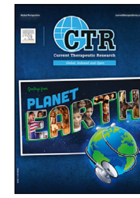
Current Therapeutic Research 93 (2020) 100617

Contents lists available at ScienceDirect

Current Therapeutic Research

journal homepage: www.elsevier.com/locate/curtheres



Effect of Pacifier Design on Nonnutritive Suck Maturation and Weight Gain in Preterm Infants: A Pilot Study

Alexander Ziegler, DDS[1,**], Jill L. Maron, MD[2,3], Steven M. Barlow, PhD[4,5], Jonathan M. Davis, MD[2,6,*]

[1] Pediatric Dental Medicine, Tufts University School of Dental Medicine, Boston, Massachusetts
[2] Department of Pediatrics, Tufts Children's Hospital, Boston, Massachusetts
[3] The Mother Infant Research Institute, Tufts Medical Center, Boston, Massachusetts
[4] Department of Special Education and Communication Disorders, University of Nebraska-Lincoln, Lincoln, Nebraska
[5] Department of Biological Systems Engineering, University of Nebraska-Lincoln, Lincoln, Nebraska
[6] The Tufts Clinical and Translational Science Institute, Tufts Medical Center, Boston, Massachusetts

ARTICLE INFO

Article history:
Received 30 June 2020
Accepted 8 November 2020

Key words:
Nonnutritive sucking
NTrainer
pacifier design
preterm infants
weight

ABSTRACT

Background: Pacifiers are effective in promoting oral feeding by increasing the maturation of nonnutritive sucking to nutritive suck in preterm neonates. It is unclear whether pacifier design can influence suck dynamics and weight loss during the first week of life.
Objectives: This pilot study examined the feasibility of studying the effect of pacifier design on suck maturation and weight loss in preterm neonates.
Methods: Twenty-five preterm neonates (mean [SD] birth weight 1791 [344.9] grams, mean [SD] gestational age 33.1 [1.2] weeks) were studied in a single newborn intensive care unit. Neonates were assigned to either an orthodontic pacifier (n = 13) or a bulb-shaped pacifier (n = 12) immediately after birth. Suck dynamics (cycles per minute, total compressions per minute, cycle bursts, and amplitude) were assessed with an NTrainer (Innara Health, Olathe, Kansas). Weight was recorded during the first week of life on day 1.2 (±2.5 days) and day 6.0 (±2.1 days). Descriptive statistics were applied to analyze data.
Results: No significant differences were seen between groups with respect to birth weight and gestational age. Reproducible nonnutritive sucking measurements could be obtained with the NTrainer, with both types of pacifiers. No differences were detected in nonnutritive sucking dynamics or weight loss over time within each group or between groups.
Conclusions: Data indicate that it is feasible to measure nonnutritive sucking dynamics and associated weight loss in relation to pacifier design in preterm neonates. Larger trials over longer time periods are needed to determine whether pacifier design influences suck dynamics and maturation, oromotor function, feeding/weight loss, and dental formation in preterm neonates. (*Curr Ther Res Clin Exp.* 2020; 81:XXX–XXX)

Introduction

The United States has the highest rate of preterm birth of any developed country in the world.[1] The costs of prematurity exceed $29 billion per year, with the smallest premature neonates (23-27 weeks' gestation) remaining in the hospital for prolonged periods of time until they demonstrate sufficient weight gain and are able to safely maintain adequate oral intake to be safely discharged. It can take months for most preterm neonates to learn how to feed orally due to significant oromotor immaturity and dysfunction.[2] Preterm neonates must progress from a nonnutritive sucking (NNS) pattern to a more mature rhythmic nutritive suck pattern in order to orally feed and be discharged home.[3] NNS using a pacifier has been shown to be an effective intervention to stimulate suck dynamics and feeding maturation, resulting in improved weight gain and faster discharge from the hospital in preterm neonates.[4]

The orthodontic pacifier was designed using the concepts of peristaltic action of the tongue, tongue proprioception, and palatal

* Address correspondence to: Jonathan M. Davis, MD, Department of Pediatrics, Tufts Children's Hospital, 800 Washington St, Boston, MA 02111.
E-mail address: jdavis@tuftsmedicalcenter.org (J.M. Davis).
** Present Address - Department of Pediatric Dentistry, LECOM School of Dental Medicine Bradenton, FL.

https://doi.org/10.1016/j.curtheres.2020.100617

Figure 1. Views of a bulb- or cherry-shaped pacifier.

Figure 2. Posterior, lateral, and superior views of the orthodontic pacifier.

support.[5] In comparison, the traditional bulb pacifier is based on the shape of the human nipple. The design concepts are important for future dentoalveolar development and may enhance NNS and growth.[6] The shape of the orthodontic bulb is ergonomically designed to the physiology of the intraoral environment. This includes concavity of the dorsal portion where tongue contact is greatest, tapering of the lateral transverse edges for tongue cupping, and sufficient stiffness to prevent bulb collapse. Bulb interaction with the tongue is an important factor for oral feeding.[7]

Previous studies have shown that the mechanical properties of pacifier design, including materials stiffness, conformation, and texture can have a significant influence on NNS patterning in term neonates.[7–9] However, little is known on how pacifier design can influence neonatal outcomes such as suck maturation/dynamics and weight gain/loss in preterm neonates. This feasibility pilot study was conducted to assess the influence of pacifier design on these clinical outcomes. We hypothesized that pacifier design could influence suck maturation and weight gain/loss.

Methods

Experimental design

Twenty-five preterm neonates were enrolled. Gestational age was determined by first trimester obstetric ultrasound or by dating. Each neonate was provided 1 of 2 pacifiers: the bulb shaped Soothie (Advent, Glamsford, Suffolk, United Kingdom) pacifier (Figure 1) or the orthodontic Smilo (Smilo, Wayland, Massachusetts) pacifier (Figure 2) continuously over the first week of life whenever the bedside nurse decided it was needed (eg, during tube feedings or if agitated). Pacifier assignment alternated between each enrolled preterm neonate. Each pacifier is Food and Drug Administration approved and routinely used in preterm neonates to promote growth and oral feeding. The NTrainer (Innara Health, Olathe, Kansas), a Food and Drug Administration-approved device for use in preterm neonates, was placed in assessment mode to record sucking rhythm and suck-breathing patterns to better determine maturation processes known to be associated with successful oral feeding. The NTrainer device comes coupled to a standard bulb-shaped silicone pacifier. The orthodontic pacifier was fit to the NTrainer and was able to generate accurate and reproducible pressure signals. At the conclusion of the study, preterm neonates received their usual care in the neonatal intensive care unit (NICU).

The designated pacifier was used for at least 1 day before being assessed with the NTrainer with both designs well tolerated. All preterm neonates were studied on day 1.5 (±2.5 days) (time point 1) and day 6.0 (±2.4 days) (time point 2) after initial introduction of the pacifier. The NTrainer recorded the compression dynamics of NNS during a 3-minute session that immediately preceded a tube feeding (not associated with any other intervention). The most active 2-minute period of NNS behavior based on suck cycle count was automatically extracted from each data file using an automated waveform feature extraction algorithm.[10] The NNS pressure waveform was band-pass filtered (0.5–20 Hz) to remove low frequency offsets due to tongue/jaw posturing and thermal drift associated with oral contact on the pacifier and to also remove high-frequency jitter. Pressure peaks >1.6 cm H_2O were subjected to feature extraction criteria, including suck cycle symmetry, cycle duration, and burst identification (defined as 2 or more NNS events occurring within 1200 ms). This algorithm permits objective identification of NNS burst activity distinct from non-NNS mouthing compressions or tongue thrusts against the pacifier. Four measures were objectively extracted, including minute-rates for: NNS cycle events defined as suck compression cycles within periods <1200 ms, NNS bursts where an individual burst includes 2 or more suck cycles, total oral compressions defined as the sum of all pressure events, and NNS compression pressure.

Preterm neonates advanced on a standardized cue-based feeding schedule known as Infant Driven Feeding.[11,12] This standardized oral feeding advancement limited confounders that could have ultimately skewed the data. Preterm neonatal data were managed with the Neonatal Oromotor Database (University of Nebraska, Lincoln, NE), a custom software program designed specifically for NTrainer studies. This software provides a paperless, efficient system for NICU study personnel to log daily information, including gestational/postnatal age, growth parameters, medications, oxygen requirements, and feeding history. Associations between suck dynamics/maturation, pacifier type, and weight loss (which normally occurs in all preterm neonates in the first week of life) were analyzed for each patient group. The neonate's weight during the 2 time periods was recorded by the NICU nurses and any weight loss calculated.

Pacifier assignment, sample size, and statistical analyses

Preterm neonates were consecutively assigned into 2 groups: neonates assigned to use the bulb-shaped pacifier and those assigned to the orthodontic pacifier. Although it was impossible to blind the bedside nurses or the technician performing the NTrainer assessment, the primary investigators and those performing the data analysis were blinded to group assignment. Descriptive statistics were used to show the mean NNS measurements and weight, absolute differences in weight, and percent change in weight over the 2 time points for each pacifier group.

Patient criteria

Inclusion criteria

Neonates born between $30^{0/7}$ and $35^{0/7}$ weeks' gestation.

Exclusion criteria

Patients were not included in the study in the case that the neonate had chromosomal and congenital anomalies, including craniofacial malformations, central nervous system anomalies, cyanotic congenital heart disease, gastroschisis, omphalocele, diaphragmatic hernia, and/or other major gastrointestinal anomalies; congenital infection; significant intrauterine growth retardation (<10%); abnormal neurological status (eg, grades III and IV intraventricular hemorrhage, seizures, or meningitis); history of necrotizing enterocolitis (stage II and III); and culture-positive sepsis at the time of study enrollment.

Table 1
Comparative data by pacifier group.

Characteristic	Orthodontic (n = 13)	Bulb (n = 12)
Gestational age*, wk	33.3 (1.1)	32.9 (1.2)
Birth weight*, kg	1.78 (0.67)	1.55 (0.55)
Sex		
Male	8	7
Female	5	5
Delivery method		
Vaginal	8	5
C-section	5	7
Race		
White	6	6
Black	4	2
Hispanic	2	4
Asian	1	0
Other	0	1

* Values are presented as mean (SD).

Subject participation

Recruitment

Parents of potential patients were approached by the investigators who explained the study and answered all questions. Recruitment occurred in the NICU at Tufts Medical Center. Because the study was considered a quality improvement project, the Tufts Health Sciences Institutional Review Board did not require informed consent. However, verbal permission from parents was obtained before study enrollment and NNS measurements.

Results

Pacifier design and growth

Twenty-five preterm neonates (mean [SD] birth weight 1791 [345] grams and mean [SD] gestational age 33.1 [1.2] weeks) received an orthodontic pacifier (n = 13) or bulb-shaped pacifier (n = 12) for the first week of life. The groups were similar with respect to birth weight, gestational age, mode of delivery, and race (Table 1). The orthodontic treated group had a mean (SD) percent weight loss of 3.0% (5.4%) compared with 4.7% (4.5%) for the bulb-shape treatment group (Table 2).

Pacifier design effect on NNS

During the study, NNS variables were measured, including bursts where an individual burst includes 2 or more suck cycles, cycle events defined as suck compression cycles with cycle periods $<$1200 ms, Total oral compressions defined as the sum of all pressure events, and amplitude (NNS compression pressure). No clinically meaningful differences were seen in NNS dynamics over time within each group or between groups (Table 2). Complete data were available on fewer neonates than initially planned because of technical errors that occurred during the study (Table 2). This included difficulties with group assignment and NNS measurements, so NNS measurements and weights were not included for these infants.

Discussion

NNS is an early motor reflex, characterized by bursts of suck and pauses for respiration.[8] It is the first stage of oromotor function and is controlled in the brainstem by a suck central pattern generator.[13] The suck central pattern generator allows the neonate to make rapid changes in NNS in the presence of a nipple.[14] Pacifier type may have a substantial influence on NNS such as burst duration, cycles per burst, and cycles per minute. A previous study suggested that the bulb-shape pacifier may promote NNS compared with other commercially available pacifiers in full-term infants.[8] However, this study only included pacifiers that were available at the hospital of study and did not include orthodontic pacifiers, which are routinely used today. Pacifiers vary in design, including the orthodontic pacifier and bulb-shape pacifier. By coupling each pacifier with the NTrainer, the effect of pacifier design on the preterm neonate could be assessed. Although these methods have been used to study full-term infants, the feasibility of accurately and reproducibly measuring NNS with different pacifier design in preterm neonates was the primary goal of the present study. The novel aspect of this study is the preterm neonatal population and the use of an orthodontic pacifier

The orthodontic shaped pacifier has been designed to optimize the peristaltic action of the tongue, tongue proprioception, and palatal support (Figure 2). In comparison, the bulb-shape pacifier is based on the shape of the human nipple (Figure 1). These concepts are important for dentoalveolar development and may serve to enhance NNS, oromotor maturation, and growth at the same time.[6]

Previous studies have shown that NNS in preterm neonates improves suck maturation and weight gain, including studies in preterm neonates who generally lack coordination between sucking, swallowing, and respiration.[3] Before neonates can be discharged from the hospital, they must be able to feed orally, maintain physiologic stability, and demonstrate adequate weight gain.[15] When compared with controls or no intervention, preterm neonates demonstrated improved sucking skills and weight gain when a pacifier was employed.[16] Pacifier use also results in a shorter time to achieve full breastfeeding and discharge compared with those who did not use pacifiers.[3] No studies have objectively examined whether or not specific pacifier design influences suck maturation and weight in preterm neonates. This study established the feasibility of studying 2 distinct pacifier designs to assess whether there were differences in NNS and weight loss in preterm neonates in the first week of life. Previous studies have shown that pacifiers are effective for improving suck patterns in preterm neonates.[4,7–9] Although this study was not able to demonstrate that NNS and weight loss were subtantially different between pacifiers, this study was not powered to make

Table 2
Changes in nonnutritive sucking (NNS) dynamics/weight by pacifier group.

Measurement	Orthodontic (n = 10) Time point 1	Orthodontic (n = 11) Time point 2	Bulb (n = 10) Time point 1	Bulb (n = 8) Time point 2
NNS cycles per minute	15.1 (12.2)	15.0 (17.1)	10.7 (9.9)	23.2 (23.8)
Total compressions per minute	108.0 (51.9)	109.4 (54.2)	118 (32.5)	113.7 (53.8)
NNS cycles burst	2.7 (1.9)	2.5 (1.4)	2.8 (1.7)	3.6 (2.6)
AMP, cm H_2O	9.0 (6.1)	8.0 (7.2)	12.0 (11.9)	18.5 (17.6)
Weight*, kg	1.87 (0.40)	1.82 (0.44)	1.70 (0.27)	1.63 (0.28)
Weight* change	−3.04 (5.4)		−4.72 (4.5)	

AMP = Amplitude.
* Values are presented as mean (SD).

clinically significant conclusions. Although there were no noted differences in weight loss or NNS suck dynamics between the 2 treatment groups, a larger sample size should be used in future studies to more definitively determine whether pacifier design can affect NNS, feeding, and weight loss/gain in preterm neonates. If significant results are seen, it may show that either the orthodontic or bulb-shape pacifier can improve the ability of infants to feed and be discharged from the hospital earlier.

Conclusions

Both pacifiers are Food and Drug Administration approved for use in preterm neonates. No safety concerns were identified. Data suggest that NNS suck dynamics can be measured with each pacifier type using the NTrainer. These findings provide support for examining distinct pacifier designs and assessing any differences in NNS, suck maturation, and weight loss in a larger sample of preterm neonates over longer periods of time. This approach would represent a low-cost, high-yield intervention to improve suck dynamics/maturation, oral feeding, and weight gain, while promoting earlier hospital discharge.

Declaration of Competing Interest

The authors have indicated that they have no conflicts of interest regarding the content of this article.

Acknowledgments

The authors thank Janis Breeze and Tara Fleckner for biostatistical support and Sara Dar for technical support.

This work was supported by the Tufts Clinical and Translational Science Award from National Institutes of Health (No. UL1TR0025).

A. Ziegler was responsible for conceptualization, formal analysis, investigation, data curation, writing the original draft, and visualization. J. L. Maron was responsible for onceptualization, development or design of methodology, validation, formal analysis, investigation, resources, data curation, writing original draft, supervision, project administration, and funding acquisition. S. M. Barlow was responsible for software, validation, resources, and writing (review/editing). J. M. Davis was responsible for conceptualization, development or design of methodology, validation, formal analysis, investigation, resources, data curation, writing the original draft, supervision, project administration, and funding acquisition.

References

1. March of Dimes 2019 Report Card Shines Spotlight on the U.S. Maternal and Infant Health Crisis. marchofdimes.org 2/10/2020
2. Asadollahpour F, Yadegari F, Soleimani F, Khalesi N. The effects of non-nutritive sucking and pre-feeding oral stimulation on time to achieve independent oral feeding for preterm infants. *Iranian J Pediatr*. 2015;25:e809.
3. Pickler Rita H, et al. Effects of nonnutritive sucking on behavioral organization and feeding performance in preterm infants. *Nursing research*. 1996;45(3):132–135.
4. Kaya V, Aytekin A. Effects of pacifier use on transition to full breastfeeding and sucking skills in preterm infants: a randomized controlled trial. *J Clin Nurs*. 2017;26:2055–2063.
5. Margolis FS. Ordinary versus orthodontic pacifiers.. *Dent Surv*. 1980;56:44–45.
6. Bishara Sarnir E, et al. Influence of feeding and non-nutritive sucking methods on the development of the dental arches: longitudinal study of the first 18 months of life. *Pediatr Dent*. 1987;9.1:13–21.
7. Oder A, Stalling D, Barlow SM. Effects of pacifier texture on NNS in neurotypical infants. *Int J Pediatrics*. 2013.
8. Zimmerman E, Forlano J, Gouldstone A. Not all pacifiers are created equal: A mechanical examination of pacifiers and their influence on suck patterning. *Am J Speech-Language Pathol*. 2017;26:1202–1212.
9. Zimmerman E, Barlow SM. Pacifier stiffness alters the dynamics of the suck central pattern generator. *J Neonatal Nursing*. 2008;14:79–86.
10. Liao C, Rosner A, Maron JL, Song D, Barlow SM. Automatic non-nutritive suck waveform discrimination and feature extraction in preterm infants. *Comput Math Methods Med*. 2019.
11. Ludwig SM, Waitzman KA. Changing feeding documentation to reflect infant-driven feeding practice. *Newborn Infant Nurs Rev*. 2007;7:155–160.
12. Waitzman KA, Ludwig SM, Nelson CL. Contributing to content validity of the infant-driven feeding scales© through Delphi surveys. *New Infant Nurs Revs*. 2014;14:88–91.
13. Iriki A, Nozaki S, Nakamura Y. Feeding behavior in mammals: Corticobulbar projection is reorganized during conversion from sucking to chewing. *Dev Brain Res*. 1988;44:189–196.
14. Barlow SM, Estep M. Central pattern generation and the motor infrastructure for suck, respiration, and speech. *J Comm Dis*. 2006;39:366–380.
15. Lessen BS. Effect of the premature infant oral motor intervention on feeding progression and length of stay in preterm infants. *Adv Neonat Care*. 2011;11:129–139.
16. Tian X, Yi LJ, Zhang L, Zhou JG, Ma L, Ou YX, Song GM. Oral motor intervention improved the oral feeding in preterm infants: evidence based on a meta-analysis with trial sequential analysis. *Medicine*. 2015;94:e1310.