Research Article

Effect of Single-Use, Laser-Cut, Slow-Flow Nipples on Respiration and Milk Ingestion in Preterm Infants

Katlyn E. McGrattan,^a David H. McFarland,^b Jesse C. Dean,^a Elizabeth Hill,^c
David R. White,^d and Bonnie Martin-Harris^d

Purpose: Single-use, laser-cut, slow-flow nipples were evaluated for their effect on respiration and milk ingestion in 13 healthy preterm infants (32.7–37.1 weeks postmenstrual age) under nonlaboratory, clinical conditions.

Method: The primary outcomes of minute ventilation and overall milk transfer were measured by using integrated nasal airflow and volume-calibrated bottles during suck bursts and suck burst breaks during slow-flow and standard-flow nipple bottle feedings. Wilcoxon signed-ranks tests were used to test the effect of nipple type on both outcomes.

Results: Prefeeding minute ventilation decreased significantly during suck bursts and returned to baseline

values during suck burst breaks across both slow-flow and standard-flow nipples. No differences were found in minute ventilation ($p > .40$) or overall milk transfer ($p = .58$) between slow-flow and standard-flow nipples.

Conclusions: The lack of difference in primary outcomes between the single-use slow-flow and standard-flow nipples may reflect variability in nipple properties among nipples produced by the same manufacturer. Future investigations examining the effect of both single-use and reusable nipple products are warranted to better guide nipple selection during clinical care.

Sucking, swallowing, and breathing must be precisely coordinated in the developing infant to maximize nutrition and hydration and minimize perturbations to cardiorespiratory function. Full-term, healthy infants are able to meet these coordinative demands within a few hours after birth. Infants normally regulate the rate of milk flow from the nipple by modifying their sucking kinematics (Colley & Creamer, 1958; Scheel, Schanler, & Lau, 2005). Preterm infants with impaired neuromotor and respiratory function, however, have difficulty self-regulating milk flow (Gewolb & Vice, 2006; Hanlon et al., 1997; Lau, Smith, &

Schanler, 2003) and may require the use of compensatory feeding strategies to facilitate the safe and efficient obtainment of oral nutrition (Goldfield, Smith, Buonomo, Perez, & Larson, 2013; Law-Morstatt, Judd, Snyder, Baier, & Dhanireddy, 2003; Park, Thoyre, Knafl, Hodges, & Nix, 2014; Scheel et al., 2005).

Slow-flow (SF) bottle nipples are a commonly used intervention to facilitate the preterm infant's obtainment of oral nutrition without cardiopulmonary compromise. This practice is based on work by Mathew (1991), who found that custom-made, laser-cut bottle nipples with reduced orifice diameters (0.033 vs. 0.043 cm) reliably reduced milk flow and improved minute ventilation among 10 preterm infants. Despite these promising findings, these custom SF nipples are not available for clinical use; instead, neonatal intensive care units within the United States frequently rely on noncustom, clinically available, single-use nipple products with differing nipple attributes. The ability of these nipples to achieve those beneficial respiratory effects obtained by Mathew's custom-made nipples remains unknown.

There is reason to believe that there may be considerable differences in the nipple attributes among the clinically available nipple products that currently have no manufacturing standards; instead, clinically available SF

^aDepartment of Health Sciences and Research, Medical University of South Carolina, Charleston

^bFaculties of Medicine, Université de Montréal and McGill University, Montréal, Québec, Canada

^cDepartment of Public Health Sciences, Medical University of South Carolina, Charleston

^dDepartment of Otolaryngology–Head and Neck Surgery, Medical University of South Carolina, Charleston

Correspondence to Katlyn E. McGrattan:

katlyn.mcgrattan@northwestern.edu

Editor: Krista Wilkinson

Associate Editor: Julie Barkmeier-Kraemer

Received April 11, 2016

Revision received September 20, 2016

Accepted January 29, 2017

https://doi.org/10.1044/2017_AJSLP-16-0052

Disclosure: The authors have declared that no competing interests existed at the time of publication.

nipples come in a variety of manufacturer-dependent shapes, compliances, and orifice sizes that generate a wide range of milk flows (7.33–14.68 ml/min; Pados, Park, Thoyre, Estrem, & Nix, 2015). This variability has even been found to exist within nipples manufactured by the same nipple brand (Jackman, 2013; Mathew & Cowen, 1988; Pados et al., 2015). Previous work has attributed this variability to the use of a mechanical drill manufacturing method (Mathew, 1991; Mathew & Cowen, 1988). Imprecision of the mechanical drill has been speculated to inadvertently generate a wide range of orifice sizes (Mathew & Cowen, 1988) that rendered previously tested clinically available SF nipples ineffective (Mathew, 1991).

Laser-cut nipples have recently become available for clinical use in the neonatal intensive care units in the form of a single-use, disposable nipple product. However, moderate variability in the attributes appears to persist (Pados et al., 2015). Thus, this has the potential to introduce an unknown amount of variability in their restriction to milk flow across nipples and may obscure their intended beneficial respiratory effects. The current investigation addressed the effect of a commonly used, single-use, laser-cut SF nipple on respiratory performance and milk ingestion. Similar to previous investigations, we used minute ventilation as our primary respiratory outcome measure (Mathew, 1991) and overall milk transfer as the primary measure of milk ingestion (Lau & Smith, 2011).

Method

Participants

A convenience sample of 13 healthy preterm infants (five boys, eight girls; 29.9–33.7 weeks gestation) was recruited from the Medical University of South Carolina Children's Hospital, Charleston. The sample of 13 healthy preterm infants studied within this pilot investigation was motivated by the sample of nine healthy preterm infants that previously provided Mathew (1991) sufficient power to demonstrate a significant change in minute ventilation, as defined by a p value < .05. Infants were excluded from participation if they were small for gestational age, had prenatal exposure to recreational drugs, or had a diagnosed congenital anomaly or chronic medical condition, including Grades III or IV intraventricular hemorrhage, periventricular leukomalacia, necrotizing enterocolitis, and pulmonary impairment requiring supplemental oxygen at the time of study participation. Table 1 provides the demographic, health, and feeding characteristics of enrolled infants. The research protocol was approved by the Medical University of South Carolina institutional review board.

Procedure

Nipples tested in the investigation were single-use, laser-cut SF and standard-flow (SDF) nipples that at the time of investigation were widely used in neonatal units in the United States (Enfamil Slow Flow and Standard Flow Nipple; Mead Johnson Nutrition, Glenview, IL). Nipples

Table 1. Sample characteristics.

Characteristic	Number (%)
Demographics	
Sex	
Male	5 (39) ^a
Female	8 (62) ^a
Race	
African American	8 (62) ^a
White	5 (39) ^a
Health	
Gestational age (weeks)	31.57 (2.4) ^b
Birth weight (g)	1,425 (860.0) ^b
Apgar score 1 min	7 (3) ^b
Apgar score 5 min	8 (2) ^b
Intubation	1 (8) ^c
CPAP	10 (77) ^c
Surfactant	3 (23) ^c
Caffeine	8 (62) ^c
Feeding	
Postmenstrual age at initiation of feeding (weeks)	33.43 (1.1) ^b
Postmenstrual age at data collection (weeks)	34.29 (1.1) ^b
Bottle volume (ml)	40 (16.0) ^b
Feeding position	
Upright	4 (31) ^a
Right-side lying	1 (8) ^a
Left-side lying	8 (62) ^a
Feeding schedule	
BID	1 (8) ^a
BID with cues	8 (62) ^a
Cues	1 (8) ^a
Every other	1 (8) ^a
Ad libitum	2 (15) ^a

Note. CPAP = continuous positive airway pressure; BID = twice a day. Percentages were rounded to the nearest whole number and may not add up to 100%.

^aValues shown as number of infants (%). ^bValues shown as median (interquartile range). ^cValues shown as number of infants with intervention (%).

had manufacturer-reported orifice sizes of 0.028 and 0.036 cm and previously reported flow rates of 14.68 and 18.92 ml/min, respectively (Pados et al., 2015). Single-use nipples were chosen because of their widespread clinical use, with the tested brand being the only single-use product available at the time of data collection. Order of nipple presentation was randomized across infants.

Infants were studied during two oral feedings each within 48 hr of each other. Study feedings were initiated within 48 hr from the time each infant consumed four consecutive bottle feedings that were ≥15 ml in volume. The four bottle feedings could be separated by enteral nutrition. Infants were fed by one of 10 Level II neonatal nurses with 3 months to 30 years of experience. Feedings were completed during the infant's scheduled eating time on the basis of physician order and infant level of arousal. Physician-determined milk type and prescribed milk volume were warmed to room temperature and presented in a disposable single-use bottle (Similac Volu-Feed; Abbott Nutrition, Abbott Park, IL). To maintain clinical relevance,

nurses were instructed to feed the infants as they would during standard clinical care, with no attempt to control feeding position, milk type, or bottle volume across infants. Feeding nurse, infant position, milk type, and bottle volume, however, remained constant across the two nipple types for each infant. SF and SDF nipples were placed in uniform nipple rings to maintain blinding of study personnel and feeding nurses. Nurses discontinued bottle feedings once the prescribed milk volume was consumed, once infants exhibited prolonged periods of sucking cessation, indicating the infant was completed with the feed, or once the infant had been attempting oral feeding for 30 min (see Table 1 for full report of clinical feeding characteristics).

Respiratory equipment was placed approximately 30 min prior to the infant's scheduled feeding time. Nasal airflow was recorded with a neonatal nasal cannula secured below the nares with allergen-free adhesive tape and connected to a 0- to 10-l/min heated linear pneumotach (Hans Rudolph Inc., Shawnee, KS). Respiratory movements of the rib cage and abdomen were recorded by using respiratory inductance plethysmography (Ambulatory Monitoring, Inc., Ardsley, NY), with bands placed along the infant's axillae and umbilicus, respectively. Nipple compression during sucking was measured, as previously described by Lau, Sheena, Shulman, and Schanler (1997). In brief, a 3.5F pressure transducer (Millar®, Houston, TX) was threaded through a preassembled silastic sheath that transcended superficially along the distal to proximal nipple surface. Care was taken upon the initiation of the oral feed to place the nipple's transducer edge inferiorly against the lingual surface. Milk ingestion was measured by weighing prepared bottles and bibs prior to the initiation and upon completion of the feedings. Differences in bottle and bib weights were converted into milk volume by applying a standard 1 g/ml of milk density conversion (Lau et al., 1997; Neville et al., 1988). All experimental sessions were video-recorded, with electronic signals sampled at 1000 Hz and synchronized by using the AcqKnowledge 4 Acquisition and Analysis System (BIOPAC Systems, Inc., Goleta, CA).

Analysis

Respiration

Experimental sessions were first evaluated for the presence of positive inflections in the sucking signal at a time when milk was visually observed in the aperture between the nipple base and bottle shaft. On the basis of the presence or absence of these nutritive sucks, feedings were then separated into suck bursts and suck burst breaks. *Suck bursts* were operationally defined as ≥ 2 sucks occurring within 2 s of each other, and *suck burst breaks* were defined as those times during which no sucking occurred. To enable evaluation of the reported rebounding respiratory effects immediately following the suck burst, only the initial 15 s of suck burst breaks were included in analysis.

The pneumotach and respiratory inductance plethysmography signals were first digitally low-pass filtered at

5 and 15 Hz, respectively. In the absence of previously reported bottle-feeding ventilation analysis methods, these cutoff frequencies were chosen on the basis of visual inspection of the frequency domain power spectrum. A semiautomated breath detection algorithm that had been developed and validated against visual review during pilot testing was then applied to identify unobstructed breaths and eliminate all obstructed breaths and movement artifacts (Brodsky, McFarland, Michel, Orr, & Martin-Harris, 2012) from further analysis (see Figure 1). In particular, negative inflections in the nasal airflow signal were identified as nonrespiratory airflow and not included in analysis if absolute tidal volume was $< 15\%$ of the prefeeding tidal volume or if rib cage and abdomen circumferential expansion was $< 15\%$ of prefeeding expansion magnitude and rate. In this way, only functional unobstructed breaths were included in the respiratory analysis.

Breaths identified by using the previously mentioned algorithm were quantified to determine respiratory rate, by dividing the total number of breaths by the total time over which they occurred, and tidal volume. These outcomes were multiplied to provide the primary respiration outcome measure of minute ventilation (see Figure 1). Minute ventilation was expressed as a percentage of prefeeding values and compared across four unique feeding periods due to previous reports of differences in respiratory characteristics: (a) 10 steady-state breaths prior to the feeding period (prefeeding), (b) suck bursts within the initial 30-s period (initial suck burst), (c) suck bursts after the initial sucking period (subsequent suck bursts), and (d) suck burst breaks (see Figure 2; Mathew, 1991; Mathew, Belan, & Thoppil, 1992; Mathew, Clark, Pronske, Luna-Solarzano, & Peterson, 1985; Shivpuri, Martin, Waldemar, & Fanaroff, 1983).

Milk Ingestion

Overall milk transfer was calculated by dividing the total volume of ingested milk by the volume of prescribed milk after each feed (Lau & Smith, 2011). Secondary outcome measures included rate of transfer and anterior bolus loss. Rate of transfer was calculated by dividing the total volume consumed by the total feeding time (Lau & Smith, 2011). Anterior bolus loss was measured by converting the difference in pre- and postfeeding bib weights to volume by using a standard 1 g/ml of milk density conversion (Lau et al., 1997; Neville et al., 1988).

Statistical Analysis

Wilcoxon signed-ranks tests assessed the impact of nipple type on minute ventilation across the measurement periods previously defined and tested for differences in overall milk transfer between the SF and SDF nipples. Values were deemed significant at the $p < .05$ level and reported as the median paired difference in values. All analyses were completed by using SPSS (Version 22) software (IBM Corp., Armonk, NY).

Figure 1. Breath detection algorithm used to identify and quantify functional breaths for comparison between slow-flow and standard-flow feedings by using measures of tidal volume (V_T) change in abdomen and rib cage circumference (Δ_C), change in time (Δ_T), abdomen and rib cage expansion rate ($m = \Delta_C/\Delta_T$), breaths (B_x), respiratory rate ($\Sigma B_{1-3}/\text{total time}$), and minute ventilation ($V_m = V_T \times \text{respiratory rate}$).

Results

Respiration

Respiratory rate slowed significantly during suck bursts when compared with prefeeding respiratory rate

across both SF (initial suck burst $p = .001$; subsequent suck burst $p = .001$) and SDF (initial suck burst $p = .001$; subsequent suck burst $p = .001$) nipples. This resulted in a significant reduction in minute ventilation during the initial and subsequent suck burst periods that returned to

Figure 2. Changes in prefeeding respiration during slow-flow and standard-flow feedings: initial suck burst, subsequent suck bursts, and suck burst breaks.

prefeeding values during suck burst breaks (see Table 2). No difference was found in the magnitude of the change in minute ventilation between SF and SDF nipples during any of the suck burst or suck burst break feeding periods (see Table 3).

Milk Ingestion

No significant differences were found between SF and SDF nipples in the primary outcome measure of overall transfer. Likewise, no significant differences were found in secondary outcomes of rate of transfer and anterior bolus loss (see Table 4).

Discussion

The present investigation was designed to test the effect of clinically available, single-use, laser-cut, SF nipples on minute ventilation and milk ingestion in a group of healthy, premature infants under nonlaboratory clinical conditions. No attempts were made to standardize feeder, feeding strategy, infant position, or prescribed milk volume, although these variables were held constant between the nipple types within a given infant. The results indicate that our primary outcome measures, minute ventilation and milk transfer, were not affected by the use of the tested SF nipple when compared with the SDF nipple.

Both of these findings are consistent with past investigations that have examined the effect of clinically available bottle nipples on preterm feeding performance. Scheel et al. (2005) found no significant differences in overall milk transfer among three clinically available nipples of differing flow rates. In a similar way, Mathew (1991) found the variability in milk flow rates generated from clinically available, mechanically drilled bottle nipples inhibited their ability to provide a significant improvement to preterm ventilation. Pados et al. (2015) revealed that moderate variability persisted among clinically available, single-use, SF nipples despite their laser-manufacturing method. Taken together, it appears the variability within clinically available, laser-cut, SF nipples introduces unknown variability in how they modify milk flow and, consequently, may hinder the ability to consistently provide the intended treatment effect in susceptible infants.

Although the current findings do not support the beneficial effect of single-use SF nipples, they do not

speak to the potential effects of commercially available reusable nipple products that are commonly purchased for home use. Under mechanical testing conditions, Pados et al. (2015) found reusable home nipples, such as Preemie and Ultra-Preemie Nipples (Dr. Brown's; Handi-Craft Co., St. Louis MO), provide significantly lower, more reliable rates of milk flow than the disposable, single-use products that were used in the current investigation. Non-disclosure of manufacturing methods, nipple attributes, or processes of quality control among nipple manufacturers limits the ability to isolate the potential source for these discrepancies. Testing of nipple flow rates by using artificial, mechanically generated pressures is clearly limited in its ability to replicate the dynamic, infant-modulated flow rates that occur during real-life feeding conditions. It does, however, provide clinicians with greater clarity into a nipple's otherwise unreported flow-restricting abilities and potential to deliver the intended therapeutic effect.

In theory, the ability of SF nipples to serve as an effective treatment modality for those infants who are unable to self-regulate milk flow successfully is dependent on the nipple's ability to consistently provide the optimal restriction to milk flow. Little is known regarding the restriction thresholds that are optimal for feeding success. In clinical practice, it is likely that these thresholds vary across infants, and when an infant's ability to self-regulate flow is compromised, custom flow restrictions are warranted to meet each infant's unique feeding needs. Reusable home nipple products that offer infants a slower, more consistent restriction to milk flow across bottle feedings may provide a greater respiratory benefit. Future investigations are necessary to elucidate the effects of these other reusable, flow-restricting products that may serve as a more reliable and effective treatment regimen.

Study Limitations, Conclusions, and Future Directions

Although investigation of these commonly used single-use nipples within the clinical setting has distinct translational advantages, the limited number of experimental controls and small numbers of experimental participants may have limited our ability to draw larger conclusions regarding the underlying mechanisms that contributed to the observed findings. The most significant of these uncontrolled variables is the true regulation of the rate

Table 2. Change in prefeeding minute ventilation during the initial SB, subsequent SB, and SB break across slow-flow and standard-flow nipples.

Minute ventilation (% PF)	Initial SB				Subsequent SB				SB break			
	Median	IQR	Difference (SB – PF) ^a	<i>p</i>	Median	IQR	Difference (SB – PF) ^a	<i>p</i>	Median	IQR	Difference (SB – PF) ^a	<i>p</i>
Slow flow	35	60	–65	.02	45	67	–55	.03	97	132	–3	.70
Standard flow	36	58	–64	.04	46	54	–54	.04	122	68	22	.20

Note. SB = suck burst; PF = prefeeding; IQR = interquartile range.

^aDifferences are reported as the median paired difference in minute ventilation between SB and PF conditions.

Table 3. Difference in respiration between SF and SDF nipples.

Parameter	Initial suck burst						Subsequent suck burst						Suck burst break					
	SF		SF		Difference (SF – SDF) ^a	<i>p</i>	SF		SDF		Difference (SF – SDF) ^a	<i>p</i>	SF		SDF		Difference (SF – SDF) ^a	<i>p</i>
	Median	IQR	Median	IQR			Median	IQR	Median	IQR			Median	IQR	Median	IQR		
Respiratory rate (bpm)	36.0	20	38.0	30	–6.0	.29	43.4	21	43.0	14	–5.0	.65	62.7	20	63.1	22	2.0	.70
Tidal volume (% PF)	69.5	56	64.4	78	4.3	.97	66.4	55	78.0	86	–8.0	.42	104.6	122	123.7	79	–37.7	.38
Minute ventilation (% PF)	34.7	60	36.5	58	–1.1	.51	44.8	67	46.0	54	–9.5	.51	97.4	132	121.9	68	–22.1	.42

Note. SF = slow flow; SDF = standard flow; IQR = interquartile range; bpm = beats per minute; PF = prefeeding.

^aDifferences are reported as the median paired difference between SF and SDF nipples.

Table 4. Difference in milk ingestion between slow-flow and standard-flow nipples.

Parameter	SF		SDF		Difference SF – SDF ^a	p
	Median	IQR	Median	IQR		
Overall transfer (%)	69.0	(31.9)	73.0	(52.0)	6.0	.58
Rate of transfer (ml/min)	2.1	(1.5)	2.2	(2.0)	–0.2	.55
Anterior bolus loss (ml)	0.0	(1.0)	0.0	(0.0)	0.0	.32

Note. SF = slow flow; SDF = standard flow; IQR = interquartile range.

^aDifference reported as the median paired difference between SF and SDF nipples.

of milk flow delivery. SF bottle nipples solely restrict the expressed volume of milk flow when compared with SDF nipples if the applied sucking and hydrostatic pressures remain constant. Therefore, adjustments to flow-modulating variables, such as bottle position and infant sucking kinematics, have the potential to counteract the nipple's intended milk restricting effect. It is possible that select infants within the investigation did possess the ability to self-regulate milk flow and that the inclusion of these infants may have limited our ability to see the SF nipple's effect among those infants without these flow-regulating abilities. In contrast, it is also possible that select infants within the investigation had such severe feeding deficits that the limited milk flow restriction provided by the tested SF nipples was not great enough to improve their ventilation. Adding additional measures of cardiopulmonary stability, such as heart rate and oxygen saturation, among infants with respiratory and neurologic comorbidities, may provide further insights into the impact of nipple properties on preterm feeding performance. Future investigations with larger sample sizes are necessary to explore further the role of internal flow regulation, neurodevelopmental maturation, and feeding practices to establish safe and independent oral-feeding regimens for the premature infant.

Acknowledgments

This work was supported by the National Institute of Deafness and Other Communication Disorders (Grant 1K24DC12801, PI: Bonnie Martin-Harris, Medical University of South Carolina), the South Carolina Clinical Translational Research Institution (Grant UL1TR000062, PI: Katlyn McGrattan, Medical University of South Carolina), and the Mark and Evelyn Trammell Trust. The research team acknowledges and thanks the neonatal nurses and the parents of the participating infants, without whom this work would not be possible.

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