

# NEONATOLOGY TODAY

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## IN THIS ISSUE

### Synthetic Orocutaneous Stimulation Entrain Suck in Preterm Infants With Feeding Difficulties

by Steven M. Barlow, PhD;  
Meredith A. Poore, MA; Emily  
A. Zimmerman, MA; and  
Donald S. Finan, PhD  
Page 1

### DEPARTMENTS

Salary Survey  
Page 12

Medical News, Products and  
Information  
Page 13

### NEONATOLOGY TODAY

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## Synthetic Orocutaneous Stimulation Entrain Suck in Preterm Infants With Feeding Difficulties

By Steven M. Barlow, PhD; Meredith A. Poore, MA; Emily A. Zimmerman, MA; and Donald S. Finan, PhD

### INTRODUCTION

Suck is a precocial ororhythmic motor behavior in humans and integral to competent oral feeds. However, premature infants often demonstrate oromotor dyscoordination and are unable to suck and feed orally [1,2]. This represents a frequent and serious challenge both to the neonatal intensive care unit (NICU) survivors and the physician-provider-parent teams. The potential causes for delayed or impaired suck development are numerous and may result from neurologic insult to the developing brain, feeding intolerance, or as a result of interventions which interfere with ororhythmic pattern formation. For example, lengthy oxygen supplementation procedures cost the preterm infant precious sensory and motor experiences during a critical period of brain development when the central patterning of suck and feeding skills are being refined. Even the presence of a nasogastric (NG) feeding tube has negative effects on sucking and breathing [3]. Trussing the lower face with tubes and tape also restricts the range and type of oral movements. Interruption of these experiences may impair fragile syntheses of how the brain maps these functions [4,5]. For some preterm infants, poor suck and oromotor dyscoordination may persist well into early childhood and lead to significant delays in the emergence of

other oromotor behaviors, including babbling, speech-language production, and feeding [6,7]. Moreover, failure to establish oral feeding skills in the NICU may result in the infant being sent home on gavage feedings, and hinder the development of coordinated oromotor behavior. The difficulties associated with establishing oral feed competence along with the additional costs for extended hospitalization underscores the need for assessment and therapeutic tools to facilitate the development of normal oral motor skills [8-10].

Infants' readiness to feed is often evaluated by their display of non-nutritive sucking [11]. Suck is manifest in-utero between 15 and 18 weeks gestational age (GA), and is remarkably stable and well-patterned by 34 weeks PMA (post-menstrual age) [12]. The non-nutritive suck is defined as any repetitive mouthing activity on a blind nipple or pacifier, which does not deliver a liquid stimulus [13,14]. The characteristic non-nutritive suck (NNS) pattern consists of a series of bursts and pauses; each burst contains 6 – 12 suck cycles that occur at approximately 2 Hz. The maturation and coordination of the NNS precedes the suck-swallow-breathe pattern associated with the nutritive suck [15-17]. Nutritive suck occurs at a slower average cycle frequency of approximately 1 Hz with fewer inter-burst pauses.

The utility of the NNS for the developing infant has been shown to benefit growth, maturation, and gastric motility, while decreasing stress

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[8,17-21] and enhancing oral feeds [22]. The NNS accelerates the transition from tube to independent oral feeding and is presumed to enhance the maturation of neural systems responsible for ororhythmic activity [23-25]. Recent evidence suggests that the sensory consequences associated with the production of NNS have beneficial effects on oral feeding performance and the development of specific sucking skills [9,10]. Accurate assessment of oromotor dyscoordination in the preterm infant extends beyond the immediate issues surrounding the transition to oral feed competency, and may serve as a powerful clinical marker for neurodevelopmental outcomes as well [26]. Research has shown that infants with perinatal distress and neurologic impairments demonstrate a significantly slower mean rate and greater variability of non-nutritive suck [27]. Also, children with severe neurodevelopmental problems at 18 months tend to have had arrhythmic nutritive expression/suction patterns as premature infants [26].

**SUCK CENTRAL PATTERN GENERATOR**

The mammalian suck is the earliest appearing somatic motor rhythm and is primarily controlled by the suck central pattern generator (sCPG), which consists of bilateral, linked internuncial circuits within the brainstem pontine and medullary reticular formation [28-30] (Figure 1). Based on animal models, the minimal circuitry for ororhythmic activity resides between the trigeminal motor nucleus and the facial nucleus in the brainstem [30]. The sCPG is centrally modulated by multiple inputs, including descending pathways from sensorimotor cortex, and reciprocal connections with the cerebellum which serve to modulate ororhythmic activity. The sCPG can also be modified by sensory input arising from oral mechanoreceptors that encode the consequences of oral movements and external stimulation (i.e., breast, pacifier or bottle nipple, touch, thermal) along central pathways of the trigeminal system. Suck entrainment has been demonstrated in term infants through 6 months of age using a patterned orocutaneous stimulus delivered to perioral and intraoral tissues [31]. Entrainment is defined as the phase locking of centrally-generated suck motor patterns to an applied external stimulus, and represents a powerful method of achieving neural synchrony among sensorimotor pathways. Therefore, it is not surprising that stimulation of the lips and tongue are common methods used to evoke sucking behaviors [9,32].

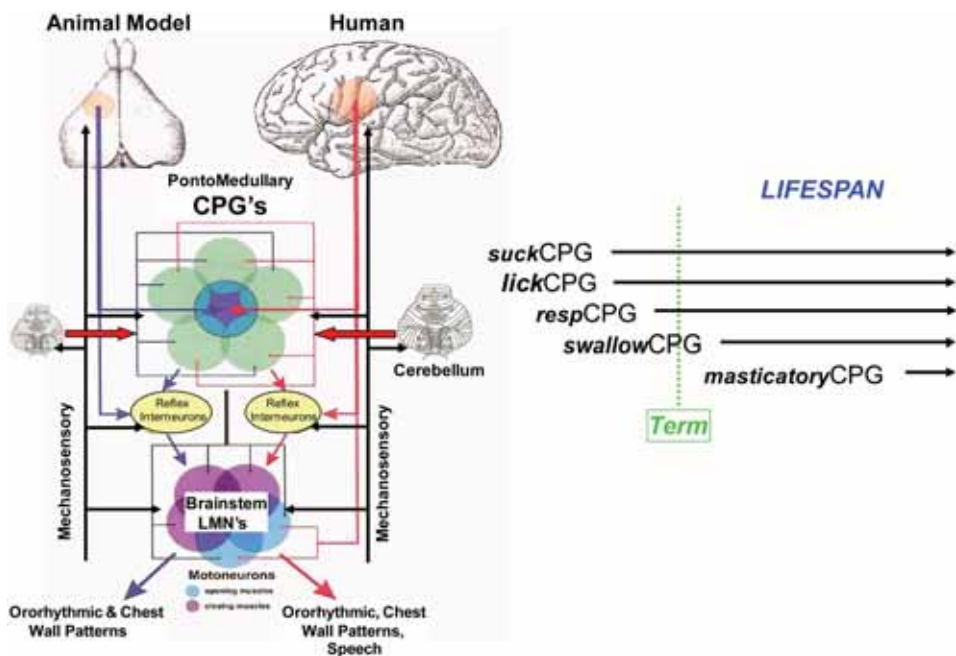


Figure 1. Ororhythmic central pattern generators. An adaptation of a model proposed by Dr. James Lund and colleagues [Lund JP & Kolta A. Brainstem circuits that control mastication: Do they have anything to say during speech? J Commun Disorders 2006; 39: 381-90], and extended to include modulatory inputs from the peripheral afferents [29-31] and the cerebellum [52,53].

**OROMOTOR ENTRAINMENT: NTRAINER™**

These fundamental neurophysiologic principles underlying ororhythmic output and sensorimotor entrainment of the human suck have been translated to a new application for preterm infants who exhibit poor suck and feeding difficulties. A new biomedical device, known as the NTrainer™, was developed in our laboratory. The NTrainer™ was specially designed to synthesize pneumatic pulse trains through a pressurized Soothie® silicone pacifier (Children’s Medical Ventures) which is presented to the infant for alternating 3-minute stimulus epochs during nasogastric gavage (NG) feeds in the NICU. The novel orosensory experience afforded by the NTrainer™ mimics the spatiotemporal dynamics of non-nutritive suck, and has been correlated to rapid organization of suck in infants who exhibit poor feeding skills [33].

The NTrainer™ system consists of a servo-controlled pneumatic actuator and microprocessor that dynamically modulate intraluminal pacifier pressure, and two real-time software modules:  
 (1) NeoSUCK RT™, designed to perform semi-automated digital sampling and

analyses of the infant’s non-nutritive suck and ororhythmic patterning at cribside in the NICU, and  
 (2) NTrain™, designed to deliver patterned orocutaneous stimulation to the infant either during NG or immediately before a scheduled feed (breast/bottle).

**NNS Assessment**

The NNS compression pressure waveforms are digitized periodically (daily recommended) from each infant at cribside 15 minutes prior to a scheduled feed using the mobile NTrainer System™ run-



Figure 2. Soothie and pacifier receiver with Luer cannula for intraluminal pressure transduction.



Figure 3. Cribside in the NICU, testing the NNS in a premature infant with the NTrainer™.

ning the real time software NeoSuck RT™ developed in our laboratory. Infants remain connected to the usual NICU monitors at all times for observation of respiration, heartbeat, and oxygen saturation. An infant-preferred Soothie® silicone pacifier serves as the interface to a specially designed receiver (see Figure 2) which incorporates a lubricated spherical acetyl head and retaining lip coupled to a Luer cannula instrumented with a Honeywell pressure transducer (DC-coupled, low-pass Butterworth @ 50Hz, 3000 samples/sec @ 16-bits voltage resolution).

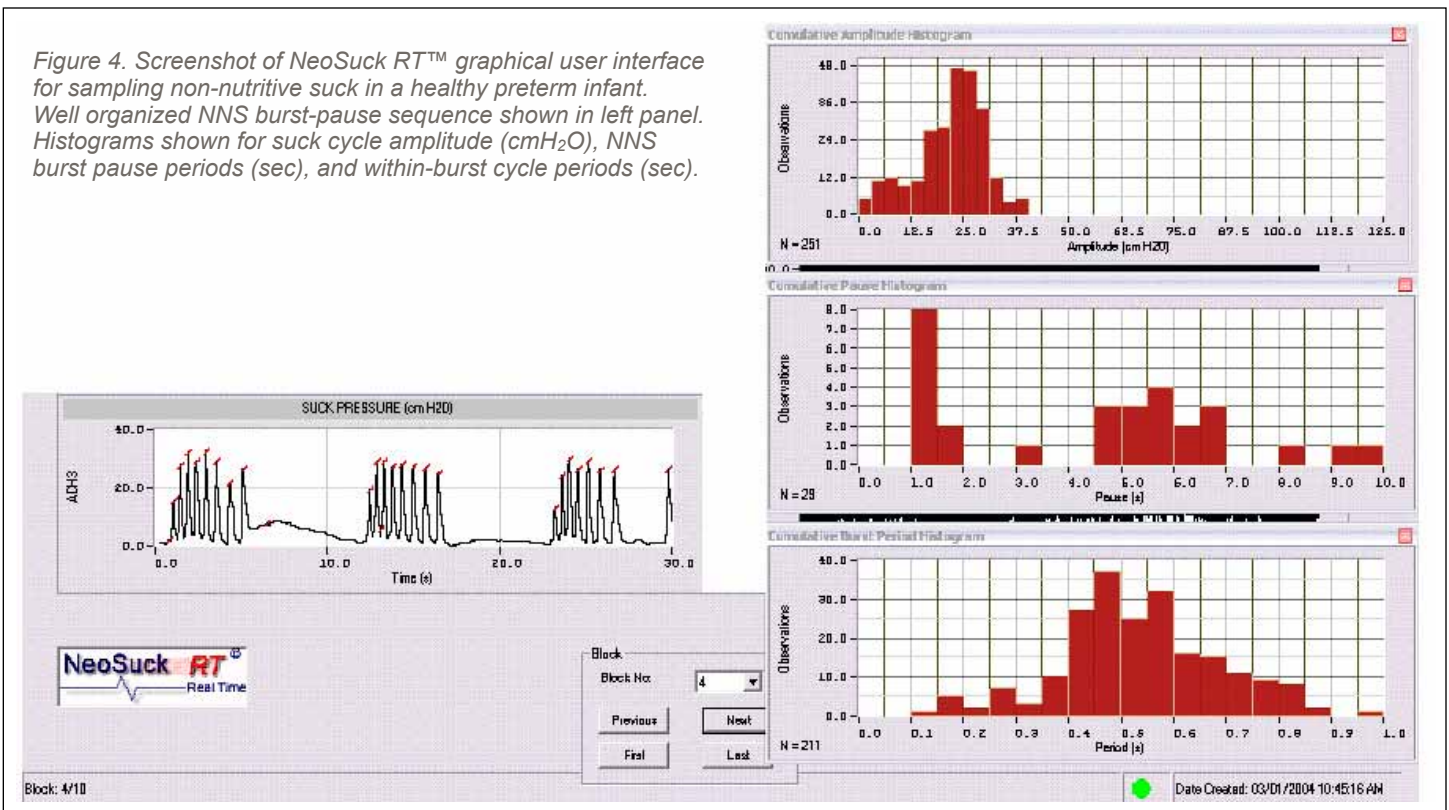
Following a brief examination of physiologic state by the NICU nursing staff, infants are held in a developmentally supportive semi-inclined posture (Figure 3). Background/overhead lighting is dimmed in the immediate area to promote eye contact between the NICU nurse or developmental feeding specialist and the infant. Sampling of NNS behavior is not initiated until the infant achieves an optimal behavioral state, i.e., drowsy to active alert (state 3, 4, or 5 as described by the Naturalistic Observation of Newborn Behavior, Newborn Individualized Developmental Care and Assessment Program; NIDCAP) [34]. Up to five minutes of NNS behavior is typically digitized for each infant per session.

A sample output from the NeoSuck RT™ is shown for a healthy preterm infant at 35 weeks PMA (Figure 4) and a tube-fed RDS preterm infant at 35 weeks PMA (Figure 5). The real time display provides the clinician with the NNS compression waveform and associated histogram updates for suck amplitude (cmH<sub>2</sub>O), inter-NNS burst pause periods (sec), and intra-NNS burst suck cycle periods (sec). For the healthy preterm infant, well-organized NNS bursts with peak pressures averaging 25 cmH<sub>2</sub>O alternate with pause periods of approximately 5.5 seconds. The NNS cycle count for the complete sample is 251. In contrast, the dissolution of the NNS burst structure for the tube-fed RDS infant corresponds to a disorganized nipple compression pattern and indistinguishable NNS bursts. The amplitude of oral compression output is likewise reduced to approximately 5 cmH<sub>2</sub>O, with NeoSuck RT™ able to identify just 65 compression cycles in the total sample of digitized records.

**NTrainer™ Patterned Orocutaneous Stimulus Regimen**

Infants assigned to the NTrain™ regimen receive alternating 3-minute epochs of patterned oral somatosensory stimulation during gavage feeds using the NTrainer™ device. The patterned

Figure 4. Screenshot of NeoSuck RT™ graphical user interface for sampling non-nutritive suck in a healthy preterm infant. Well organized NNS burst-pause sequence shown in left panel. Histograms shown for suck cycle amplitude (cmH<sub>2</sub>O), NNS burst pause periods (sec), and within-burst cycle periods (sec).





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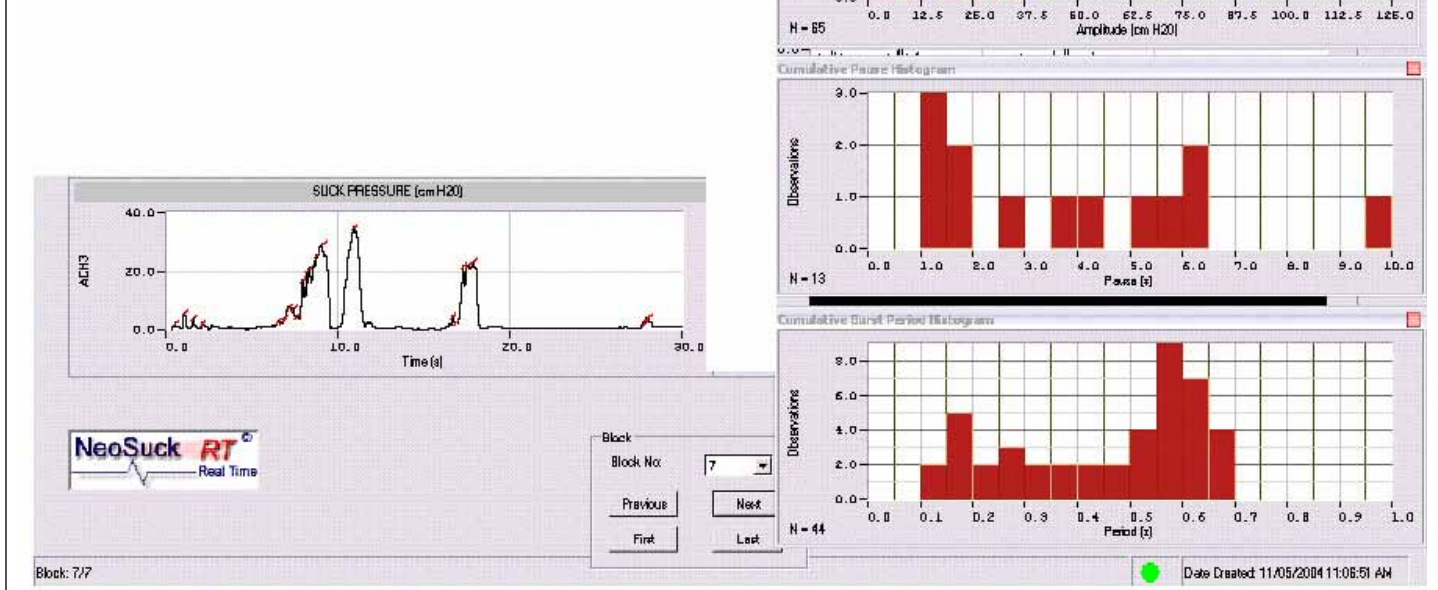
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Figure 5. Screenshot of NeoSuck RT graphical user interface for sampling non-nutritive suck in an RDS preterm infant. Poorly developed NNS burst-pause sequence shown in left panel. Histograms shown for suck cycle amplitude (cmH<sub>2</sub>O), NNS burst pause periods (sec), and within-burst cycle periods (sec).



oral cutaneous stimulation has been programmed to mimic the temporal features of NNS. As shown in Figure 6, precision stimulus control is achieved with a custom designed servo linear motor (H2W Technologies, Inc.) operating under position feedback and coupled in series with a pneumatic Airpel<sup>®</sup> actuator and the pacifier receiver. The device includes an MTS<sup>®</sup> sensor for position feedback control, which is essential for precision stimulus control at the infant's face. A 16-bit digital-to-analog converter is used to synthesize an orocutaneous pneumatic pulse train which consists of a series of 6-cycle bursts and 2-second pause periods. Individual cycles within-burst were presented at 1.8 Hz. This synthetic pulse train is used to drive the servo motor to modulate the intraluminal pressure and shape of the infant's Soothie<sup>®</sup> silicone pacifier (Children's Medical Ventures, Respironics, Inc.). As shown in Figure 7, the changes in intraluminal pressure yield a radial expansion of the pacifier nipple of approximately 135 microns within a 25 millisecond rise/fall time. This novel instrumentation transforms the infant's pacifier into a "pulsating nipple" that resembles the temporal pattern of a well-formed NNS burst. A total of 34 synthetic NNS burst-pause trains are presented to the infant during a single 3-minute NTrain<sup>™</sup> session. Infants are typically treated with the NTrainer<sup>™</sup> stimulus three to four times per day during scheduled gavage feeds over a 10-day period, or until the infant attains 90% oral feeds for two consecutive days.

### Advanced NNS Digital Signal Processing

In our studies of NNS fine structure [35-37], two-minute samples reflecting the most active period of NNS behavior generated by the preterm infant are selected from each data file based on a waveform discrimination-pressure threshold detection algorithm in the NeoSuck<sup>™</sup> software program to index pressure peaks at a user-defined pressure threshold. Identification of the time-amplitude intercepts for individual pressure peaks is achieved by calculation of the first derivative of the pressure signal. Zero-

crossings in the pressure derivative function along with a pressure recruitment rate and hysteresis function are used to index nipple compression pressure peaks in the digitized waveforms. This algorithm permits objective identification of NNS burst activity as distinct from non-organized mouthing compressions. Six objective measures can be extracted from indexed records of suck, including the following minute-rate variables: (1) Total Compressions, defined as the sum of all pressure events per minute, (2) Non-NNS Events, defined as nipple compression pressure events not associated with an NNS burst sequence, (3) NNS Cycles, defined as suck compression cycles with cycle periods less than 1000 milliseconds AND occurring within the NNS burst structure per minute, and (4) the number of NNS Bursts that consisted of two or more nipple compression cycles. The two remaining salient NNS performance measures include (5) mean number NNS Cycles/Burst and (6) a ratiometric calculation known as NNS Cycles%Total, defined as NNS Cycles expressed as a percentage of total nipple compressions ( $[\text{Burst-related NNS Cycles}/\text{Total Mouthing Events}] \times 100$ ).

### NNS Spatiotemporal Index

Our physiological approach to the assessment and habilitation of suck in the NICU includes a functional assessment of the integrity of the neural circuitry driving the suck central pattern generator through an analysis of suck pattern structure and stability. Coordinated non-nutritive suck that is minimally variable from burst-to-burst indicates motor system integrity and is an important foundation for coordination with other emergent behaviors, such as swallow and respiration. A highly promising digital signal processing technique known as the Non-Nutritive Suck Spatiotemporal Index (NNS STI) has been developed to quantify the emergence of stable non-nutritive suck in preterm infants. The mathematical tenets underlying this computational technique have been used successfully to assess kinematic variability and pattern

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- To Tube or Not to Tube Babies with RDS
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Kris Sekar, MD, FAAP

In their in-depth lectures, speakers will describe the use of surfactant pre-extubation, developments in synthetic vs. natural surfactants, and prebiotics/probiotics. Research into inhaled nitric oxide, relative adrenal insufficiency, and hypotension in preterm infants will also be discussed. Nicholas J. Evans, DM, MRCPCH, of the University of Sydney and Royal Prince Alfred Hospital in Australia will deliver the keynote address on "Low Systemic Blood Flow and Neurodevelopmental Outcome."

Kris Sekar, MD, FAAP, of the University of Oklahoma Health Sciences Center and

The Children's Hospital in Oklahoma City, will serve as Chair of this thought-provoking conference. Other members of the Organizing Committee are Jatinder Bhatia, MBBS (Medical College of Georgia), Rangasamy Ramanathan, MD (Keck School of Medicine of USC), and Istvan Seri, MD, PhD (also of the Keck School of Medicine). Faculty members include neonatologists from the United States, Europe and Australia.

The target audience for this important conference includes physicians, nurse practitioners, nurses and other clinicians caring for preterm infants. The faculty will encourage the audience to participate fully in the program, interacting with not only the speakers but also with one another, and offering their own insights and perspectives into recent research and patient care in neonatal medicine. An Audience Response System will be used to help determine what participants have learned.

This annual conference will be co-sponsored by the Annenberg Center for Health Sciences at Eisenhower and the Keck School of Medicine of USC and supported by an independent educational grant from DEY, L.P.

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#### Introduction

In 2004, there were more than half a million preterm births in the US (about 12.5% of live births). The problems encountered by a premature infant are related to the immaturity of the organ systems. The infant requires specialized care until his or her organ systems have developed enough to sustain life without specialized support. Depending on the extent of prematurity, this may take weeks to months. This meeting will continue the examination of newly developing treatment options for these problems, while reviewing current evidence for treatment protocols. International thought leaders in the field will help clarify desired and efficacious treatment options.

#### Learning Objectives

Upon completion of this activity, participants should be better able to:

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2. Incorporate current knowledge of surfactants into practice
3. Utilize appropriate interventions for hemodynamic problems
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formation in limb [38,39] and speech [40,41] motor subsystems. The NNS STI provides the clinician with a single numerical value, calculated from the cumulative sum of the standard deviations of an amplitude- and time-normalized set of suck pressure waveforms, and represents the stability of the infant's oromotor sequence. In essence, this measure provides a quantitative composite index of non-nutritive suck pattern stability. This metric eliminates the need to count suck pressure peaks or measure individual cycle periods. Instead, the Non-Nutritive Suck Spatiotemporal Index is designed to quantify the infant's suck over a selected burst pattern epoch, thereby providing NICU clinicians with a summative index or 'gestalt' of oromotor pattern formation and stability. Obtaining a two-minute sample of NNS behavior daily in the NICU with the NTrainer™ cribside system is sufficient to chart an infant's progress toward stable suck production [42].

The NNS STI measure has also been used successfully to document the effects of the NTrainer™ patterned orocutaneous therapy on suck development among tube-fed premature infants with respiratory distress syndrome who have endured, on average, 40 days of oxygen supplementation therapy [43]. An example of suck pattern formation at 35 and 38 wks PMA is shown for two tube-fed RDS infants designated as Control (Figure 8A) and NTrainer™ (Figure 8B). The Control infant was given a regular Soothie® pacifier during gavage feeds, whereas the NTrainer™ infant received the patterned orocutaneous stimulation through the pressurized Soothie® silicone pacifier, all other conditions being equal. For Figures 8A and 8B, the upper panels include 5 superimposed raw NNS waveforms. The lower panels in each figure show the result of the waveform normalization associated with the NNS STI digital signal process, along with the Spatio-temporal Index value. A higher value translates to poor suck burst pattern formation, whereas a lower value indicates suck burst pattern stability. As shown for the Control infant who did not receive NTrainer™ therapy, a small gain (STI=89 @ 35 wks PMA versus STI=81 @ 38 wks PMA) was apparent in the NNS burst pattern, whereas the NTrainer™ infant manifests remarkable improvement (STI=99 @ 35 wks PMA versus STI=50 @ 38 wks PMA) in suck pattern formation and stability of the NNS burst.

## SUMMARY AND CONCLUSIONS

Fortunately for the human infant, the brainstem sCPG is responsive to peripheral input [28,31,32] and adapts to changes in the local oral environment [37]. The collective results from studies in our laboratory demonstrate the potent effects of a motorized silicone pacifier nipple on the development of NNS in preterm infants. The patterned orocutaneous experience is physiologically salient and spectrally patterned to resemble the 'burst-pause' structure of the NNS. This form of stimulation serves to entrain the activity patterns of populations of mechanoreceptor afferents located in the lips, tongue, and jaw of the neonate, which in turn influence the firing patterns of the respective orofacial lower motor neurons. This is a central tenet of one of the basic principles of pathway formation, namely 'neurons that fire together, will wire together' [44].

The application of mechanosensory entrainment as a habilitation strategy has ecological validity in assisting the infant to produce appropriate oromotor output. Moreover, this approach is consistent with contemporary ideas on the role of sensory-driven neural activity in pathway formation [45,46], and the notion that appropriate oral experiences may be critical in the final



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weeks of gestation for the formation of functional central neural circuits.

The richness of the patterned orocutaneous experience offered by the NTrainer™ presents a new and exciting neurotherapeutic application for the habilitation of suck in premature infants in the NICU [47]. Repeated exposure to patterned orocutaneous events, on the order of 30 minutes per day in the NICU concurrent with NG tube feeds over the course of 7 to 10 days, provides the preterm infant with a neural entrainment experience



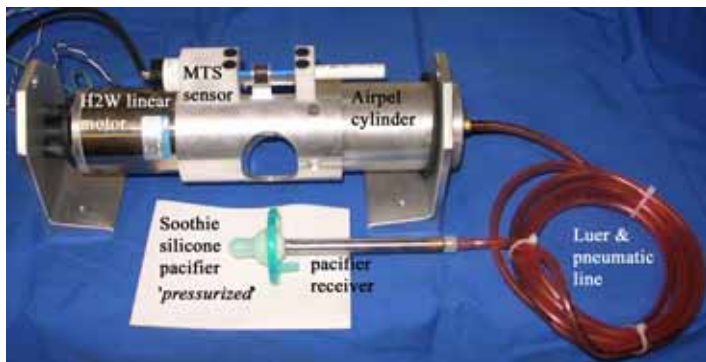


Figure 6. The servo-controlled pneumatic linear actuator engineered in our laboratory for the NTrainer™ system to produce synthetic patterned orocutaneous stimulation in preterm infants.

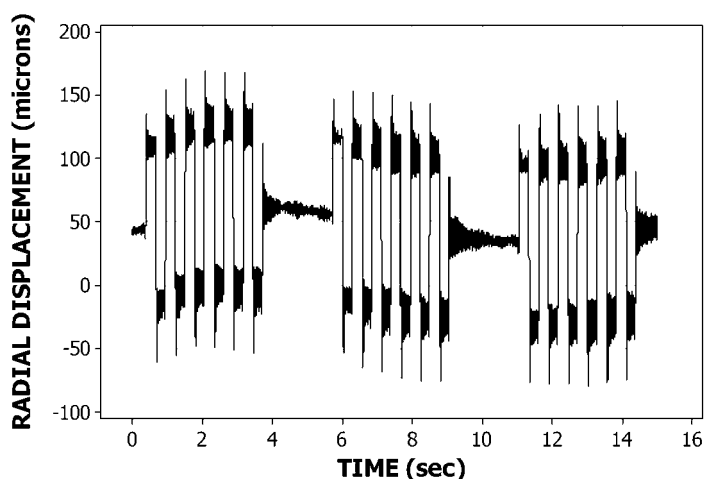


Figure 7. A sample waveform representing the radial displacement of the pacifier nipple during NTrainer™ stimulation. The synthetic pulse train used to mimic NNS burst-pause structure consisted of a series of 6-cycle bursts and 2-second pause periods. Within-burst cycle rate was 1.8 Hz. Radial displacement of the silicone Soothie® nipple is approximately 135 μm.

that facilitates the development and strengthening of central pathways that regulate suck. Use of an orocutaneous entrainment stimulus also has the distinct advantage of being safe and pleasurable for the neonate, and easily administered by the physician-provider-parent teams in the NICU. Establishing the non-nutritive suck provides the infant with additional benefits, including improved state control pre-feed [18,20,48-50] and post-feed [51], growth, maturation, and gastric motility, while decreasing stress and enhancing the transition to oral feeds [22].

Establishing the NNS with patterned orocutaneous stimulation promotes the development of specific sucking skills [9,10], provides the infant a significant advantage in the transition from tube to independent oral feeding, and is presumed to enhance the maturation of neural systems regulating ororhythmic activity [23-25].

The NTrainer™ system has received the 510K certification from the United States Food and Drug Administration and is being commercially developed by KC BioMedix, Inc. (23733 West 83rd Terrace; Shawnee, KS 66227; Michael Litscher, CEO [mlitscher@kcbiomedix.com](mailto:mlitscher@kcbiomedix.com); TL: 913 585 3500; FX: 913 585 3501; CL: 913 515 0116), with patent licensing through the

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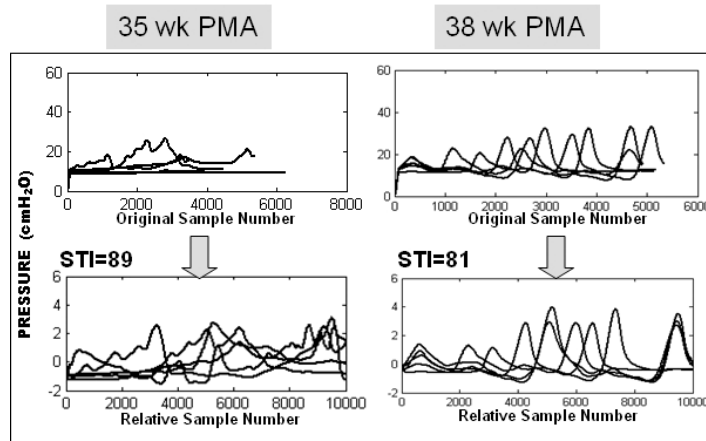


Figure 8A. Depicts the Non-Nutritive Suck Spatiotemporal Index digital processing results for a Control (non-stimulated) tube-fed infant with RDS at 35 weeks post-menstrual age (PMA) and again at 38 wks PMA. Upper panels show 5 superimposed raw NNS records. Bottom panels show the normalized NNS records and resultant STI values.

NTRAINER

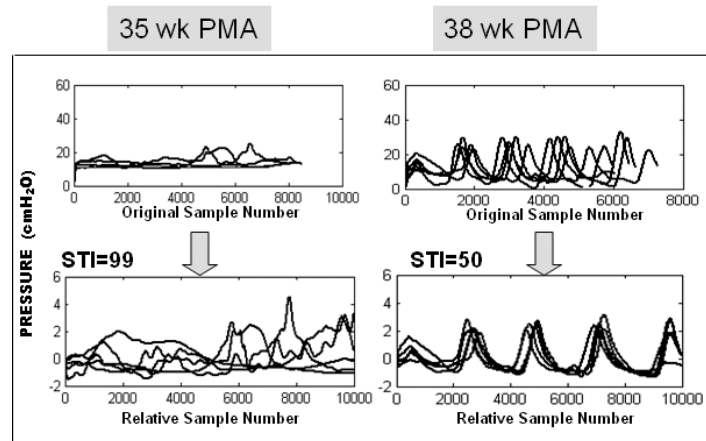


Figure 8B. Depicts the Non-Nutritive Suck Spatiotemporal Index digital processing results for an NTrainer™(received patterned orocutaneous stimulation) tube-fed infant at 35 weeks post-menstrual age (PMA) and again at 38 wks PMA. Upper panels show 5 superimposed raw NNS records. Bottom panels show the normalized NNS records and resultant STI values.

University of Kansas. Phase II randomized clinical trials are currently underway at two centers, including Wake Medical Center in Raleigh, North Carolina and Overland Park Regional Medical Center in Overland Park, Kansas. These trials will explore issues of feeding readiness and oral feed competence in preterm infant populations at-risk for feeding disorders and poor neurodevelopmental outcome.

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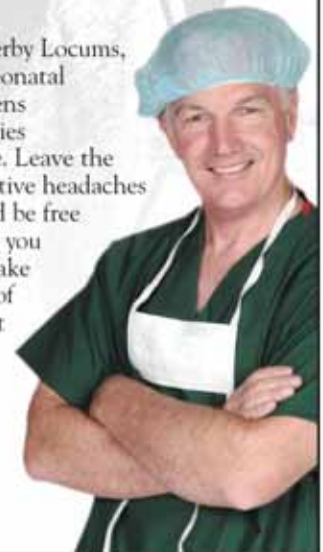
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**Corresponding Author:**

*Dr. Steven M. Barlow*  
 Professor, SPLH-Neuroscience  
 University of Kansas  
 1000 Sunnyside Avenue  
 Lawrence, KS 66045, USA  
 sbarlow@ku.edu  
 TL: 785-864-4447; FX: 785-864-4403



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## Medical News, Products and Information

### LA BioMed Researchers Find Few Emergency Rooms Fully Equipped for Pediatric Patients

In the first survey to specifically measure hospital pediatric preparedness, a team of Los Angeles Biomedical Research Institute (LA BioMed) researchers found few U.S. emergency rooms are properly equipped for children.

The survey by Drs. Marianne Gausche-Hill, Charles Schmitz and Roger J. Lewis was reported in the December issue of *Pediatrics*, the peer-reviewed journal of the American Academy of Pediatrics. The team of LA BioMed researchers found only 6% of the 1,489 emergency rooms that responded to the survey had all the medicine and equipment the American Academy of Pediatrics (AAP) and the American College of Emergency Physicians (ACEP) recommend.

For instance, half of those responding reported that they were missing the laryngeal airways mask used for ventilating children.

Seventeen percent of the hospitals that responded to the survey did not have Magill forceps for removing foreign bodies from a child's airway, said Dr. Gausche-Hill. This equipment may be life-saving, so this study highlights important issues for patient safety.

The study found 89% of pediatric (ages: 0-14 years) emergency department visits occur in non-children's hospitals. About a fourth of these visits take place in rural or remote facilities. Only 6% occur in a separate pediatric emergency department.

More than half the emergency departments reported they had a quality improvement or performance improvement plan for pediatric patients, and 59% said they were aware of the American Academy of Pediatrics/American College of Emergency Physicians guidelines.

Hospitals that were more prepared tended to be urban, to have higher volumes, to have a separate care area for pediatric patients, to have physician and nursing coordinators for pediatrics, to be aware of the AAP/ACEP guidelines, and to be interested in guideline implementation, the researchers concluded. The study also demonstrates that much work is left to be done to improve pediatric preparedness of (Emergency Departments) EDs. Additional work should explore the relationship of preparedness to quality of care delivered, delineate barriers to guideline implementation, and identify best practices that can be coordinated within emergency care systems to improve the preparedness of EDs to care for children.

*Pediatrics* is the official, peer-reviewed journal of the American Academy of Pediatrics. It may be viewed at <http://pediatrics.aappublications.org/>.

#### About LA BioMed

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#### Caffeine Use to Regulate Breathing of Very Preterm Babies, Long-term Benefits

Very premature babies who were given caffeine to regulate their breathing have a significantly lower incidence of disabilities at the age of two years, according to an international study led by researchers at

McMaster University, Hamilton, ON, Canada.

Researchers studied more than 2000 premature babies who were either treated with caffeine or given a placebo. The latest results of this large clinical trial will appear in the Nov. 8 issue of the *New England Journal of Medicine (NEJM)*. Babies receiving the caffeine were less likely to develop cerebral palsy and cognitive delay.

Caffeine and similar drugs have been used for more than 30 years to make the breathing of very preterm babies more regular, but without sufficient knowledge of the possible benefits and risks.

The study involved infants who weighed between 500 and 1250 grams at birth, and who were at risk of apnea interrupted or irregular breathing due to immaturity. The ongoing study, with colleagues in Canada, Australia, the US, Europe and Israel, will continue to follow the children until they reach the age of five. The project is funded by the Canadian Institutes of Health Research and the National Health and Medical Research Council of Australia.

According to Dr. Barbara Schmidt, the principal investigator of the research project, the latest results of the study showed that 46% of the infants receiving the placebo died or survived with a neurodevelopmental disability. Among the babies receiving caffeine therapy, only 40% had an unfavourable outcome by the time they reached the end of their second year of life.

It definitely gives hope to parents, Dr. Schmidt concluded. Of all the drugs we use in the neonatal intensive care unit, caffeine is the first to have been shown conclusively to reduce long-term disability in very preterm babies. Caffeine reduced the rates of cerebral palsy and cognitive delay but had no significant effect on the rates of death, bilateral blindness and severe hearing loss.



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"This international study provides important follow-up to the earlier results reported by Dr. Schmidt and her colleagues and should have a major impact on the treatment and prevention of apnea in preterm infants," said Dr. Michael Kramer, Scientific Director of the CIHR Institute of Human Development, Child and Youth Health.

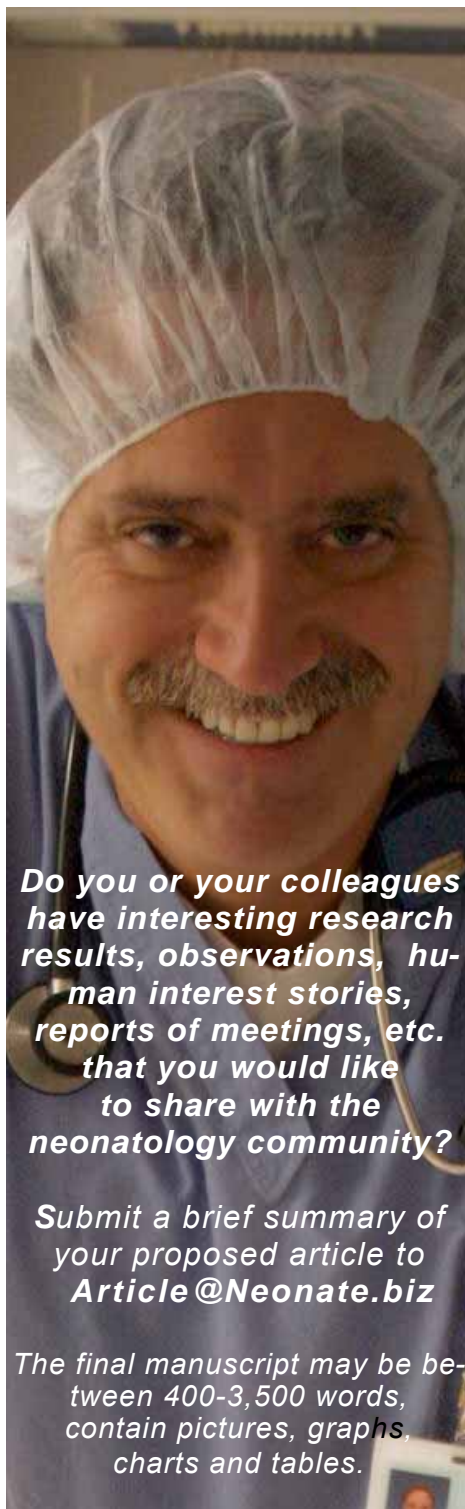
The Caffeine for Apnea of Prematurity (CAP) project enrolled 2006 premature infants who were born between October 1999 and October 2004 in nine countries. The research project was designed to address long-standing concerns about possible adverse effects of caffeine therapy in pre-term infants. All children will be re-assessed at five years to obtain more precise information on their development as they approach school age.

Apnea occurs in about 85% of infants who are born at less than 34 weeks gestation. For more than 30 years, therapies known as methylxanthines, including caffeine, have been used to reduce the frequency of apnea and the need for mechanical ventilation. However, it has remained uncertain whether the use of methylxanthines has any additional benefits or risks in premature infants.

Earlier findings released last year by the same research team revealed that babies who received caffeine had a lower incidence of abnormal lung development than infants who were given a placebo.

Dr. Schmidt said that half of the beneficial treatment effect at two years of age was explained by the fact that babies receiving caffeine therapy came off ventilators sooner. Ventilation is a double-edged sword, she said. While it is life-saving, at the same time, it causes injury scarring the immature lung which is very susceptible to damage.

At McMaster, Dr. Schmidt is a part-time professor in the department of clinical epidemiology and biostatistics of the Michael G. DeGroot School of Medicine. She is also a professor of pediatrics at the University of Pennsylvania School of Medicine and will hold the inaugural Kristine Sandberg Knisely Chair in Neonatology at the Children's Hospital of Philadelphia.



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