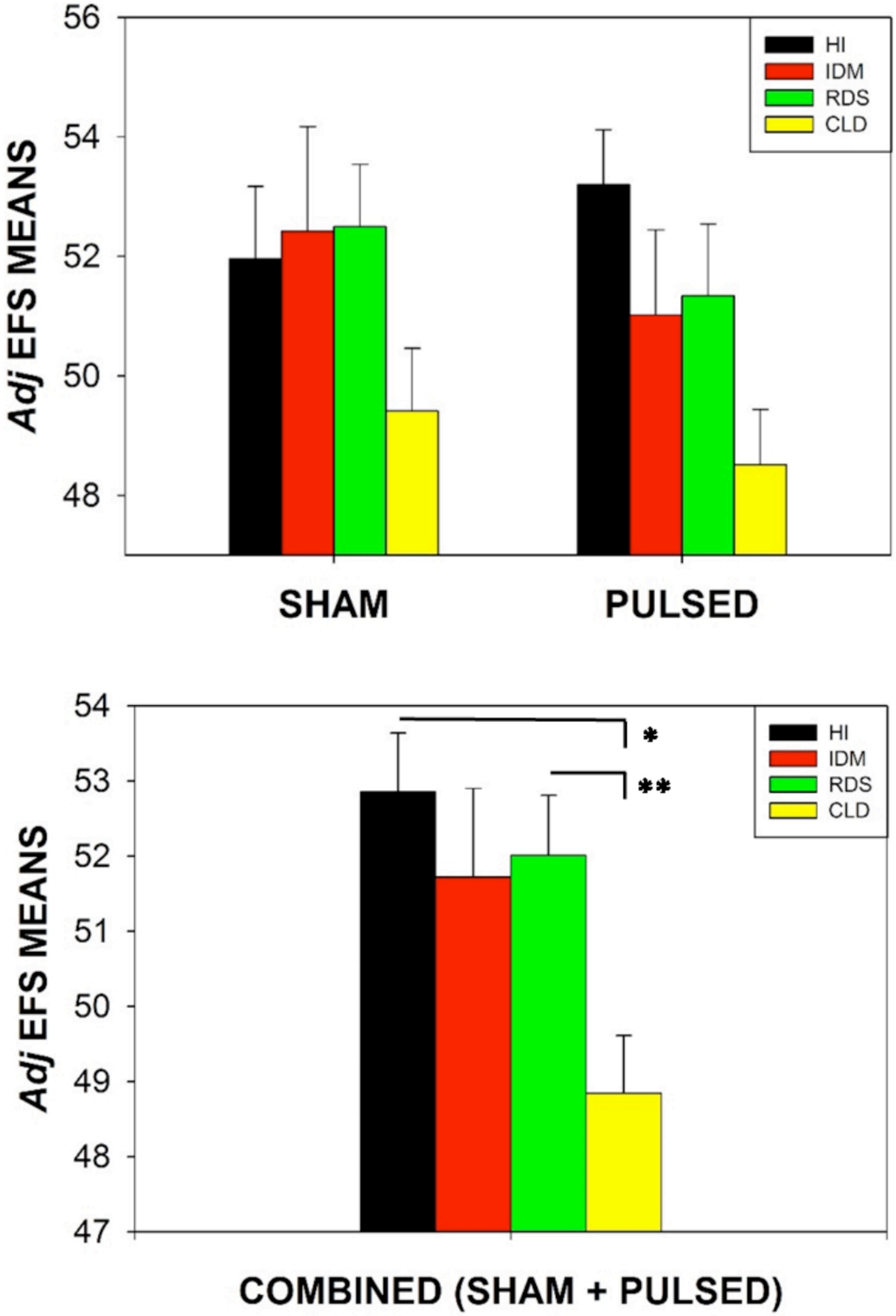
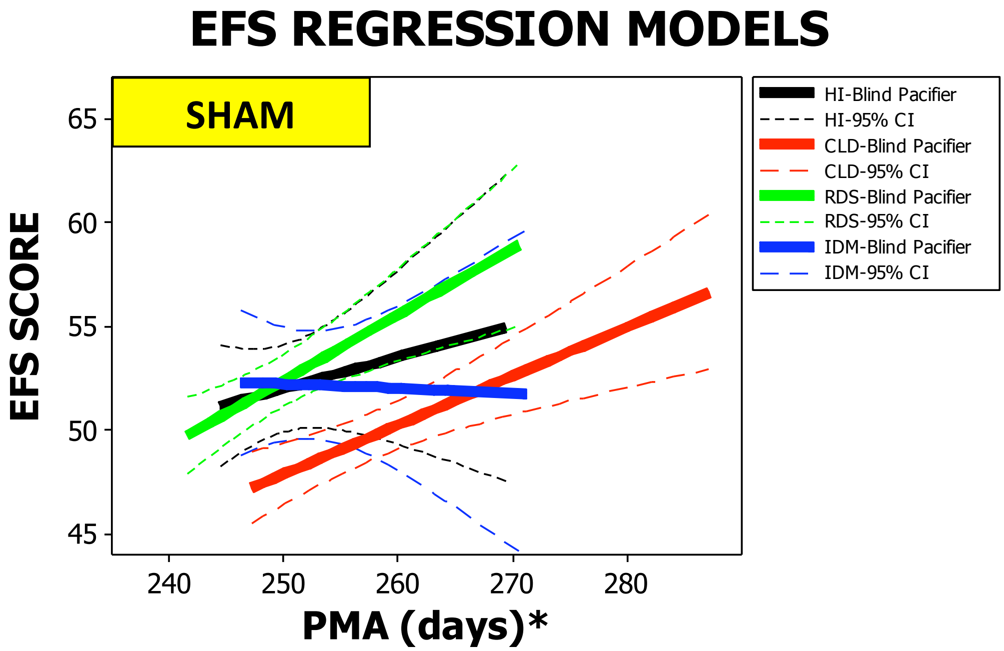


Figure 3. Adjusted group means from mixed model analysis. CLD preterm infants (combined) had significantly lower EFS scores than HI and RDS preterm infants.



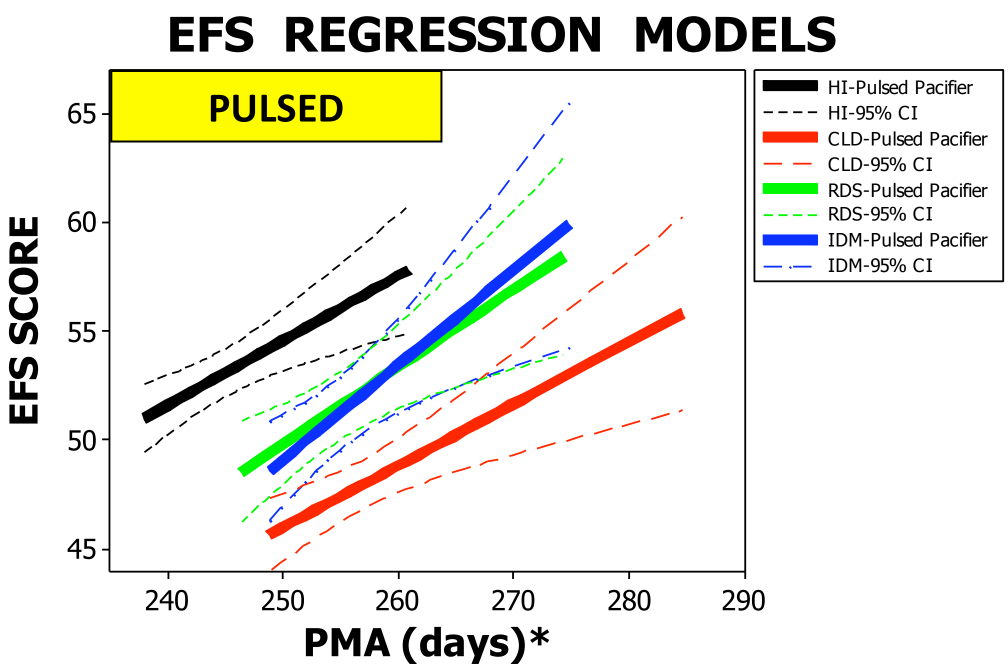


Figure 4. EFS regression models for SHAM versus PULSED stimulation conditions. Solid lines indicate the predicted Y-fits and dotted lines indicate the corresponding 95% confidence intervals.

	Healthy Infants		***Infants of Diabetic Moms***		***Respiratory Distress Syndrome***		***Chronic Lung Disease***	
	HI (N=56)		**IDM** (N=28)		**RDS** (N=44)		**CLD** (N=71)	
	Control	Pulsed	Control	Pulsed	Control	Pulsed	Control	Pulsed
	N=20	N=36	N=11	N=17	N=26	N=18	N=30	N=41
Gender (♂ : ♀)	**12:8**	**20:16**	**8:3**	**8:9**	**16:10**	**10:8**	**14:16**	**21:20**
GA_{birth} (days)	**227.5** (12.8)	**218.8** (10.3)	**228.9** (20.3)	**226.5** (22.6)	**214.2** (13.2)	**216.1** (15.2)	**188.3** (14.3)	**189.9** (12.3)
BW (gms)	**1886.3** (474.2)	**1624.3** (312.1)	**2186.2** (905.2)	**2011.3** (851.0)	**1498.1** (335.3)	**1465.9** (533.7)	**936.7** (374.8)	**881.8** (247.6)
PMA_{start} (days)	**242.7** (10.2)	**237.0** (7.88)	**244.1** (17.3)	**249.7** (17.0)	**238.6** (10.1)	**244.7** (14.2)	**243.6** (12.8)	**247.4** (16.2)
$\%PO_{start}$	**29** (31)	**8** (19)	**13** (21)	**19** (25)	**11** (18)	**8** (15)	**11** (17)	**6** (9)
O_2 Hx (days)	**2.6** (6.0)	**5.4** (8.7)	**5.7** (9.6)	10.7 (13.4)	**18.0** (12.4)	**17.2** (8.9)	**61.4** (26.1)	**66.2** (30.2)

Table 1. Clinical characteristics of 199 preterm infants.

Effect	Num. *df*	Den. *df*	*F*	*p*
GA	1	528	0.17	0.681
Birth weight (g)	1	528	1.45	0.230
EFS day*	1	528	116.24	**0.000**
Group*	3	528	3.79	**0.010**
Treatment	1	528	0.32	0.573

Table 2. Mixed Model results. Significant main effects for EFS score was noted in EFS days ($p<.001$) and preterm Group ($p=.01$).

Group	SHAM		PULSED		SHAM+PULSED (combined)	
	M	*SE*	*M*	*SE*	*M*	*SE*
CLD	49.41	1.05	48.51	0.93	48.84	0.77
HI	51.96	1.21	53.20	0.92	52.85	0.79
IDM	52.42	1.72	51.02	1.42	51.72	1.18
RDS	52.50	1.04	51.34	1.20	52.01	0.80
Total	51.56	0.60	51.15	0.53		

Table 3. Adjusted group means with mixed model analysis**.** Significant differences were found between the clinical infant groups when combined across stimulation conditions (SHAM+PULSED). The combined CLD infant group had significantly lower scores compared to that of the combined HI group and combined RDS group.

Group	SHAM	PULSED
HI	EFS_Score = 51.1859 + 0.150918(EFS_days) + e_i	EFS_Score = 50.9705 + 0.297205(EFS_days) + e_i
IDM	EFS_Score = 52.3398 - 0.0210752(EFS_days) + e_i	EFS_Score = 48.5681 + 0.434685(EFS_days) + e_i
RDS	EFS_Score = 49.7495 + 0.317294(EFS_days) + e_i	EFS_Score = 48.5166 + 0.353637(EFS_days) + e_i
CLD	EFS_Score = 47.2398 + 0.235769 (EFS_days) + e_i	EFS_Score = 45.6216 + 0.282508(EFS_days) + e_i

Table 4. Regression equations for EFS score as a function of PMA days representing *SHAM* and *PULSED* conditions across the four clinical infant groups. A significant difference was found between SHAM and PULSED for the HI preterm infants for slope (p=.005) and intercept (p=.004).

Appendix A: The Early Feeding Skills (EFS) Assessment

Infant______________________________ Date____________ Assessor____

EARLY FEEDING SKILLS ASSESSMENT (EFS)

Oral Feeding Readiness (Immediately Prior to Feeding)	
Able to hold body in a flexed position with arms/hands toward midline.	Yes No
Awake state.	Yes No
Demonstrates energy for feeding – maintains muscle tone and body flexion through assessment period.	Yes No
(Offering infant finger or pacifier) Attention is directed toward feeding – infant searches for nipple or opens mouth promptly when lips are stroked and tongue descends to receive the nipple.	Yes No
Baseline oxygen saturation > 93%.	Yes No

Oral Feeding Skill

(Skills scored along shaded left hand column are considered stable and optimal)

Ability to Maintain Engagement in Feeding				
1. Most common state during the feeding	Quiet alert	Drowsy	Sleep	Fuss/cry
2. Second most common state during the feeding	Quiet alert	Drowsy	Sleep	Fuss/cry
3. Most common muscle tone (Energy infant demonstrates for feeding)	Maintains flexed body position with arms toward midline	Inconsistent tone; variability in tone	Some tone is consistently felt but is somewhat hypotonic	Little or no tone is felt; flaccid, limp most of the time

Ability to Organize Oral-Motor Functioning			
4. Opens mouth promptly when lips are stroked at feeding onsets.	All of the onsets	Some of the onsets	Never
5. Tongue descends to receive the nipple at feeding onsets.	All of the onsets	Some of the onsets	Never
6. Immediately after the nipple is introduced, infant's sucking is organized, rhythmic, and smooth. (Organized sucking has a burst-pause pattern, dysfunctional sucking is demonstrated when the infant bites or clenches jaw, retracts tongue, or shows tongue thrusting)	All of the onsets begin with organized sucking	Some of the onsets	No organized sucking at the onsets
7. Once feeding is underway, maintains an organized, rhythmical, and smooth pattern of sucking. (see above item for further description)	Stable, consistently observed	Some disorganized sucking once feeding is underway	Unable to maintain organized sucking
8. Sucking pressure is steady and strong (i.e., sucks with steady and strong suction).	Stable, consistently observed	Some weak sucking	Frequent weak sucking
9. Able to engage in long sucking bursts (7-10 sucks) without behavioral stress signs or an adverse or negative cardiorespiratory response. (Behavioral stress signs include eyebrow raise, worried look, movement away from nipple, etc.)	Stable, consistently observed	Some long sucking bursts without signs of stress	No long sucking bursts or all long bursts lead to signs of stress
10. Tongue maintains steady contact on the nipple – does not slide off the nipple with sucking creating a clicking sound.	No tongue clicking	Some tongue clicking	Frequent tongue clicking

Ability to Coordinate Swallowing			
11. Manages fluid during swallow without loss of fluid at lips (i.e., no "drooling").	No loss of fluid	Some loss of fluid	Frequent loss of fluid
12. Pharyngeal sounds are clear – no gurgling sounds created by fluid in the nose or pharynx.	Clear	Some gurgling sounds	Frequent gurgling sounds
13. Swallows are quiet – no gulping or hard swallows.	Quiet swallows	Some hard swallows	Frequent hard swallows
14. Airway re-opens immediately after the swallow (high-pitched crowing, "yelping" behavior) after swallow.	No "yelping" sounds	Some "yelping" sounds	Frequent "yelping" sounds
15. A single swallow clears the sucking bolus – multiple swallows are not required to clear fluid out of throat.	All swallows are single	Some multiple swallows	Frequent multiple swallows
16. Coughing or choking sounds.	No event observed	At least one event observed	

Ability to Maintain Physiologic Stability			
17. In the first 30 seconds after each feeding onset, oxygen saturation is stable and there are no behavioral stress cues.	Stable for all of the onsets	Stable for some of the onsets	No stability for any of the onsets
18. Stops sucking to breathe. Feeder does not need to provide a break for breathing.	Consistently stops sucking to breathe	Emerging skill; stops most of the time	Does not yet stop on own to take a breath
19. When the infant stops sucking to breathe, a series of full breaths is observed – sufficient in number and depth	Consistently takes sufficient breaths	Emerging skill; takes sufficient breaths on own most of the time	Frequently does not take sufficient breaths on own
20. Infant stops to breathe before behavioral stress cues are evidenced. (Behavioral stress signs include eyebrow raise, worried look, movement away from nipple, etc.)	Consistently stops to breathe before stress signs	Emerging skill; stops before signs of stress most of the time	Frequently does not stop before stress signs are noted
21. Breath sounds are clear – no grunting breath sounds (prolonging the exhale, partially closing glottis on exhale).	No grunting	Some times of grunting	Frequent grunting
22. Breath sounds are clear – no stridulous breath sounds suggestive of air passing through a restricted airway.	No stridor	Some times of stridor	Frequent stridor
23. Nasal flaring and/or blanching.	Never	Occasional nasal flaring	Frequent nasal flaring
24. Uses accessory breathing muscles (e.g., chin tugging/pulling head back, head bobbing, retracting, tracheal tugging).	Never	Occasional use of accessory muscles	Frequent use of accessory muscles
25. Color change during feeding (pallor, circum-oral or circum-orbital cyanosis).	Never	Occasional color change	Frequent or prolonged color change
26. Oxygen saturation drops below 90%.	Never	Occasionally	Often
27. Heart rate drops below 100 beats per minute.	Never	Occasionally	Often
28. Heart rate rises 15 beats per minutes above the infant's baseline.	Never	Occasionally	Often

Oral Feeding Tolerance (During the 1st 5 minutes Post-Feeding)				
Predominant state	Quiet alert	Drowsy	Sleep	Fuss/cry
Predominant tone of muscles	Maintains flexed body position with arms toward midline	Inconsistent tone; variability in tone	Some tone is consistently felt but is somewhat hypotonic	Little or no tone is felt; flaccid, limp most of the time
Range of oxygen saturation (%):				
Range of heart rate (bpm):				

Feeding Descriptors:

Baseline oxygen saturation ______ Baseline respiratory rate ______ Baseline heart rate ______

Amount of supplemental oxygen pre-feeding _________ during feeding _______

Feeding skills: ☐ maintained across the feeding ☐ improved during the feeding ☐ declined during the feeding

Fed with NG/OG tube in place: Yes / No Type of bottle/nipple used ______________________________

Length of feeding (minutes) ___ Volume consumed ____ cc Position: cradled ☐ side-lying ☐ semi-upright in front ☐

Supportive actions used:	**Oral support provided: Assess infant's tolerance – may increase flow rate**	**Passive actions used which are NOT developmentally supportive:**
☐ Repositioned infant	☐ Support to jaw	☐ Moved jaw up and down
☐ Rested infant	☐ Support to base of tongue	☐ Twisted/turned nipple to encourage sucking
☐ Re-alerted infant	☐ Support to cheeks	☐ Provided rhythmical squeezing action on the cheeks
☐ Slow flow nipple		☐ Jiggled nipple to encourage sucking
☐ Pacing		☐ Pulled nipple in and out to encourage sucking

Primary feeding concerns/recommendations for next feeding: