

Research Article

Milk Flow Rates From Bottle Nipples Used for Feeding Infants Who Are Hospitalized

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Purpose: This study tested the milk flow rates and variability in flow of currently available nipples used for bottle-feeding infants who are hospitalized.

Method: Clinicians in 3 countries were surveyed regarding nipples available to them for feeding infants who are hospitalized. Twenty-nine nipple types were identified, and 10 nipples of each type were tested by measuring the amount of infant formula expressed in 1 min using a breast pump. Mean milk flow rate (mL/min) and coefficient of variation were used to compare nipples within brand and within category (i.e., Slow, Standard, Premature).

Results: Flow rates varied widely between nipples, ranging from 2.10 mL/min for the Enfamil Cross-Cut to 85.34 mL/min

for the Dr. Brown's Y-Cut Standard Neck. Variability of flow rates among nipples of the same type ranged from a coefficient of variation of 0.05 for Dr. Brown's Level 1 Standard- and Wide-Neck to 0.42 for the Enfamil Cross-Cut. Mean coefficient of variation by brand ranged from 0.08 for Dr. Brown's to 0.36 for Bionix.

Conclusions: Milk flow is an easily manipulated variable that may contribute to the degree of physiologic instability experienced by infants who are medically fragile during oral feeding. This study provides clinicians with information to guide appropriate selection of bottle nipples for feeding infants who are hospitalized.

Feeding can be physiologically challenging for premature and medically fragile infants who are learning to feed orally. Whereas breast-feeding may be the ultimate goal, most infants who are hospitalized will receive some bottle-feedings. Many variables contribute to an infant's ability to bottle-feed safely and effectively, but one easily manipulated variable is the rate of milk flow from the bottle nipple. Milk flow is defined as the rate of transfer of milk from the bottle into the mouth during sucking. The rate of milk flow can affect an infant's ability to integrate fluid management with respiration, as well as the degree of ventilatory compromise associated with feeding (al-Sayed, Schrank, & Thach, 1994; Mathew, 1991a). When an infant swallows, the airway is closed for about 1 s to prevent aspiration of milk (Mathew, 1991b). As milk flow increases and requires increased swallowing frequency, ventilation is increasingly interrupted and respiratory rate decreases (al-Sayed et al., 1994). When milk flow slows, the swallow is delayed until a critical volume is accumulated (al-Sayed

et al., 1994), allowing the infant to breathe more frequently and better maintain physiologic stability during feeding.

Rate of milk flow varies considerably across different brands and types of nipples (Jackman, 2013; Mathew & Cowen, 1988). Healthy, full-term infants are typically resilient feeders and are able to alter their sucking rate (Schrank, Al-Sayed, Beahm, & Thach, 1998) and pressure (Colley & Creamer, 1958; Mathew, Belan, & Thoppil, 1992) in order to regulate milk flow. On the other hand, infants who are medically fragile, such as those born preterm, have a limited ability to self-regulate flow (Mathew, 1991a). When milk flow is too high, the infant must swallow at a frequency adequate to clear the oropharynx of fluid and prevent aspiration (at the expense of ventilation; al-Sayed et al., 1994), allow the milk to pool in the oropharynx (and risk aspiration), divert the milk away by allowing it to drool out the mouth (Schrank et al., 1998), or stop feeding.

Clinicians caring for infants who are hospitalized are faced with decisions about nipple selection to support infants who are medically fragile in learning to feed orally, but there is only one recently published study of flow rates from currently available nipples to support these decisions. Jackman (2013) conducted a study of flow rates from 23 types of nipples, six of which were identified as being used in the setting of neonatal intensive care units. Wide variability was found in the flow rates of nipples tested, ranging from 6 to 60 mL/min. Nipples marketed as "slow-flow"

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varied considerably in the flow rates delivered, with some having three times the flow of others. Furthermore, significant variation was reported between nipples of the same type. Given the variability between nipples of the same type, Jackman's study was limited in that only one nipple per type was tested for nipples intended for multiple use, and three nipples per type were tested for single-use nipples. To account for the variability between nipples and to determine an accurate mean flow rate of each nipple type, more tests were needed. No statistical analysis was presented in the report of Jackman's study.

Speech-language pathologists are among the clinicians who assess feeding in infants who are hospitalized and recommend feeding management strategies, which may include specification of bottle nipples to be used for feeding. More information is needed to support clinicians in decision making regarding nipple selection for feeding infants who are hospitalized. Without this information, infants are often exposed to multiple types of nipples in an effort to find a good match. The variability in nipples during early oral feeding may contribute to the length of time required to successfully feed and, ultimately, to length of stay. This comparative, descriptive study tested the milk flow rates and variability of nipples used for bottle-feeding infants who are hospitalized.

Method

This study was exempt from review by the institutional review board, because no human or animal subjects were involved in the study. Clinicians from the United States, the Netherlands, and Australia were informally surveyed regarding nipples available to them for feeding infants in the hospital. Twenty-nine nipples were identified and tested (see Table 1). A power analysis was conducted

using data from the first eight nipple types tested ($n = 80$ individual nipples) to determine the sample size required to compare flow rates between nipple types with 80% power at an α of .05. This analysis revealed that a sample size of 10 nipples from each nipple type would provide ample power, even in the event of an effect size $< .3$ and moderate correlation between nipples of the same type. Ten nipples of each nipple type were tested.

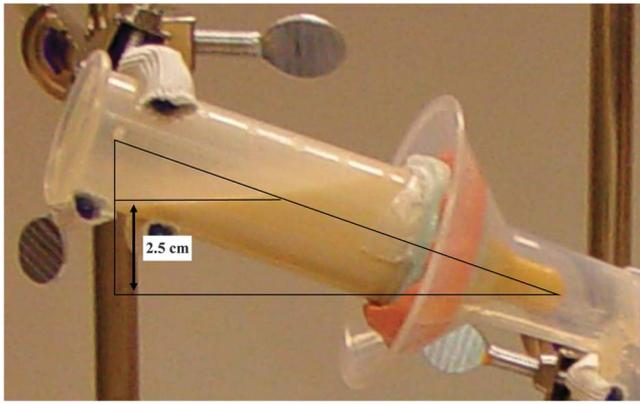
The method used in this study was designed to test nipples under standardized and controlled conditions as a means to compare flow rates between nipple types. Infants feed with varying sucking rates and pressures and will achieve different flow rates within and between feedings. The flow rates established by this method are not necessarily the flow rates that an infant will achieve when feeding.

All of the nipples except the Dr. Brown's Level 1 Wide-Neck fit on a 60-mL Grad-U-Feed Nurser (Mead Johnson & Co., Glenview, IL) and were tested with this bottle. The Dr. Brown's Level 1 Wide-Neck nipple was tested using a Dr. Brown's Wide-Neck bottle. Bottles were filled with Similac Advance Stage 1 (20 cal/oz) ready-to-feed formula (Abbott Laboratories, Abbott Park, IL). To ensure equal levels of hydrostatic pressure, the height from the level of the liquid surface to the tip of the nipple was maintained at 2.5 cm (see Figure 1), requiring 50 mL of formula for nipples tested with the Grad-U-Feed Nurser and 70 mL for the Dr. Brown's Wide-Neck bottle. The formula was changed after every 10 tests to prevent increased viscosity as a result of denaturation of proteins from prolonged exposure to air. Changing the formula after every 10 tests ensured that formula was never used after being open for more than 30 min. The manufacturer, Similac (Abbott Laboratories, Abbott Park, IL), recommends using formula within 1 hr of opening or mixing. In addition, using the ready-to-feed formula reduced the potential for variability

Table 1. Nipples tested.

Brand name	Company and location	Nipples tested
Bionix	Bionix Medical Technologies, Toledo, OH	Controlled Flow Baby Feeder Levels 1–5 (nipples and flow-restrictor systems tested separately)
Difrax	Difrax BV, Bilthoven, the Netherlands	Teat Natural Standard-Neck Small (0+ months)
Dr. Brown's	Handi-Craft Co., St. Louis, MO	Level 1 Standard-Neck Level 1 Wide-Neck Ultra-Preemie Preemie Y-Cut Standard Neck
Enfamil	Mead Johnson & Co., Glenview, IL	Standard-Flow (royal-blue collar) Slow-Flow (turquoise collar) Preemie (light-blue collar) Cross-Cut (yellow collar)
Medela	Medela Inc., McHenry, IL	SpecialNeeds Feeder (formerly Haberman Feeder)
NUK	NUK USA LLC, Hackensack, NJ	Orthodontic Silicone Slow-Flow Standard-Neck
Pigeon	Pigeon, Tokyo, Japan	Standard-Flow Slow-Flow No-Drip
Similac	Abbott Nutrition, Lake Forest, IL	Infant (yellow nipple, clear collar) Slow Flow (yellow nipple, yellow collar) Orthodontic (yellow nipple, clear collar) Premature (red nipple, clear collar)

Figure 1. Hydrostatic pressure measured as the height from the level of the nipple opening to the level of fluid.

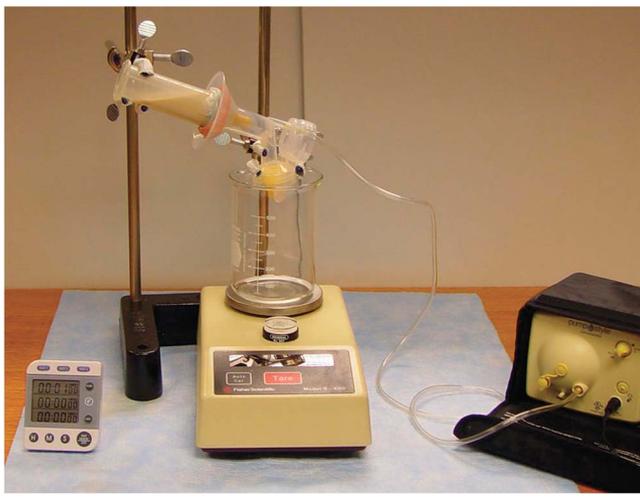


in milk thickness due to differences in formula preparation over time.

The bottle-and-nipple unit being tested was attached to the breast shield of a breast pump using a layer of plastic paraffin film followed by a silicone-based polymer to create a seal. The bottle-and-nipple unit was held at a 30° angle (see Figure 2). A negative-pressure system was created using a Pump in Style Advanced breast pump (Medela Inc., McHenry, IL). The stimulation-phase suction pattern with a suction pressure of 180 mmHg was used for all tests. Given the opportunities for loss of suction from the pump to the nipple, negative pressure within the bottle was tested after every 50 tests using the Samba 201 Micro Pressure Measurement System (BIOPAC Systems, Inc., Goleta, CA). Mean suction rate was 110 c/min and mean negative pressure within the bottle was 14 mmHg.

Formula was expressed for 1 min into a 500-mL beaker situated on a calibrated platform scale (Thermo Fisher Scientific, Inc, Waltham, MA), accurate to 0.01 g. At the

Figure 2. Nipple testing equipment.



conclusion of 1 min, the weight of formula expressed was recorded. Outliers were retested to ensure accuracy of the measurement. Tests were video-recorded and measurements were confirmed by video review. Milk flow rates (mL/min) were calculated using the density of Similac Advance formula of 0.97 mL/g (AVCalc, 2014).

The Bionix Controlled Flow Baby Feeder consists of two parts that may contribute to variability in milk flow: the nipple with the silicone inner channel and the flow-restrictor (FR) system, consisting of the yellow flow restrictor, purple seal, and green flow adjuster (Bionix Medical Technologies, 2014). Because the nipple and FR system may contribute to flow in different ways, 10 nipples were tested using the same FR system, and separately, 10 FR systems were tested using the same nipple. For both the nipple and FR tests, the Bionix was tested on each of the five flow levels, resulting in a total of 100 tests. Also of note, the Dr. Brown's nipples were tested with the venting system in place, which is how the nipple is intended to be used. The venting system comprises the cream-colored vent insert and the blue vent reservoir (Handi-Craft Company, 2015a). The Medela SpecialNeeds Feeder was tested without the white circular valve membrane or the yellow circular disc (Medela Inc., 2015). The method used in this study for applying negative pressure to the nipple could not work with the valve membrane in place. The SpecialNeeds Feeder is intended to have three flow levels—zero, medium, and maximum—depending on the position of the slit opening in the infant's mouth when positive pressure (i.e., compression) is applied by the infant's mouth (Medela Inc., 2014). In this study, no positive pressure was applied. In the presence of negative pressure only, the slit opening should, theoretically, respond similarly regardless of positioning, but nipples were tested in the same position for consistency.

Statistical Analysis

Mean milk flow rate (mL/min) and standard deviation were calculated for each nipple type. Variability within nipple types was assessed using the coefficient of variation (CV; SD/M). To compare variability across nipple types, CV was categorized into three levels: low (<0.1), moderate (0.1–0.2), and high (>0.2).

The Shapiro–Wilk statistic was used to assess nipples for normality, with an α of .05 considered significant. Comparisons between nipple types were made within brand and within category (Slow, Standard, and Premature) using one-way analysis of variance (ANOVA) when normally distributed; nonparametric one-way ANOVA was used otherwise. Multiple comparison tests for the post hoc analysis of one-way ANOVA utilized Duncan's multiple range test, with an α of .05 being significant. When nonparametric one-way ANOVA was utilized, pairwise comparisons were made using the Wilcoxon rank-sum test, and the alpha was adjusted using a Bonferroni adjustment.

For the purpose of comparing nipples within the categories of Slow, Standard, and Premature, nipples were categorized by name, with a few exceptions. The Bionix Level 1

is intended to “introduce taste” and the Level 2 is intended to deliver a slow flow (Bionix Medical Technologies, 2014); these two levels were categorized as Slow. The Bionix Level 5 is intended to deliver flow “at or near a flow rate of a Stage 1 nipple” (Bionix Medical Technologies, 2014), so this was categorized as Standard. For comparisons within category, the Bionix nipple and FR tests were combined for each level. Dr. Brown’s Premie and Ultra-Premie were included in the categories of both Slow and Premature. Dr. Brown’s Level 1 Wide- and Standard-Neck were categorized as Standard. The Medela SpecialNeeds Feeder was categorized as Slow.

Results

Flow rates varied widely between nipples, ranging from 2.10 mL/min for the Enfamil Cross-Cut (also change four lines down) to 85.34 mL/min for the Dr. Brown’s Y-Cut Standard Neck (see Figure 3). Variability of flow rates among nipples of the same type ranged from a CV of 0.05 for Dr. Brown’s Level 1 Standard- and Wide-Neck to 0.42 for the Enfamil Cross-Cut (see Figure 4). Mean CV by brand ranged from 0.08 for Dr. Brown’s to 0.36 for Bionix (see Figure 5).

Comparisons Within Brand

Bionix Controlled Flow Baby Feeder

This system was tested to evaluate the flow and variability of the nipples (indicated by an *N* after the level in

the text) and the FR systems (indicated by an *FR* after the level in the text and figures) separately. For both the nipple and FR tests, milk flow increased overall in the direction intended (Level 1 being the slowest and Level 5 being the fastest). Within the nipple tests, each level provided a significantly different flow rate ($p < .001$), with the exception of Levels 2N and 3N, which were not significantly different. Within the FR tests, 2FR and 3FR were not significantly different and 4FR and 5FR were not significantly different.

Comparing the FR tests to the nipple tests, Levels 1N and 1FR were comparable and Levels 2N and 2FR were comparable. For all levels above 2, the nipple tests were significantly ($p < .001$) slower than the FR tests. For all levels above 1, there was overlap between levels. Levels 2N, 2FR, and 3N were all similar to one another. Level 3FR was comparable to Levels 4N and 5N. At each level, the CV was higher for the FR tests than the nipple tests. Bionix Levels 3N and 5N were the only levels with CV < 0.1.

Dr. Brown’s

All levels of Dr. Brown’s nipples were found to be significantly different ($p < .005$), with the exception of the Premie and Level 1 Wide-Neck, which were found to be comparable. Dr. Brown’s Ultra-Premie performed as intended, with the lowest flow (3.39 mL/min) of all the nipples by this brand; this nipple had the second lowest flow of the 29 nipple types tested in this study. Dr. Brown’s Y-Cut

Figure 3. Milk flow rates of all nipples tested (mL/min). FR = flow restrictor.

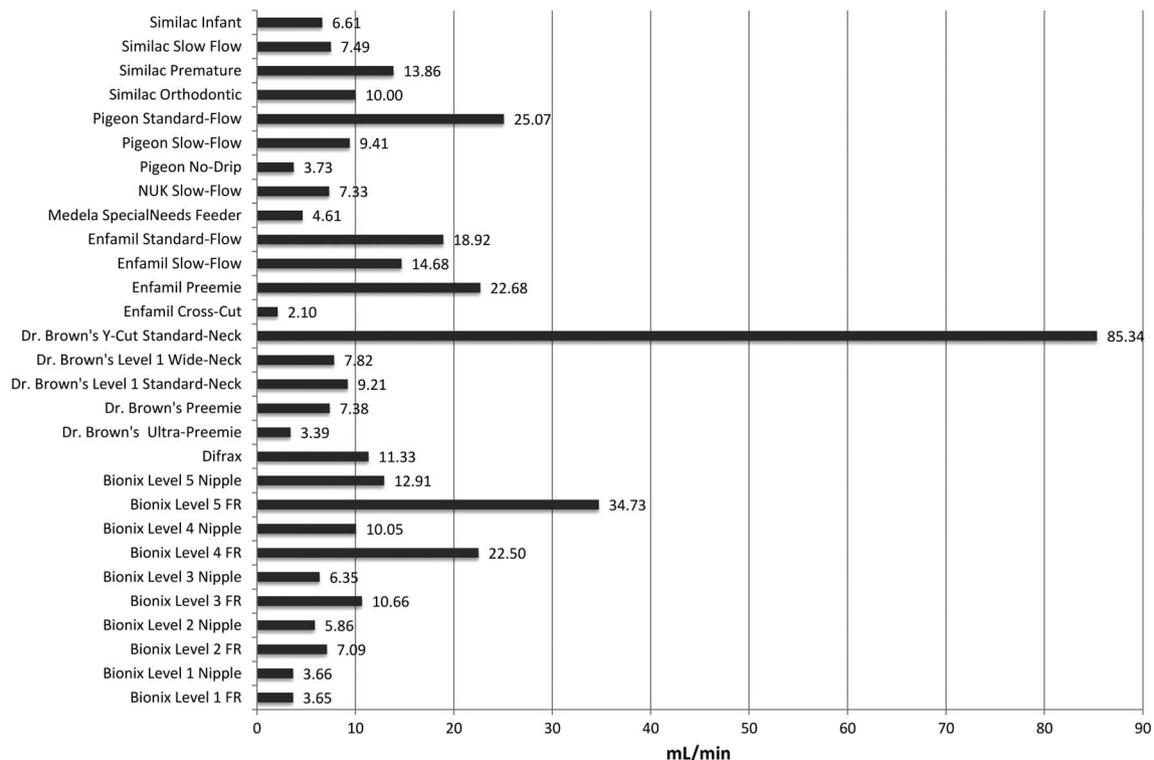


Figure 4. Coefficient of variation (CV) of milk flow of all nipples. Nipples are color coded by category of CV. Diagonal pattern indicates CV < 0.1, gray indicates CV 0.1–0.2, and black indicates CV > 0.2. CV = M/SD ; FR = flow restrictor.

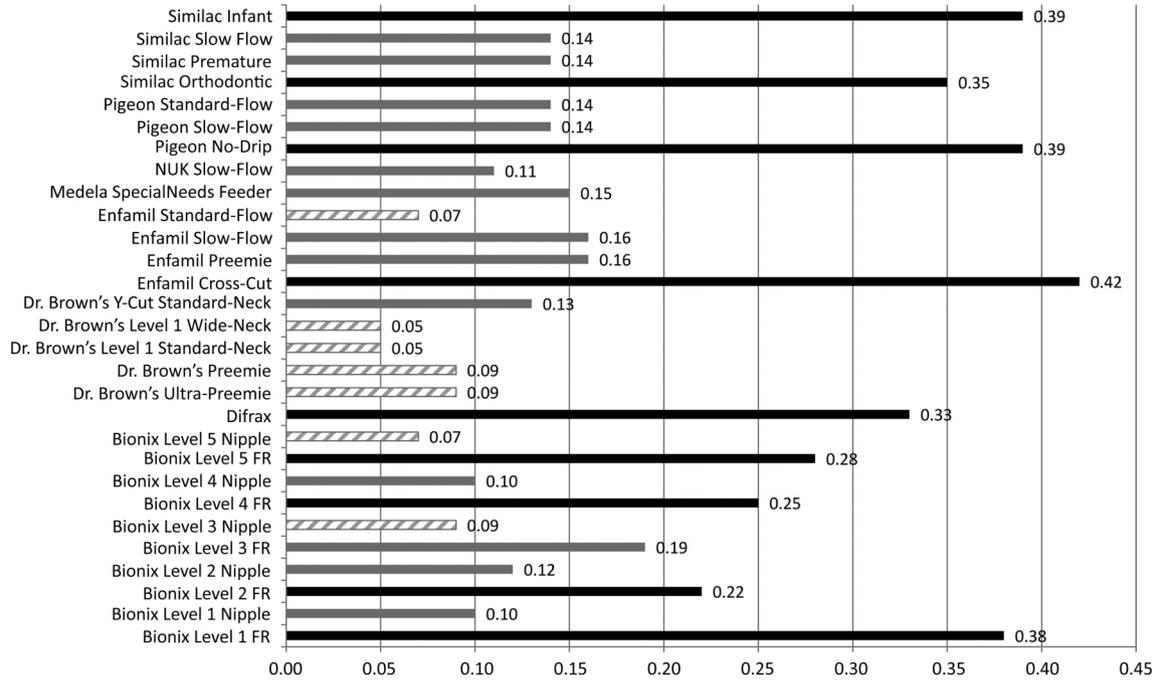
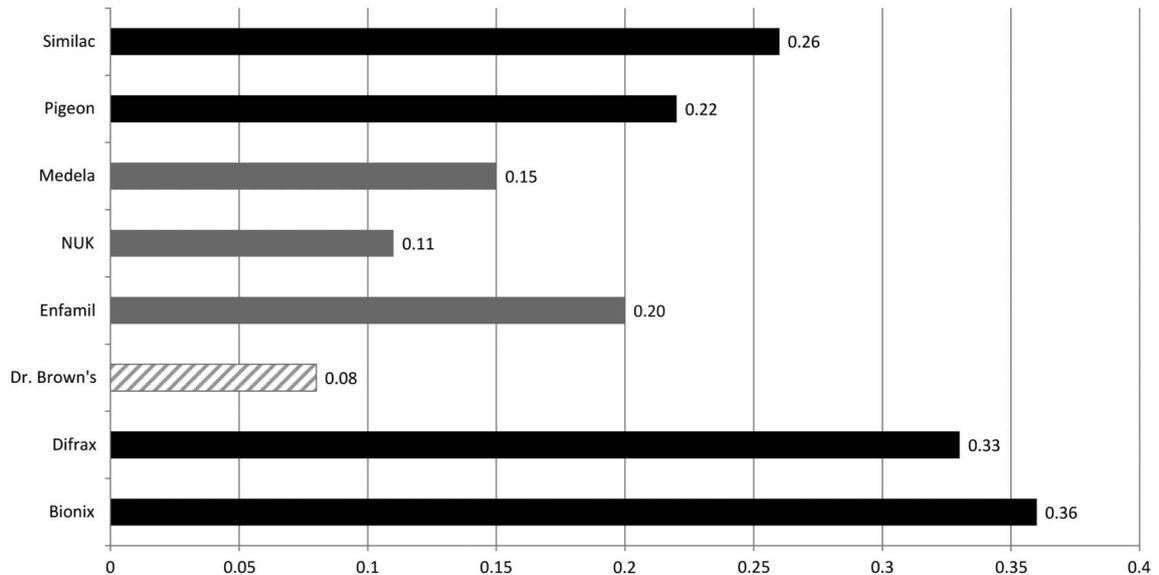


Figure 5. Mean coefficient of variation (CV) of milk flow rates by nipple brand. Calculated as the mean of the CV of each nipple type by each brand. Brands are color coded by category of CV. Diagonal pattern indicates mean CV < 0.1, gray indicates CV 0.1–0.2, and black indicates CV > 0.2.



Standard Neck had the highest flow of all the nipples tested (85.34 mL/min) and was moderately variable, with a CV of 0.13. All of the other Dr. Brown's nipples had a CV < 0.1.

Enfamil

All levels of Enfamil nipples were found to be significantly different ($p < .05$), with the Cross-Cut being the slowest and the Premie being the fastest. Enfamil Standard-Flow was the only nipple with a CV < 0.1.

Similac

Slow Flow and Infant nipples did not have significantly different flow rates. Similac Slow Flow ranged from 6.16 to 9.38 mL/min (CV 0.1–0.2), whereas Similac Infant ranged from 3.8 to 12.0 mL/min (CV > 0.2). Similac Orthodontic was significantly faster ($p < .05$) than Slow Flow or Infant and was highly variable (CV > 0.2). Similac Premature was the fastest of all Similac products ($p < .05$).

Pigeon

All levels of Pigeon nipples were significantly different ($p < .05$). The No-Drip was the slowest but also the most variable (CV > 0.2).

Comparisons Within Category

Slow Nipples

Nine of the 29 nipples tested were categorized as Slow, with flow ranging from 3.39 to 14.68 mL/min (see Figure 6). Dr. Brown's Ultra-Premie, Bionix Level 1, and Medela

SpecialNeeds Feeder were comparable to one another; these were all significantly slower ($p < .001$) than the other Slow nipples. Bionix Level 2, Dr. Brown's Premie, NUK Slow-Flow, and Similac Slow Flow all delivered comparable flow. Enfamil Slow-Flow was significantly faster ($p < .001$) than all other Slow nipples. Pigeon Slow-Flow was significantly slower than Enfamil Slow-Flow ($p < .001$) but significantly faster ($p < .05$) than all other Slow nipples.

Standard Nipples

Seven nipples were categorized as Standard, with flow ranging from 6.61 to 25.07 mL/min (see Figure 7). Similac Infant, Difrax, and Dr. Brown's Level 1 Wide- and Standard-Neck nipples were comparable to one another; these were all significantly slower than the other Standard nipples ($p < .05$).

Premature Nipples

Four nipples were categorized as Premature, with flow ranging from 3.39 to 22.68 mL/min (see Figure 8). All four Premature nipples delivered significantly different flow rates ($p < .05$).

Discussion

Choosing a nipple for feeding an infant who is medically fragile is an important decision, given the wide range of flow rates found in this study. The name of a nipple (e.g., "Slow") is not always an accurate indicator of the flow rate. In addition, variability in flow rate between and

Figure 6. Milk flow rates of Slow nipples (mL/min). Nipples indicated by the same color/pattern are comparable in flow rate.

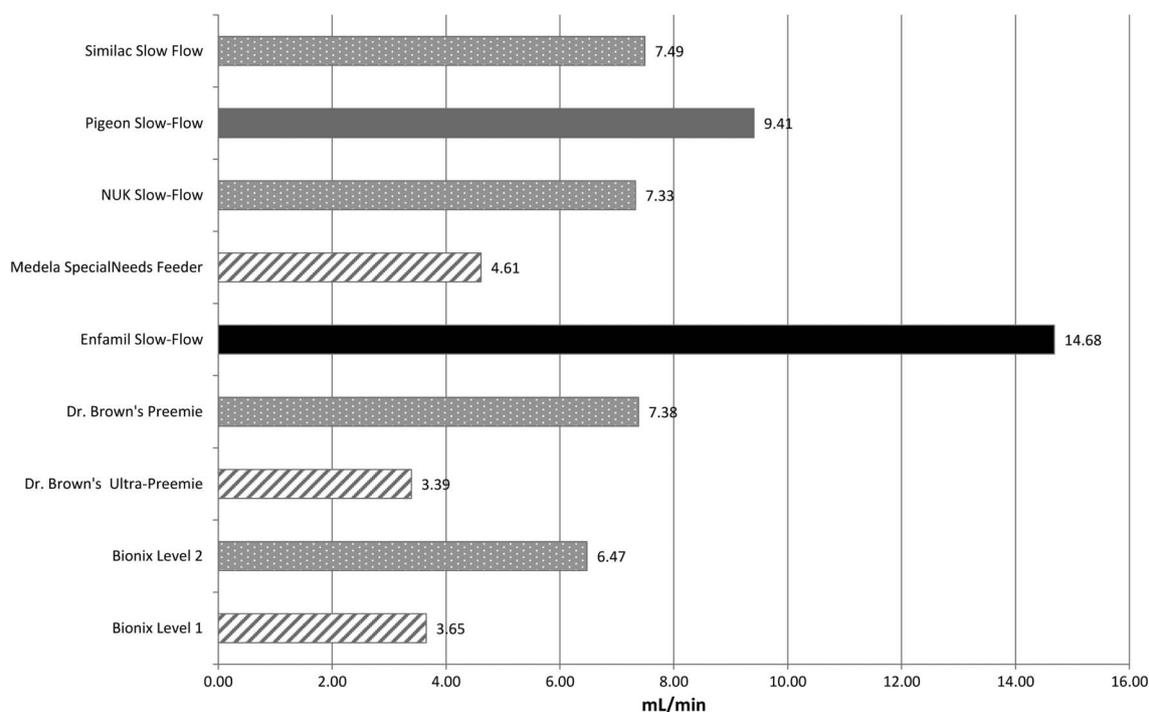


Figure 7. Milk flow rates of Standard nipples (mL/min). Nipples indicated by the same color/pattern are comparable in flow rate.

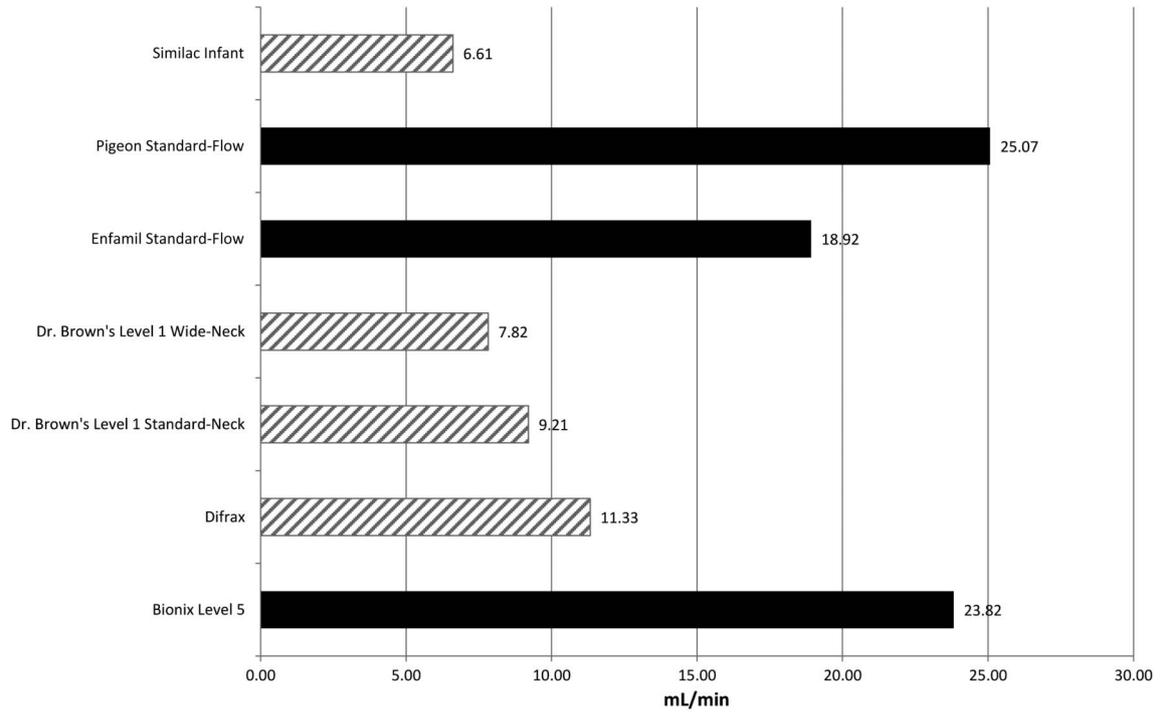
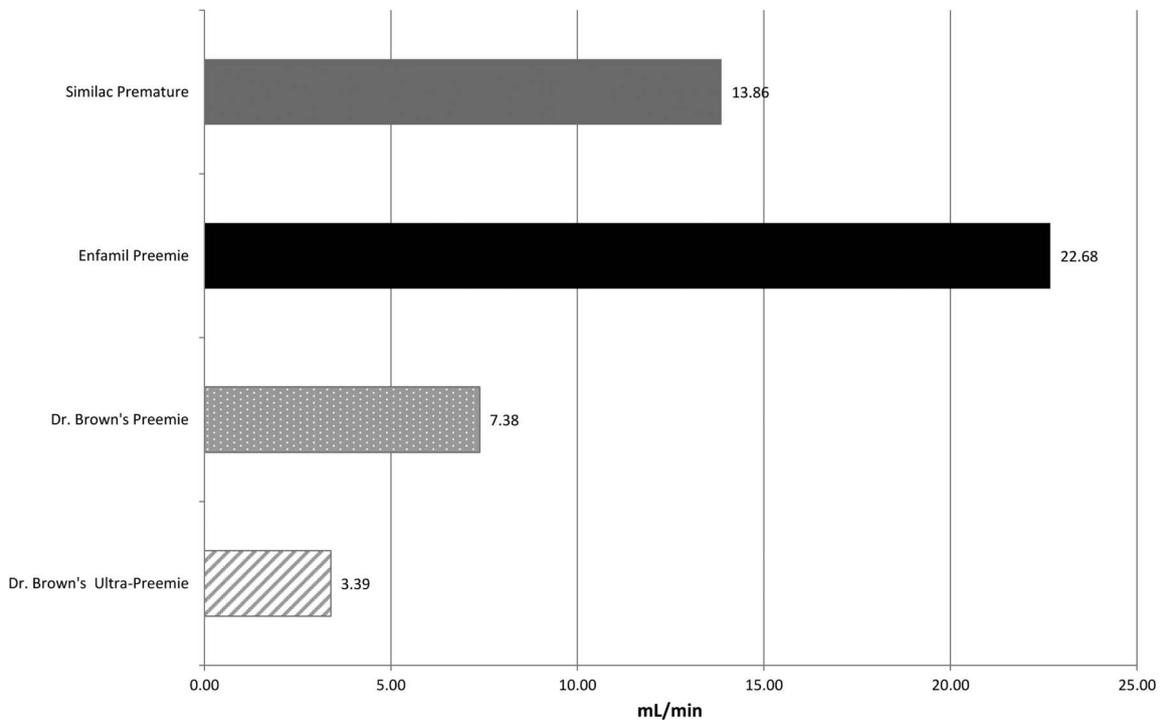


Figure 8. Milk flow rates of Premature nipples (mL/min). Nipples indicated by the same color/pattern are comparable in flow rate. Note that all four Premature nipples had significantly different flow rates.



within nipple types is an added challenge that may contribute to feeding difficulty.

Within the Bionix brand, for all levels above Level 1, there was overlap in flow rates between levels, suggesting that the Bionix Controlled Flow Baby Feeder may not perform as expected when the user increases the flow adjuster from one level to the next. The FR systems were particularly variable, with four of the levels having $CV > 0.2$. Changing the nipple or the FR may inadvertently change the flow rate delivered, even if the user sets the flow adjuster to the same position.

Bionix does provide a Flow Rate Comparison chart on its website (Bionix Medical Technologies, 2014). According to Bionix, a similar, but not completely transparent, method was used to test flow rates for 50 s using a Medela Classic Breast Pump (S. Herzig, personal communication, March 2014). Our results were consistent with Bionix's for the increase in flow between Levels 1 and 2; the company found a 75% increase where we found 77%. Both our tests and Bionix's found the greatest increase in flow to be between Levels 3 and 4. Bionix also tested nipples made by other companies, but it is difficult to make comparisons because the names of the nipples have changed and the methods may have been different. In the current study, Bionix Level 1 was among the slowest of the nipples tested and may be useful for feeding infants who require a very slow flow.

Dr. Brown's markets the Ultra-Premie nipple as being 35% slower than the brand's Premie nipple (Handi-Craft Company, 2015b). In our tests, the Ultra-Premie was 54% slower than the Premie nipple. Dr. Brown's brand was the most consistent brand, with the lowest mean CV of all brands (see Figure 5).

The Enfamil Cross-Cut was the slowest of all nipples tested. Cross-cut nipples have two slits that form a cross at the tip of the nipple. Enfamil advertises this nipple as having a faster flow than the brand's standard nipple (Enfamil Cross-Cut Nipple, n.d.), which is not consistent with our findings. Cross-cut nipples are described as varying in flow, with increasingly faster flow as the infant applies suction and opens the cross wider (Start & St James-Roberts, 2000). Two clinical studies have evaluated the physiologic effects of feeding with either a cross-cut or a single-hole nipple and found that, at sucking pressures established by preterm infants, the cross-cut yielded slower flow than the single hole (Chang, Lin, Lin, & Lin, 2007; Kao, Lin, & Chang, 2010). These studies did not use Enfamil nipples, but they may support further investigation of our findings and of how the cross-cut performs in practice.

For both the Enfamil and Similac brands, the Premature nipple was faster than the Slow and Standard nipples. This is important for clinical practice, as many clinicians assume that a nipple labeled "Premature" has a slower flow rate. Premature infants typically generate lower sucking pressures than full-term infants (Medoff-Cooper, McGrath, & Shults, 2002) and may become fatigued early in the feeding, before adequate volume is ingested. There was a previously held popular belief that increasing the flow rate for these

infants would make it easier for them to transfer milk, given low sucking pressures (Mathew, 1990), and that faster feedings would allow them to intake volume before becoming fatigued. Certain premature nipples may have been designed on the basis of these assumptions. More current evidence supports slower flow for maintaining physiologic stability during feeding for these infants, allowing them to breathe more (al-Sayed et al., 1994; Mathew, 1991a; Park, Thoyre, Knafl, Hodges, & Nix, 2014), maintain better oxygenation, and endure oral feeding longer.

The variability found between nipples of the same nipple type is likely the result of differences in manufacturing processes. Nipple holes may be created through a variety of methods, including mechanical drilling, laser cutting, and hole punching. In addition, nipples may be created in a mold with a standardized hole opening. The process for creating the nipple hole or cut likely contributes to the variability in nipple hole size and, therefore, the variability in flow rates found in this study. There may also be other qualities of nipples, such as the mechanical stiffness of the nipple material, that affect flow from the nipple or the infant's sucking during feeding that could not be detected using our methods (Barlow, 2009).

This study has some limitations. The method used in this study applied only negative pressure to nipples. Nipples with a slit opening as opposed to a hole opening are likely to perform differently when positive pressure is applied during feeding, changing the shape of the opening. The two nipples in this study with slit openings were the Enfamil Cross-Cut and the Medela SpecialNeeds Feeder; caution should be used when interpreting these results, as the flow rates may be different in practice. Also, the Dr. Brown's Y-Cut Standard Neck nipple was tested with standard-thickness formula. In clinical practice, this nipple is typically used with thickened milk for infants who are medically fragile, which likely affects flow rate.

Conclusions and Future Directions

Milk flow is an important variable in the complex task of oral feeding for infants who are medically fragile. This study confirmed results of previous studies (Jackman, 2013; Mathew & Cowen, 1988) which found a wide range in milk flow rates from different nipple types. This study has built on previous work by testing additional nipples that are currently available for feeding infants who are hospitalized, further exploring variability within nipple types, and improving upon the testing and analysis methods.

Clinicians may use these data to guide nipple selection for infants who are medically fragile by comparing the flow rates and variability of the nipples that are available within their institutions. Evidence-based decisions regarding nipple selection may support optimal oral feeding for infants who are fragile and facilitate earlier discharge home. Given the importance of milk flow for infants who are fragile, manufacturers of nipples should consider providing information on nipple packaging that reflects flow rate and variability of each nipple type; this would help to reduce

any confusion related to the naming of nipples (i.e., “Slow,” “Standard,” “Premature”), which may not accurately reflect flow rate. Manufacturers could also use the information from this study to improve upon nipple construction to reduce variability, particularly in nipples intended for infants who are fragile.

Researchers should use these data to make decisions about nipples used in tests of feeding interventions and select nipples with low variability in order to ensure consistency of flow. The specific nipple(s) used, flow rate, and variability of nipples should be documented in reports of feeding intervention studies.

Testing of flow rates of the nipples in this study will need to be repeated periodically to reflect currently available nipples. In addition, testing of milk flow rates of nipples used for feeding infants after discharge is currently underway and will provide clinicians with information to guide parents in selecting nipples for use at home that are comparable in flow to those with which the infant has been successful in the hospital. Future research should consider testing the effect of milk type (e.g., formula vs. breast milk), caloric density, and thickness on flow rates from bottle nipples. In addition, testing the flow rate and variability in bottle nipples on the sucking parameters (e.g., sucking pressure and rate) of infants who are fragile would provide information to tailor nipple selection to sucking pattern to further support infants who are fragile as they learn to eat.

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