

## A Controlled-flow Vacuum-free Bottle System Enhances Preterm Infants' Nutritive Sucking Skills

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**Abstract** We have shown that a controlled-flow vacuum-free bottle system (CFVFB) vs. a standard bottle (SB) facilitates overall transfer and rate of milk transfer, and shortens oral feeding duration in very-low-birth-weight (VLBW) infants. We aimed to understand the basis by which this occurs. Thirty infants (19 males;  $27 \pm 1$  weeks gestation) were randomized to a CFVFB or SB. Outcomes monitored at 1–2 and 6–8 oral feedings/day when infants were around 34 and 36 weeks postmenstrual age, respectively, included: overall transfer (% volume taken/volume prescribed), rate of milk transfer (ml/min), sucking stage, frequency of suction (#S/s) and expression (#E/s), suction amplitude (mmHg), and sucking burst duration (s). At both periods we confirmed that infants using a CFVFB vs. SB demonstrated greater overall transfer and rate of milk transfer, along with more mature sucking stages. Suction and expression frequencies were decreased with CFVFB vs. SB at 1–2 oral feeding/day; only that of suction was reduced at 6–8 oral feedings/day. No group differences in suction amplitude and burst duration were observed. We speculate that oral feeding performance improves without significant change in sucking effort with a CFVFB vs. SB.

In addition, we have shown that VLBW infants can tolerate faster milk flow than currently presumed. Finally, the use of a CFVFB may reduce energy expenditure as it enhances feeding performance without increasing sucking effort.

**Keywords** Bottle feeding · Oral feeding · Suck-swallow-breathe · VLBW · Prematurity · Deglutition · Deglutition disorders

Up to 30% of preterm infants experience difficulty making the transition from tube to oral feeding [1]. This is often due to immaturity in sucking, swallowing, uncoordinated suck-swallow-respiration, inappropriate behavioral states, and/or poor endurance [2–5]. Oral feeding difficulties are associated with delayed attainment of independent oral feeding and hospital discharge [5–7]. In recent years, an estimated 40% of the patients seen in feeding disorders clinics were children born prematurely [7]. Until recently, the difficulty in transitioning from tube to oral feeding has received little attention due to concerns over more immediate life-threatening medical complications, e.g., bronchopulmonary dysplasia, intraventricular hemorrhage, necrotizing enterocolitis. Nevertheless, with the rise in the preterm infant population over the last two decades, there is an urgent need to develop interventions that can safely enhance preterm infants' oral feeding performance [1, 8–13]. Improving oral feeding skills will not only accelerate attainment of independent oral feeding and shorten hospitalization, but, importantly, reduce medical cost, allow earlier family reunification, and facilitate the development of a more appropriate mother-infant interaction and bonding [14]. Potentially, it may also decrease long-term feeding difficulties/disorders.

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To develop efficacious interventions, it is necessary to gain a better understanding of the development of oral feeding skills [5, 15–21]. Safe and successful oral feeding requires not only appropriate sucking, swallowing, and respiration, but also the appropriate coordination of these three functions in order to prevent adverse episodes of apnea, bradycardia, oxygen desaturation, and/or aspiration. Studies have described the maturation of sucking in terms of suction and/or expression, the two components of sucking [16, 19, 22], as well as coarse and fine “structures,” as defined by earlier investigators, e.g., sucking burst duration and suction force/amplitude, respectively [16, 22, 23]. Suction is the negative intraoral pressure exerted by the infant while drawing milk into the mouth; expression is the lingual component implicated in the stripping/compression of the nipple to eject milk. This latter is also implicated in bolus formation, i.e., the oral phase of swallowing [16, 24–27]. In earlier studies [19, 28], we noted that the presence of these two components was not critical for the successful completion of oral feeding as the use of expression alone was sufficient, albeit not as efficient. We descriptively characterized the nutritive sucking pattern of preterm infants using a five-point developmental nutritive sucking scale based on the presence/absence of suction and expression and their rhythmicity [19]. This sucking scale correlated positively with postmenstrual age, overall transfer, and rate of milk transfer. These observations support the notion that maturation of nutritive sucking plays a significant role in improving oral feeding performance. As the stage of nutritive sucking is also reflective of the maturation of suck-swallow-respiration coordination, it is implied that an appropriate development of swallowing, respiration, and suck-swallow-respiration coordination is occurring concurrently. This is supported also with the observation that a mature nonnutritive sucking pattern does not imply mature nutritive sucking and/or successful oral feeding [29].

The use of a controlled-flow vacuum-free bottle system (CFVFB) has been shown to accelerate attainment of independent oral feeding in very-low-birth-weight (VLBW) infants [30]. Namely, it improved their ability to complete more of their feedings in a shorter feeding time and at a faster rate (ml/min) compared to their counterparts’ feeding with a standard bottle (SB). Therefore, it was deemed of interest to gain a better understanding of the basis upon which such improvement occurred. Such information would be of significant value in the development of new intervention(s) to facilitate transition from tube to oral feeding.

In this study we hypothesized that the use of a CFVFB, when compared to that of a SB, will enhance infants’ stage of sucking, along with a greater use of the suction component, greater suction amplitude, and longer sucking burst duration.

## Methods

### Subjects

Infants were recruited from the Neonatal Intensive Care Unit at Texas Children’s Hospital, Houston, Texas, USA. The study was approved by the Institutional Review Board for Human Subjects at Baylor College of Medicine and Affiliated Hospitals. Informed parental consent was obtained following consultation with the attending physicians.

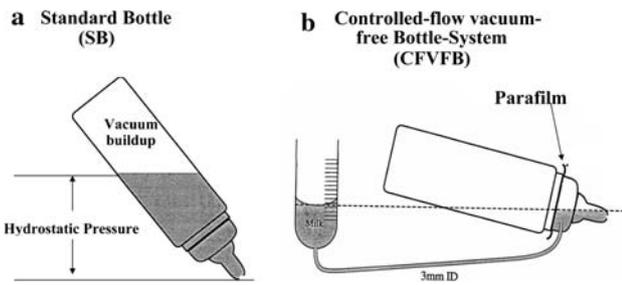
A total of 30 clinically stable preterm infants (19 males, 11 females) participated. Infants were enrolled if they were (1) born between 26 and 29 weeks gestational age (GA) as determined by obstetrical ultrasound and clinical exam; (2) of appropriate size for GA; (3) without congenital anomalies (e.g., oral, cardiac); and (4) without chronic medical conditions, including severe bronchopulmonary dysplasia [31], intraventricular hemorrhages (IVH) grade III or IV [32], periventricular leukomalacia (PVL), or necrotizing enterocolitis (NEC). Infants who had their enteral feeding stopped for greater than 7 consecutive days and/or developed IVH III or IV, PVL, and NEC after recruitment were dropped from the study.

### Study Design

Infants were randomly assigned to the CFVFB or SB group. Management of oral feeding, i.e., introduction and advancement, was left to the discretion of the attending physician. Sucking skills were monitored when infants were taking 1–2 and 6–8 oral feedings/day. Infants were not disturbed for at least 30 min prior to each feeding session. The orogastric tube, if present, was removed prior to oral feeding assessment. Because nurses choose the nipples they feel are most appropriate for their patients, the ones used for the study were left to the nurses’ discretion as it was representative of infants’ oral feeding performance in the clinical setting. Caregivers fed the infants in their customary way; no encouragement, e.g., chin and/or cheek support, was provided during these feeding sessions. The duration of the oral feeding session was limited to 20 min as per nursery protocol.

### Methodology

The SB used in this study was straight and cylindrical in shape (Fig. 1a). The CFVFB consisted of a nipple-bottle system that delivered milk to the nipple chamber from an open reservoir that was adjusted such that the milk level was maintained continually at the level of the infant’s mouth (Fig. 1b). The milk reservoir was held secure on an IV pole and was readily adjusted to the level of the infant’s mouth during feeding. Sucking parameters were recorded



**Fig. 1** Schematic representation of the regular standard (SB) and controlled-flow vacuum-free (CFVFB) bottles

using a methodology described in previous studies [28, 33]. Briefly, the suction and expression components were monitored via two miniature pressure transducers (Model SPR-524, Millar Instruments, Houston, TX). For suction, one of the transducers was inserted through a polyethylene tubing flush with the tip of the nipple without protruding into the infant’s mouth. Expression was monitored via a second transducer connected to a catheter made up of soft silastic tubing connected, in turn, to polyethylene tubing such that the compressible silastic portion was exteriorized along the nipple. To ensure the proper recording of the expression component, the catheter was positioned upward against the hard palate.

**Fig. 2** Descriptive scale of sucking stages: This scale comprises five stages based on presence/absence of suction and rhythmicity of suction and expression components during nutritive sucking from a bottle. Sample tracings with corresponding range of amplitudes are presented [from Lau C, Kusnierczyk I, Quantitative evaluation of infant’s nonnutritive and nutritive sucking. *Dysphagia* 2001; 16:58; reproduced with permission from Springer Science and Business Media]

Stage	Sample tracings	Suction/ expression amplitude range of tracings, mm Hg	Description
<b>1A and/or 1B</b>	Suction	Absent	No Suction
	Expression	+0.5 to +1.0	Arrhythmic expression
	Time, sec		<b>and</b>
	Suction	-2.5 to -12.5	Arrhythmic alternation of Suction/expression
	Expression	+0.5 to 1.0	
<b>2A and/or 2B</b>	Suction	Absent	No Suction
	Expression	+0.2 to +0.4	Rhythmic expression
	Time, sec		<b>and</b>
	Suction	-7.5 to -15.0	Arrhythmic alternation of: - Suction/expression - Presence of sucking bursts
	Expression	~ +0.2	
<b>3A and/or 3B</b>	Suction	Absent	No Suction
	Expression	+0.8 to +1.0	Rhythmic expression
	Time, sec		<b>and</b>
	Suction	-15 to -75	Rhythmic suction/expression: - Suction amplitude increase - Wide amplitude range - Prolonged sucking bursts
	Expression	+0.5 to 0.7	
<b>4</b>	Suction	-50 to -75	Rhythmic suction/expression: - Suction well defined - Decreased amplitude range
	Time, sec		
	Expression	+0.4 to +1.0	
<b>5</b>	Suction	-110 to -160	Rhythmic/well defined suction/expression: - Suction amplitude increases - Sucking pattern similar to that of fullterm infant
	Time, sec		
	Expression	+0.6 to +0.75	

Study Outcomes

Oral feeding outcomes included overall transfer (percent volume of milk taken over the prescribed volume) and rate of milk transfer (volume transferred per unit time, ml/min). Sucking outcomes consisted of the stages of sucking using a five-point scale (Fig. 2) [19]: frequency of suction (#S/s) and expression (#E/s), suction amplitude (mmHg), and sucking burst duration. Postmenstrual age (PMA, weeks) at 1–2 and 6–8 oral feedings/day, nipple types (standard and premature nipple, ROSS Products, Abbott Laboratories, Columbus, OH, USA), and the number of infants who experienced episodes of apnea (cessation of breathing/ 20 s), bradycardia (heart rate < 100), and oxygen desaturation (<85%) were monitored as potential confounders in data analyses.

Statistical Analyses

A weighted average was used for the analyses of sucking outcomes. At both time periods (1–2 and 6–8 oral feedings/day), weighted averages were computed from two sucking bursts selected within the first and last 5 min of an oral feeding session. The following formula was used:  $(T1*B1 + T2*B2)/T1 + T2$ , with T1, T2 corresponding to

the duration (s) of the respective sucking bursts, and B1, B2 relating to the average value of a particular sucking outcome. Sucking bursts were delineated by periods of pauses of 1.5 s or longer. The two sucking bursts analyzed were selected so that their sucking stage and duration were closest to the respective averages computed from all the sucking bursts during the first and last 5 min of the monitored sessions.

Independent *t* tests and paired *t* tests were used for continuous variables to compare between and within groups at 1–2 and 6–8 oral feedings/day, respectively. The  $\chi^2$  test was used to assess differences in categorical variables. Based on an average rate of milk transfer of  $1.6 \pm 1.1$  ml/min for infants born earlier than 30 weeks gestation, measured in an earlier study [30], an estimated sample size of 30 was calculated with an  $\alpha$  level of 0.05, using a type 1 error of 0.05 and a power of 0.80. In order to detect a difference of 1.5 ml/min, 9 infants per group were estimated. Six additional participants per group were recruited for potential outliers.

## Results

Subjects' characteristics are summarized in Table 1. Both groups were comparable for GA, birth weight, gender distribution, and PMA at 1–2 and 6–8 oral feedings/day. Table 2 shows that at both periods the types of nipple used and number of infants experiencing episodes of apnea/bradycardia or oxygen desaturation were comparable between groups.

*Overall intake* was significantly greater in infants feeding with a CFVFB as opposed to a SB at both monitored periods ( $p \leq 0.007$ ) (Fig. 3). It is of note that at 1–2 and 6–8 oral feedings/day, the percent overall transfer was similar for the CFVFB infants ( $p = 0.469$ ), whereas it increased in the SB group ( $p = 0.016$ ). The percentage of infants who completed their feeding was significantly

different ( $p < 0.001$ ) for the CFVFB vs. SB group. They were 80 vs. 13% and 93 vs. 47% at 1–2 and 6–8 oral feedings/day, respectively. *Rate of milk transfer* (Fig. 4) was significantly greater in the CFVFB vs. the SB group at both times ( $p < 0.001$ ) and improved over time for both groups of infants ( $p \leq 0.002$ ). *Feeding durations* were significantly shorter in the CFVFB group than in the SB group at both periods ( $p \leq 0.025$ , Table 3). *Stages of sucking*, on the other hand, were consistently more mature in infants using the CFVFB vs. SB ( $p < 0.05$ ) (Fig. 5). Stages of sucking matured as both groups of infants advanced in oral feeding ( $p \leq 0.003$ ). *Suction frequency* (Fig. 6) decreased in CFVFB infants at 1–2 and 6–8 oral feedings/day compared to their SB counterparts ( $p \leq 0.017$ ) and increased over time only in the SB group ( $p = 0.022$ ). *Expression frequency* (Fig. 6) decreased in CFVFB vs. SB infants at 1–2 oral feedings/day ( $p = 0.003$ ) and increased over time only in the CFVFB infants ( $p = 0.002$ ). *Suction amplitude* and *sucking burst duration* were similar in the two groups at both periods (Table 3).

## Discussion

With the increased survival of preterm infants, awareness of oral feeding difficulties in this population is growing. Development of safe interventions is needed to facilitate the transition of preterm infants from tube to oral feeding [8, 12, 13]. The use of a CFVFB is one such intervention. In the present study we confirmed our earlier observation that the use of a CFVFB, when compared to that of a SB, improves oral feeding performance in infants born between 26 and 29 weeks gestation, i.e., greater overall intake, rate of milk transfer, shorter feeding duration, with a greater number of these infants completing their feedings at both monitored periods. The present results confirm our hypothesis that infants offered a CFVFB demonstrate a

**Table 1** Subjects' characteristics

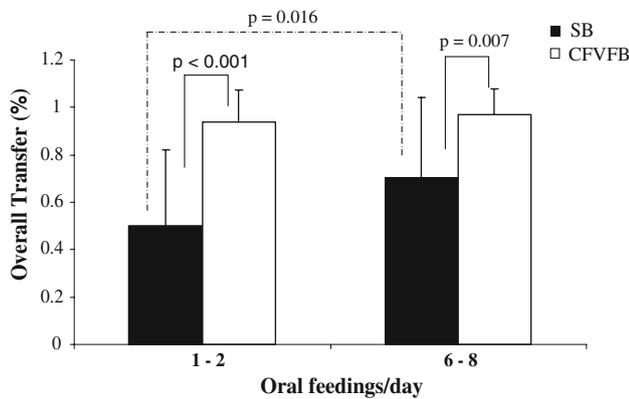
	SB <sup>a</sup> ( <i>n</i> = 15)	CFVFB <sup>a</sup> ( <i>n</i> = 15)	<i>p</i> <sup>*</sup>
Gestational age (GA, weeks)	27.7 ± 1.2 (26–29)	27.9 ± 1.0 (26–29)	0.738
GA distribution			
26–27 weeks	6	6	1.000**
28–29 weeks	9	9	
Birth weight (g)	956 ± 276 (560–1300)	1037 ± 200 (727–1310)	0.365
Gender distribution			
Male	9	10	0.705**
Female	6	5	
Postmenstrual age (PMA, weeks)			
1–2 oral feedings/day	34.3 ± 1.0 (33–37)	34.2 ± 0.8 (33–36)	0.695
6–8 oral feedings/day	36.3 ± 1.5 (34–39)	36.8 ± 2.0 (34–42)	0.425

<sup>a</sup> Values are mean ± sd (range)

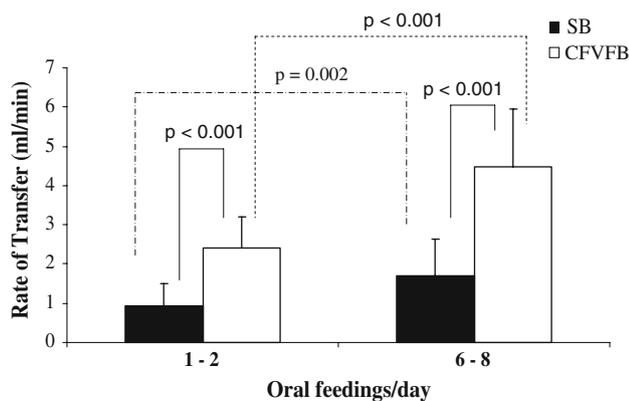
\* Independent *t* test; \*\*  $\chi^2$

**Table 2** Potential confounders

	1–2 oral feedings/day		6–8 oral feedings/day	
	SB	CFVFB	SB	CFVFB
Nipple type distribution				
Number of standard nipples used	2	5	12	14
Number of premature nipples used	13	10	3	1
Number of infants experiencing episode(s) of apnea/bradycardia	2	4	2	3
Number of infants experiencing episode(s) of oxygen desaturations	2	4	3	2



**Fig. 3** Percent overall transfer (percent volume taken over volume to be taken) at 1–2 and 6–8 oral feedings per day



**Fig. 4** Rate of milk transfer (ml/min) at 1–2 and 6–8 oral feedings per day

more mature stage of sucking. However, they do not support the greater use of the suction component, greater suction amplitude, and longer sucking burst duration.

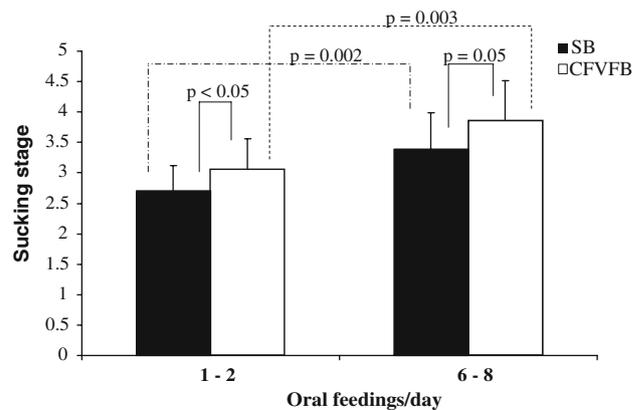
Two equally important considerations come into play when interpreting these results: first, the physical properties within standard bottles resulting from the physics of fluid mechanics as a feed progresses, and second, the level of maturation achieved by preterm infants at particular times in their advancement toward full oral feeding. These two conditions, although independent of each other, need to

**Table 3** Feeding outcomes

	SB <sup>a</sup>	CFVFB <sup>a</sup>	<i>p</i> <sup>*</sup>
Feeding duration (min)			
1–2 oral feedings/day	17.7 ± 4.7	14.1 ± 3.5 <sup>§</sup>	0.025
6–8 oral feedings/day	18.9 ± 3.4	12.3 ± 4.7	<0.001
Suction amplitude (mmHg)			
1–2 oral feedings/day	–26.2 ± 19.8	–35.8 ± 21.2	0.257
6–8 oral feedings/day	–35.7 ± 25.7	–52.0 ± 47.3	0.266
Sucking burst duration (s)			
1–2 oral feedings/day	16.2 ± 16.2	12.8 ± 7.6	0.449
6–8 oral feedings/day	13.4 ± 7.6	16.1 ± 11.3	0.464

<sup>a</sup> Values are mean ± sd

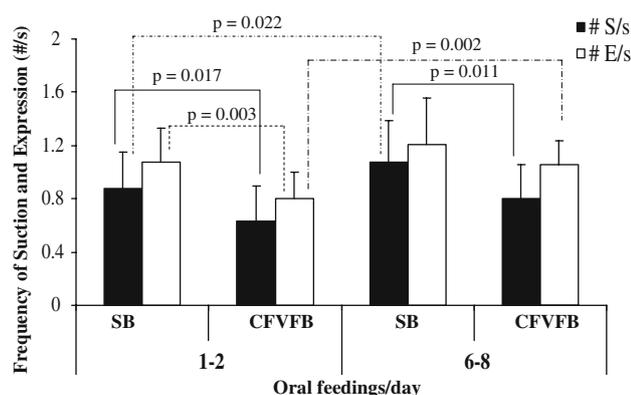
\* Independent *t* test



**Fig. 5** Stages of sucking at 1–2 and 6–8 oral feedings per day

interact “fittingly” in order for infants to feed safely and efficiently by mouth.

*Physical properties of baby bottles* With the use of a SB, vacuum builds up within the bottle as an infant withdraws milk [29]. As a feed progresses, this negative pressure/force increases, opposing the suction exerted by the infant, until the nipple seal is broken to allow equilibration inside and outside the bottle. For the infant, this situation leads to difficulty in generating suction and/or results in a net decrease in suction amplitude, hence, a decrease in the rate of milk flow. Consequently, the elimination of vacuum



**Fig. 6** Frequency of suction (#S/s) and expression (#E/s) at 1–2 and 6–8 oral feedings per day

build-up offered by a CFVFB mechanically would be expected to increase suction efficiency and thus improve oral feeding performance as demonstrated in our results. In addition, the elimination of the hydrostatic pressure within the bottle, further offered by a CFVFB, allows the infant to control intake, as milk would flow only when sucking occurs and thus enhances safety.

*Maturation level of preterm infants' oral feeding skills* Nutritive sucking in clinically stable preterm infants matures as they progress toward full oral feeding [19]. However, as mentioned earlier, this functional development is the result not only of their sucking skill but also of their swallowing and respiratory competence, along with the adequate coordination of these three functions [20]. These factors, individually or combined, limit the rate of milk transfer that infants can generate and tolerate at a particular time in their progression toward full oral feeding [29, 34, 35].

With the advantages offered by a CFVFB and the functional limitations of preterm infants' oral feeding skills, we conclude that the observed enhanced oral feeding performance resulted from the use of a more mature nutritive sucking pattern, likely the rhythmicity of sucking, along with increased sucking efficacy. The latter may result from infants generating faster rates of milk flow without significant changes in sucking parameters, i.e., no increased use of suction and suction amplitude. From this observation we advance that VLBW infants can tolerate faster milk flow than currently presumed, i.e., the rate of milk transfer being 2.5 to 3 times faster with a CFVFB than with a SB. In an earlier study [35], we advanced that infants can regulate their sucking skills so as to obtain a flow rate they can tolerate based on their level of suck-swallow-respiration coordination. This aptitude is indirectly confirmed by two observations made in this study: (1) Infants did not increase the use of suction or suction amplitude when the elimination of vacuum in the bottle

would have readily facilitated such a response. (2) Infants using the CFVFB showed an increase in expression but not suction frequency between 1–2 and 6–8 oral feedings per day, whereas their counterparts using a SB demonstrated an increase in suction but not expression frequency. It should be remembered that expression is less efficient than suction [19, 28]. Finally, we speculate that the use of a CFVFB system may reduce energy expenditure as it enhances feeding performance without increasing sucking effort.

Sucking burst duration has been used as an index of oral feeding performance: the longer the sucking burst, the greater the expected intake [5, 36]. However, this may not be necessarily valid if the sucking pattern and amplitude change. With a more efficient sucking pattern due to maturation or facilitated by a particular intervention, as is the case in this study, burst durations need not increase.

In summary, this study provides a clearer understanding of the basis that allowed improved oral feeding performance with the use of a CFVFB. It demonstrates that (1) by eliminating the resistance to flow engendered by the vacuum buildup normally occurring in a standard bottle, oral feeding performance is improved with no significant change in sucking effort, (2) developmentally, VLBW infants can tolerate faster milk flow than currently presumed, and (3) use of a CFVFB may offer an additional advantage as reduced sucking effort would lead to energy conservation.

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