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Randomized Clinical Trial of Pacifier Use and Bottle-Feeding or Cupfeeding and Their Effect on Breastfeeding

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ABSTRACT. *Objective.* To enhance breastfeeding practices, the World Health Organization discourages pacifiers and bottle-feeding. However, the effect of artificial nipples on breastfeeding duration is poorly defined. The effects of 2 types of artificial nipple exposure on breastfeeding duration were evaluated: 1) cupfeeding versus bottle-feeding for the provision of in-hospital supplements and 2) early (2–5 days) versus late (>4 weeks) pacifier introduction.

Methods. A total of 700 breastfed newborns (36–42 weeks, birth weight ≥ 2200 g) were randomly assigned to 1 of 4 intervention groups: bottle/early pacifier ($n = 169$), bottle/late pacifier ($n = 167$), cup/early pacifier ($n = 185$), or cup/late pacifier ($n = 179$). The cup/bottle intervention was invoked for infants who received supplemental feedings: cup ($n = 251$), bottle ($n = 230$). Data were collected at delivery and at 2, 5, 10, 16, 24, 38, and 52 weeks' postpartum. Intervention effects on breastfeeding duration were evaluated with logistic regression and survival analyses.

Results. Supplemental feedings, regardless of method (cup or bottle), had a detrimental effect on breastfeeding duration. There were no differences in cup versus bottle groups for breastfeeding duration. Effects were modified by the number of supplements; exclusive and full breastfeeding duration were prolonged in cup-fed infants given >2 supplements. Among infants delivered by cesarean, cupfeeding significantly prolonged exclusive, full, and overall breastfeeding duration. Exclusive breastfeeding at 4 weeks was less likely among infants exposed to pacifiers (early pacifier group; odds ratio: 1.5; 95% confidence interval: 1.0–2.0). Early, as compared with late, pacifier use shortened overall duration (adjusted hazard ratio: 1.22; 95% confidence interval: 1.03–1.44) but did not affect exclusive or full duration.

Conclusions. There was no advantage to cupfeeding for providing supplements to the general population of healthy breastfed infants, but it may have benefited mother–infant dyads who required multiple supplements or were delivered by cesarean. Pacifier use in the neonatal period was detrimental to exclusive and overall breastfeeding. These findings support recommendations to avoid exposing breastfed infants to artificial nipples in the neonatal period. *Pediatrics* 2003;111:511–518; *breastfeeding, pacifiers, bottle-feeding, cupfeeding.*

ABBREVIATIONS. WHO, World Health Organization; ITT, intention-to-treat; CI, confidence interval; OR, odds ratio; HR, hazard ratio.

Infants must learn to attach and suckle properly at the breast during the first few days of life to breastfeed successfully.^{1,2} Exposures to artificial nipples are believed to contribute to breastfeeding problems and early weaning.^{3–6} Indeed, the UNICEF/World Health Organization (WHO) Baby Friendly Hospital Initiative specifically proscribes 2 such exposures, pacifier use and bottle-feeding, citing their avoidance as important to the successful establishment of breastfeeding.⁷ However, there is no strong evidence for this belief.^{8–10}

Pacifier use is common both in the hospital and during the early months of life when nonnutritive sucking is useful in helping to calm infants.^{11,12} Although many observational studies suggest a negative impact of pacifiers on breastfeeding,^{6,12–16} 2 randomized trials have failed to support a causal association between pacifiers and breastfeeding problems.^{17,18}

Bottle-feeding is routinely used to provide supplements to breastfed infants. Supplemental formula feeding is strongly associated with early breastfeeding termination, but there is little empiric evidence to show that artificial nipple exposure during bottle-feeding shortens breastfeeding duration.^{17,19,20} Healthy breastfed infants are unlikely to need supplemental feedings, but infants who are small for gestational age or hypoglycemic or whose mothers become ill postpartum often require such feedings. The best way to supply these feedings without interfering with breastfeeding remains unknown, yet some experts purport that early exposure to bottle nipples contributes to breastfeeding failure.⁵

"Nipple confusion" is the term commonly applied to a breastfeeding problem hypothesized to result from the mechanical differences between suckling at the breast and sucking on a pacifier or bottle nipple.⁵ Scientific studies of nipple confusion are lacking, but there are studies indicating that the mechanics of bottle-feeding and breastfeeding differ.^{21–26} In addition, in areas of the world where pacifier use is rare and cupfeeding is used to supplement breastfed infants who require artificial feedings, nipple confusion is reported to be uncommon.²⁷ Cupfeeding also has been shown to be a safe and easily learned technique useful in both premature and term infants.^{28,29}

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It has been recommended by the Baby Friendly Hospital Initiative, WHO, and the International Infant Food Action Network as a method for supplementing breastfed infants who require supplemental feedings.³⁰⁻³²

Given the scarcity of scientifically rigorous studies that address the impact of artificial nipple exposure on breastfeeding, we conducted a dual-intervention, randomized, clinical trial to evaluate the effects of pacifier use and in-hospital cupfeeding and bottle-feeding on breastfeeding. Outcomes for the study were the times to cessation of overall, full, and exclusive breastfeeding and breastfeeding-associated maternal and infant problems. Because primiparous women, those with low educational attainment, and women delivered by cesarean section are known to be at increased risk for poor outcomes, we also assessed intervention effects in these subgroups.

METHODS

This study protocol was approved by the institutional review board of the University of Rochester School of Medicine and Dentistry, and informed consent for study participation was obtained. Enrollment occurred between January 1997 and October 1998 from mother-infant couplets that delivered at Rochester General Hospital. Rochester General is a 526-bed community hospital affiliated with the University of Rochester School of Medicine and at the time of this study held an active certificate of intent to become baby-friendly. In 1998, approximately 2800 births occurred at this hospital, and approximately 64% of women breastfed their infants. US breastfeeding initiation rates in 1998 were 64%.³³ Sample size calculations determined that 700 infants would be needed to detect a 10% difference in breastfeeding cessation at 4 weeks' postpartum with an $\alpha = .05$ and a power of .90.

Initial prenatal contacts were made with approximately 3700 women. Women who intended to breastfeed their infants for at least 4 weeks; had uncomplicated, singleton pregnancies; and were undecided or wanted their infants to use a pacifier were

eligible for the trial. On admission to the hospital, the yet unborn infant was randomized to 1) a cup or bottle supplemental feeding group and 2) an early (2-5 days) or late (>4 weeks) pacifier introduction group. The randomization process used an opaque envelope system and blocks of 20.

A total of 807 infants who were healthy (2200 g or more at delivery, ≥ 36 weeks' gestation, with Apgar scores ≥ 7 at 1 minute and ≥ 8 at 5 minutes) were identified and considered eligible for enrollment (Fig 1). Of this group, 107 infants were not enrolled because they required admission to the neonatal intensive care unit on delivery ($n = 70$) or because the mother decided not to breastfeed ($n = 6$) or declined further participation after delivery ($n = 31$). Mothers who dropped from the study were more likely to be primiparous ($P = .004$) and to smoke ($P = .03$) but did not differ in terms of race, age, education, or number of prenatal visits from the 700 mothers who were enrolled.

Supplemental Feeding Intervention (Cup Versus Bottle)

After delivery, the infant was identified as a study participant by a special crib tag, and the infant's feeding records were labeled with the appropriate supplemental method (cup or bottle). Infants who developed medical indications for or whose mothers requested supplemental feedings were enrolled in this portion of the study (cup [$n = 251$], bottle [$n = 230$]). Maternal requests for supplemental feedings are known to account for a large proportion of such feedings. Nurses routinely documented the reason for supplementation, counseled mothers without medical indications about the risks, but honored persistent requests. Inclusion of these data allowed us to evaluate the modifying effects of medically indicated as opposed to nonindicated supplements on breastfeeding. Supplemental feedings were administered by the nurse assigned to the care of the couplet.²⁸ Small plastic medicine cups were used to administer cupfeedings, and standard bottle nipples were used for bottle-feeding. Infants received supplements by the designated method while in the hospital and were allowed to feed ad libitum during feedings. Occasionally, an infant who cup- or bottle-fed poorly was encountered and it was necessary to administer the feeding by the alternative method. Data from such infants were analyzed according to intention-to-treat (ITT).

We encountered no instances of infants' being discharged while continuing to medically require supplementary feedings. Parents were routinely instructed about the advantages of full breastfeed-

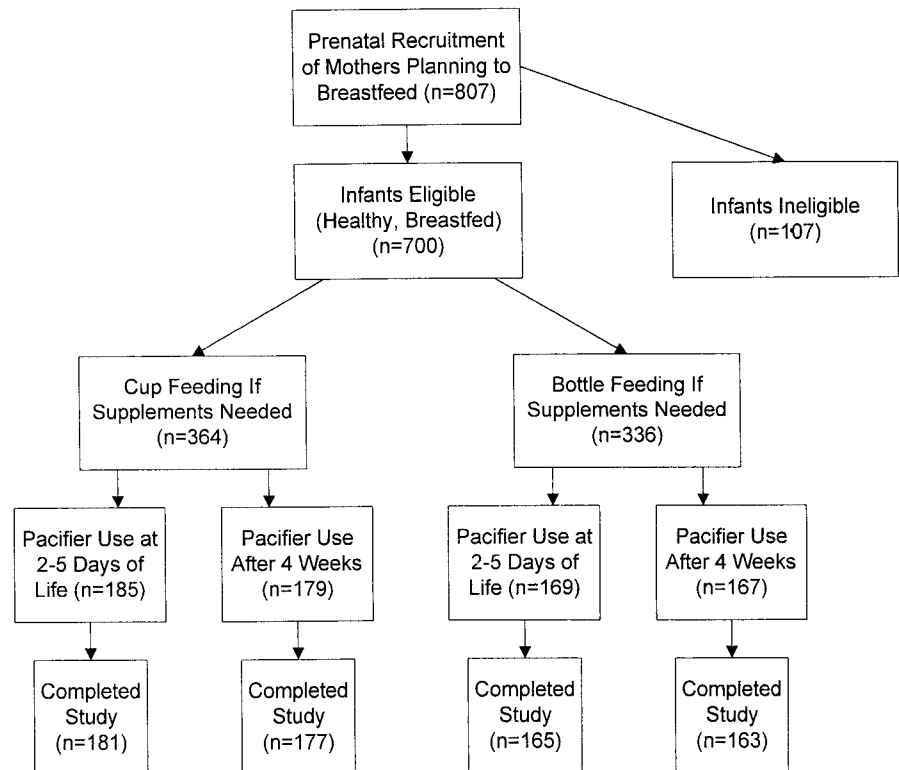


Fig 1. Flow of study.

TABLE 1. Summary of Interventions Based on Randomization and Whether the Infant Received In-Hospital Supplemental Feedings*

Randomization	Supplements	Pacifier Exposure	
	Were Supplements Received During Hospital Stay?*	Pacifier Use in First Month	Pacifier Use After 1 Month
Cup	Early	+	+
	Late	+	+
Bottle	Early	+	+
	Late	+	+

* All infants were randomized to a potential supplemental feeding group; however, such feedings were given only when the infant developed medical indications for feedings or upon maternal request.

ing during the first 6 months of life and cautioned about the effects of supplements on milk supply. No specific instructions were given regarding supplemental feeding methods after hospital discharge; parents were not instructed in the cupfeeding technique.

During our original data collection, we recorded numbers, composition, and methods used during supplemental feeding but did not record the volume of feeding. After completing our initial analyses, we wondered whether differences in the volume consumed by infants in cup and bottle groups was affecting our findings.^{28,29} To evaluate possible differences in the total volume of non-breast milk supplements consumed by cup and bottle study groups, we randomly selected and reviewed the hospital records of 100 supplemented infants in each study group.

Pacifier Intervention

Before discharge, mothers were interviewed by a research assistant, masked to group assignment, about family characteristics, plans for infant care, return to work and school, and past and current infant feeding experiences. A research nurse also instructed families about alternative methods of soothing infants (eg, skin-to-skin contact, walking, massage, music, swaddling). This nurse also provided generic instruction about the pacifier intervention and gave the family a study pack in accordance with their pacifier group assignment. Packs were opaque and pre-labeled with study identification; thus, the staff and family remained masked to the intervention until the packs were opened, per instructions, after hospital discharge.

The pack contents for the 2 groups were identical except that the early pacifier group received 2 Soothie pacifiers (Children's Medical Ventures, Inc, Youngwood, PA) and the late pacifier group received electric outlet covers. Both packs contained appropriate pacifier introduction instructions (early or late) and educational materials on infant development, comforting a crying infant, and colic. The early pacifier group was instructed to introduce the pacifier as soon as possible, using it as a mode of comforting in addition to any other techniques they wished to use. The late group was instructed to avoid use of a pacifier until the infant's fifth week of life and in the interim to use alternative forms of comforting. During the fourth week of life, the late group received 2 Soothie pacifiers by mail.

Postnatal Follow-up

Participating mothers were interviewed at 2, 5, 10, 16, 24, 38, and 52 weeks by a nurse masked to the group assignment. Interviews were conducted by telephone using standardized questionnaires with categorical or quantitative responses designed to assess breastfeeding duration and any intervening problems. Nurses also provided support for maternal and infant health care questions and breastfeeding within the limitations imposed by the protocol (eg, recommendations to discontinue use of a pacifier were avoided). On enrollment and completion of the 24-week and the 52-week interviews, participants were awarded gift certificates to a local grocery store as compensation. Prenatal and perinatal health data and some demographic data were obtained from infant birth certificates and maternal and infant chart reviews.

Masking

Study investigators, research assistants, and nurses conducting postpartum interviews were masked to group assignment for both interventions. The nurse who instructed parents in comfort measures and who distributed the research packs was not masked to group assignment for the supplemental feeding intervention. She did not participate in any interviews or data collection. It was not possible to mask the families to their group assignment for either intervention; however, we attempted as much as possible to mask the outcomes of interest.

Analysis

Data were entered and analyzed using SAS and Epi Info version 6.³⁴ Statistical tests used to compare baseline characteristics of the 4 study groups included analysis of variance, χ^2 tests, and Kruskal-Wallis tests as appropriate.³⁵ Baseline characteristics of infants who received supplemental feedings were compared with those who did not require supplements. In addition, among infants who required supplemental feeding, baseline characteristics of those randomized to cup or bottle were compared.

Comparisons of the times to breastfeeding cessation were made using the Kaplan-Meier method (SAS, PROC LIFETEST).³⁶ ITT analyses were conducted comparing early and late pacifier groups and among supplemented infants comparing cup and bottle groups. Subjects who were lost to follow-up were included in these analyses as censored observations. Because nipple confusion theoretically results in early cessation, the Wilcoxon test was used to determine statistical significance. Kaplan-Meier analyses also compared times to breastfeeding cessation among the following groups (6-group model): 1) no supplement, pacifier early; 2) no supplement, pacifier late; 3) cupfed, pacifier early; 4) cupfed, pacifier late; 5) bottle-fed, pacifier early; and 6) bottle-fed, pacifier late (Table 1).

Adjusted analyses were conducted using the Cox proportional hazards model (SAS, PROC PHREG).³⁶ For each of the 3 breastfeeding cessation variables, a stepwise process was used to select predictor variables from the following list: maternal race (white versus nonwhite), previous live births, infant's gender, receives federal assistance, plans to return to work/school, mother smokes, any smoker in the household, previously breastfed an infant, infant's father lives with mother, cesarean-section delivery, birth weight, gestational age, maternal age, maternal education, and personal breastfeeding goal. Predictors with $P \leq .10$ were retained in the model. After development of a baseline model, intervention variables were forced into the model to ascertain their effects on breastfeeding cessation as follows: cup versus bottle among supplemented infants and early versus late pacifier use in the whole study group. A final analysis assessed the relative importance of the 2 interventions simultaneously.

Because the late group did not begin pacifier use until 4 weeks, we were able to assess the effect of pacifier use versus no use on breastfeeding at 1 month. Baseline adjusted logistic regression models were developed as previously described. Similarly, the variables of interest, supplements given (yes/no), bottle use (yes/

no), and early pacifier use (yes/no) were then added to the model.³⁷

Postpartum breastfeeding frequency and infant and maternal breastfeeding complications were investigated among cup- versus bottle-supplemented infants and early versus late pacifier groups using *t* tests, Kruskal-Wallis tests, and χ^2 tests as appropriate. All analyses were conducted using the ITT principle, and the significance level was set at $\alpha = .05$.

Breastfeeding definitions used in this study³⁸ reflect the practices of women after hospital discharge and do not account for supplemental feedings in the hospital. Breastfeeding duration was measured in days and was categorized as exclusive, full, or overall. Exclusive breastfeeding implies that the infant had received no liquid or solid food other than breast milk. Full breastfeeding includes the infrequent use (less than daily) of water, juice, or ritualistic feeds. Overall breastfeeding was defined as the length of time an infant received any breastfeedings. The primary outcome variable was the time to cessation of overall breastfeeding, and analyses were repeated for full and exclusive breastfeeding.

RESULTS

The 700 mother–infant dyads that participated in this research formed 4 intervention groups: bottle/early pacifier ($n = 169$), bottle/late pacifier ($n = 167$), cup/early pacifier ($n = 185$), and cup/late pacifier ($n = 179$). Complete information on breastfeeding duration was obtained for 686 (98%) of the 700 participants (Fig 1).

Participating mothers were 29.0 ± 5.3 years old and well educated (14.3 ± 2.1 years). Eighty-one percent of participants were married, 87% were white, and 39% were primiparous. Infants were term (39.7 ± 0.9 weeks), with average birth weights of 3550 ± 462 g (Table 2). Study groups did not differ by maternal race, parity, employment status, smoking, breastfeeding experience or goal, mode of delivery, age, or education. Similarly, among infants who participated in the supplemental feeding intervention, there were no significant differences between study groups. Mothers of infants who received supplements were more likely to be primiparous (41% vs 35%), to receive federal assistance (17% vs 9%), to be breastfeeding for the first time (49% vs 39%), and to

be delivered by cesarean (20% vs 6%) as compared with those who were not supplemented.

Compliance with the supplemental feeding intervention was assessed by chart review. Among supplemented infants assigned to the bottle group, 89% received supplements by bottle and 11% by cup; among infants assigned to the cup intervention, 93% received supplements by cup and 7% by bottle.

We assessed pacifier use at every contact beginning with the 5-week contact. Daily pacifier use was measured using a Likert scale of no daily use, rare, some, often, and most of time and by amounts of time, no use, <30 minutes, 30 to 120 minutes, and 120 minutes or more. Among infants still breastfeeding at the preceding contact (eg, at 2 weeks for the 5-week contact), the scaled amount of use and minutes of pacifier use were significantly higher in the early group at 5 weeks but not at any other contact (Fig 2). Median time to pacifier introduction in the early pacifier group was 7 days (95% confidence interval [CI]: 4–14) and 28 days (95% CI: 21–30) in the late group. Ninety-four percent of parents reported introduction of a pacifier by 6 weeks' postpartum and 97% by 6 months.

Unadjusted, ITT, Kaplan-Meier analyses of the effects of both interventions on the time to breastfeeding cessation are displayed in Table 3. Kaplan-Meier estimates of median days of breastfeeding duration according to the 6-group model are displayed in Table 4 (also see Table 1).

Supplemental Feeding Intervention (Cup Versus Bottle)

Adjusted analyses failed to demonstrate that the supplemental feeding intervention (cup vs bottle) significantly affected either the likelihood of continued breastfeeding at 1 month postpartum or longer-term breastfeeding.

Sixty-nine percent (481 of 700) of infants participated in the supplemental feeding intervention. Infant chart reviews indicated that 33% of supplements

TABLE 2. Baseline Characteristics of 4 Treatment Groups

Characteristic	Bottle Early Pacifier ($n = 169$)	Bottle Late Pacifier ($n = 167$)	Cup Early Pacifier ($n = 185$)	Cup Late Pacifier ($n = 179$)	<i>P</i> Value
	<i>n</i> (%) or Mean (SD)	<i>n</i> (%) or Mean (SD)	<i>n</i> (%) or Mean (SD)	<i>n</i> (%) or Mean (SD)	
Mother's race (white)	148 (88%)	141 (84%)	156 (84%)	161 (90%)	.34
Previous live births	103 (61%)	107 (64%)	105 (57%)	110 (61%)	.56
Receives federal assistance	24 (14%)	30 (18%)	27 (15%)	19 (11%)	.28
Mother employed in pregnancy	130 (77%)	130 (78%)	144 (78%)	136 (76%)	.97
Plans to return to work/school	115 (68%)	116 (69%)	126 (68%)	132 (74%)	.61
Smoker in household	37 (22%)	30 (18%)	38 (21%)	31 (17%)	.67
Previously smoked	89 (53%)	93 (56%)	92 (50%)	104 (58%)	.41
Mother smokes	8 (5%)	6 (4%)	12 (6%)	9 (5%)	.66
Father lives in household	154 (91%)	147 (89%)	169 (91%)	162 (91%)	.80
Cesarean section delivery	31 (18%)	24 (14%)	33 (18%)	26 (15%)	.64
Maternal age (y)	29.4 (5.6)	28.9 (5.3)	28.4 (5.1)	29.4 (5.1)	.23
Maternal education (y)	14.3 (2.2)	14.2 (2.1)	14.4 (2.2)	14.5 (2.1)	.74
No. of prenatal visits	9.7 (3.1)	10.0 (3.3)	9.8 (2.7)	9.5 (3.0)	.44
Breastfeeding goal (wk)	27.5 (16.1)	27.3 (18.1)	27.6 (16.7)	28.5 (16.4)	.93
Infant gestational age (wk)	39.7 (0.9)	39.8 (0.7)	39.6 (1.0)	39.8 (0.9)	.22
Infant birth weight (g)	3499 (469)	3612 (456)	3555 (485)	3535 (434)	.15
Length of stay (h)	55.0 (18.6)	53.8 (17.0)	54.5 (18.4)	53.7 (16.8)	.92

SD indicates standard deviation.

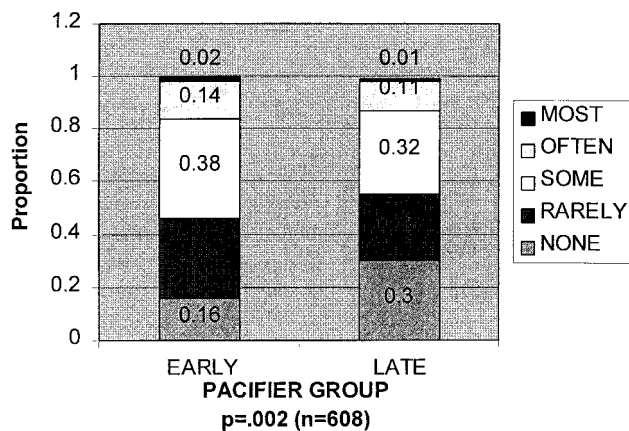
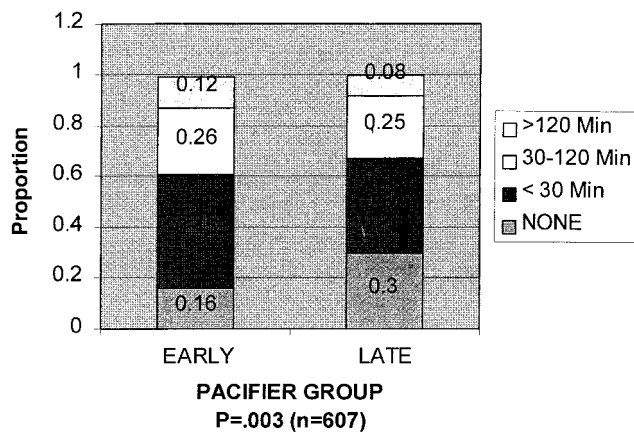


Fig 2. Daily pacifier use at 5 weeks among infants still breastfed at 2 weeks.

were given for medical indications (eg, hypoglycemia, weight loss $\geq 10\%$), 51% were given as a result of maternal request, and in 16% there was no documentation. Supplemental feedings regardless of method (cup or bottle) had a detrimental effect on breastfeeding duration (Tables 4 and 5). There was no significant effect of the cup or bottle intervention on the frequency of breastfeeding in the hospital or the occurrence of early breastfeeding problems, including maternal nipple trauma, infant weight loss from birth, latch problems, peripartum breastfeeding cessation, type of supplement given, number of times the infant was breastfed or received a supplement while in the hospital, peak bilirubin level, or need for early follow-up as a result of breastfeeding concerns.

Among women who delivered by cesarean, cupfeeding led to significantly lengthened breastfeeding duration (Table 6). Cupfeeding prolonged exclusive breastfeeding by approximately 10 days, full breastfeeding by 5 weeks, and overall breastfeeding by 10 weeks among these mother–infant dyads.

Infants who were delivered by cesarean and received supplements received more supplemental feedings (5.9 ± 4.6) than those who were delivered vaginally (3.0 ± 2.4) and were more likely to receive supplements for medical indications (33% vs 20%).

Infants who were delivered by cesarean were more likely to lose $\geq 10\%$ of their birth weight (11% vs 1%) and to be observed in special care nursery (10% vs 7%), and their mothers were more likely to experience postpartum complications (13% vs 5%).

To investigate the possibility of effect modification, we conducted additional whole-group analyses separating infants into those receiving 3 or fewer versus >3 supplemental feedings. Similar analyses were conducted on the basis of indications for supplementation. When 3 or fewer supplements were received, there was no significant effect on breastfeeding duration; however, when >3 supplements were given, cupfeeding significantly improved exclusive ($P < .0001$) and full ($P = .0002$) breastfeeding duration. Similar results were seen when data were grouped looking at 2 or fewer versus >2 feedings ($P = .0001$ exclusive and $P = .0018$ for full). Effects were limited to exclusive and full breastfeeding with no significant impact on overall duration. There was no evidence of effect modification based on indications for supplementation.

Our subgroup evaluation of 200 infants in the supplemental feeding intervention demonstrated significant differences in the total volume of non–breast milk supplements consumed by cup (67 ± 67 mL) and bottle (121 ± 167 mL) infants. Cup or bottle assignment did not affect the type of supplement (pumped breast milk vs formula) offered to infants who continued to receive supplements after hospital discharge. At 2 weeks, among infants receiving supplements at home, those in the cup group were significantly more likely to receive formula (13% vs 0%; $P = .003$) and expressed breast milk (19% vs 1%) by cup as opposed to other methods (eg, bottle, spoon, eye dropper, supplemental nursing system). By 5 weeks, there were no differences between the study groups in the methods used to provide supplements at home.

Pacifier Intervention

Pacifier use versus no use at 4 weeks' postpartum (Table 1) caused a significant decline in exclusive breastfeeding among infants exposed to pacifiers (pacifier odds ratio [OR] 1.5; 95% CI: 1.0–2.0 [$P = .03$]; bottle use OR: 1.4; 95% CI: 0.9–2.1 [$P = .09$]; received supplement OR: 2.0; 95% CI: 1.3–2.9 [$P = .001$]) but did not affect full and overall breastfeeding. Early pacifier use significantly shortened overall breastfeeding duration when adjusted for other important predictors (hazard ratio [HR]: 1.20; 95% CI: 1.02–1.42; $P = .03$) and when adjusted additionally for the effect of supplemental feedings (yes/no) and the method of supplementation (cup versus bottle, ITT among those supplemented; HR: 1.22; 95% CI: 1.03–1.44; $P = .02$). Adjusted analyses did not show significant effects of early pacifier use on full or exclusive breastfeeding duration (Table 5).

Across all types of breastfeeding (exclusive, full, and overall), the most significant predictor of duration was the receipt of supplemental feedings while in the hospital ($P \leq .0001$). The method by which supplements were supplied was not a significant predictor, and early pacifier introduction was, as

TABLE 3. Kaplan-Meier Estimates of Breastfeeding Duration, Supplemental Feeding, and Pacifier Interventions

Breastfeeding Duration (D)	Supplemental Feeding Intervention			Pacifier Intervention		
	Bottle (<i>n</i> = 230) Median (95% CI)	Cup (<i>n</i> = 251) Median (95% CI)	<i>P</i> Value	Early (<i>n</i> = 354) Median (95% CI)	Late (<i>n</i> = 346) Median (95% CI)	<i>P</i> Value
Exclusive	14 (11–21)	21 (14–25)	.29	21 (17–27)	28 (25–30)	.04
Full	37 (28–49)	45 (35–49)	.74	56 (42–63)	49 (42–60)	.57
Overall	140 (112–157)	105 (90–150)	.50	140 (120–157)	163 (140–180)	.18

TABLE 4. Kaplan-Meier Estimates of Breastfeeding Duration, 6-Group Model

Breastfeeding Duration (D)	Supplements Given in Hospital				No Supplements in Hospital	
	Bottle Early Pacifier (<i>n</i> = 119) Median (95% CI)	Bottle Late Pacifier (<i>n</i> = 111) Median (95% CI)	Cup Early Pacifier (<i>n</i> = 129) Median (95% CI)	Cup Late Pacifier (<i>n</i> = 122) Median (95% CI)	Early Pacifier (<i>n</i> = 104) Median (95% CI)	Late Pacifier (<i>n</i> = 112) Median (95% CI)
Exclusive	14 (8–21)	14 (10–21)	17 (12–21)	21 (14–34)	29 (28–37)	35 (31–56)
Full	42 (28–56)	31 (25–49)	35 (28–56)	49 (37–56)	101 (75–115)	101.5 (63–115)
Overall	135 (105–165)	150 (105–166)	91 (84–124)	135 (97–185)	195 (154–221)	210 (180–280)

TABLE 5. Adjusted Effects on Breastfeeding Duration, Cox Model HR

Breastfeeding Duration	Bottle Supplement			Early Pacifier			Received Supplements		
	HR	95% CI	<i>P</i> Value	HR	95% CI	<i>P</i> Value	HR	95% CI	<i>P</i> Value
Exclusive	1.06	0.88–1.27	.54	1.09	0.94–1.27	.26	1.49	1.23–1.80	<.0001
Full	1.01	0.84–1.22	.88	1.04	0.89–1.21	.64	1.50	1.24–1.81	<.0001
Overall	0.92	0.76–1.12	.42	1.22	1.03–1.44	.02	1.53	1.24–1.89	<.0001

TABLE 6. Supplemental Feeding Intervention and Breastfeeding Duration Among Women Who Delivered by Cesarean Section (Kaplan-Meier Estimates)

Breastfeeding Duration (D)	Supplemental Feeding Intervention in Women Who Delivered by Cesarean		
	Bottle (<i>n</i> = 47) Median (95% CI)	Cup (<i>n</i> = 51) Median (95% CI)	<i>P</i> Value
Exclusive	11 (6–21)	21 (13–33)	.04
Full	21 (10–39)	56 (37–91)	.02
Overall	90 (42–196)	161 (105–240)	.04

previously stated, a less potent predictor (Table 5). Subgroup analysis demonstrated a more potent impact of early pacifier use on exclusive breastfeeding among first-time mothers ($P = .004$). In the first 6 months postpartum, there were no significant effects of the pacifier intervention on breastfeeding frequency or in the occurrence of problems, including maternal nipple trauma, refusal of the infant to nurse, the chances of a mother seeking help for breastfeeding problems, the development of a low milk supply, the occurrence of jaundice, or the time until an infant regained its birth weight.

DISCUSSION

This is the third randomized, clinical trial to investigate the effects of artificial nipple exposure on breastfeeding but the first to demonstrate an impact. We found that pacifier use in the first 4 weeks of life lessened the likelihood of exclusive breastfeeding at 1 month. Furthermore, early pacifier introduction as compared with later introduction had a negative impact on overall breastfeeding duration. We also found that cupfeeding was a better way to provide supplemental feedings to breastfed infants; cupfeeding benefited mother–infant dyads delivered by ce-

sarean and infants who received more than 2 supplemental feedings.

The findings from this trial are in contrast to 2 previously published negative trials of artificial nipple exposure on breastfeeding.^{17,18} There are significant differences in the conduct of those published trials and the current study that we believe account for the differences in findings.

Schubiger et al¹⁷ published a negative trial in Sweden testing the effect of a baby-friendly versus standard postpartum nursery environment, with specific avoidance of pacifiers, bottle-feeding, and supplements in the baby-friendly environment. The intervention was limited to the peripartum hospitalization and was thus both earlier and shorter than the pacifier intervention in the current study. In addition, the Schubiger study was not designed to evaluate separately effects of pacifiers and bottle-nipple exposure. Compliance was also a problem in the study, in which 46% of the participants in the baby-friendly intervention were exposed to supplemental feedings or pacifiers.

Similarly, Kramer et al¹⁸ recently published a negative randomized trial of the effect on breastfeeding of providing anticipatory guidance to avoid pacifier use. It is an excellent efficacy study of an intervention to limit long-term pacifier exposure of breastfed infants. The investigators were able to reduce pacifier use in the experimental group, but the intervention (anticipatory guidance) is a relatively weaker test of pacifier use than the present study. In addition, the smaller sample size of the Kramer study limits its power to detect effects. The current study population also was composed of breastfeeding families who wished to use a pacifier, as opposed to the general population of breastfeeding families enrolled in the Schubiger and Kramer studies. The current study

thus addresses the effects of pacifier use in a population that is more likely to experience ill effects if any exist.

Our findings indicate detrimental effects from pacifier use begun in the first week of life on exclusive breastfeeding at 1 month and on overall breastfeeding duration. Although these findings will need to be confirmed with additional research, they are worrisome. Even in the developed world, the intensity and duration of breastfeeding are closely tied to infant health benefits, including reduced risks for otitis media and diarrheal disease.^{39–44} Furthermore, an important maternal benefit of breastfeeding, fertility reduction, is highly dependent on the practice of exclusive breastfeeding. The lactational amenorrhea method is an effective and widely practiced method of birth control for many women, especially those in the developing world.^{45,46} In light of these concerns and the recently published PROBIT trial,⁴³ we believe that recommendations to avoid pacifier use during breastfeeding should continue as specified in the UNICEF/WHO Baby Friendly Hospital Initiative.

Our data also indicate that early introduction intensified pacifier use at 5 weeks of life. It is not clear, however, why the observed differences in pacifier use between study groups negatively affected breastfeeding. Our data do not indicate less frequent or more problematic breastfeeding among couplets with early exposure to pacifiers. The biological mechanism of action by which pacifier use harms breastfeeding thus remains uncertain.

Findings from this study also provide the first comparison of cupfeeding and bottle-feeding for providing supplements to breastfed infants. Our findings indicate a detrimental effect of supplemental feedings on breastfeeding and no overriding benefit of cupfeeding for supplying such feedings to healthy breastfed infants. We found, however, a significant benefit to cupfeeding among mothers and infants delivered by cesarean, a risk factor for shortened breastfeeding duration.¹² In this study, cesarean delivery was highly correlated with antenatal and peripartum maternal health problems and infant problems, including difficulty making the transition to the extrauterine environment, medical risks for supplemental feedings (eg, small or large for gestation age), and excessive weight loss ($\geq 10\%$) from birth. Infants who were delivered by cesarean and received supplements by cup breastfed significantly longer at all stages of breastfeeding (exclusive, full, and overall). We believe that 10 weeks is a clinically significant difference in overall breastfeeding duration.

Although these results will need to be confirmed, cupfeeding may be beneficial for vulnerable mother-infant dyads for whom multiple supplemental feedings are required. There seems to be a protective effect among infants when >2 supplemental feedings are given. The safety of cupfeeding as a method of providing supplemental feedings to breastfed infants is supported by several studies.^{17,28,29,43,47,48} Our findings and at least 1 other study indicate that less volume is consumed by infants during cupfeed-

ing.²⁹ Whether the lower volume of feeding is the biological mechanism whereby cupfeeding preserves breastfeeding remains unanswered but offers an appealing explanation. Nevertheless, as it is impossible to predict all newborns who might receive >2 supplemental feedings, these findings support recommendations by the Baby Friendly Hospital Initiative to use cupfeeding as the method of choice when providing supplemental feedings. Furthermore, our findings also dramatically illustrate the need to avoid supplemental feedings absent medical indications.

There are a number of limitations to this study. The population studied was primarily white and well-educated married women and their healthy infants. We studied families who wished to use or were undecided about using pacifiers and consented to participate in a study as opposed to the general population of families who choose to breastfeed an infant. This is both advantageous, in that we selected a population most likely to be affected by pacifier use, and a limitation, in that our results are not necessarily generalizable to other populations of women and infants. We would have preferred to conduct a trial in which infants were randomized to long-term use or avoidance of pacifiers, but our clinical experiences convinced us that families would not participate. Thus, our findings are limited to what could be tested by this specific study design. We are limited to differences between infants exposed to early (2–5 days introduction) and late (>4 weeks) pacifier use. We cannot address effects as a result of use in the immediate postpartum period or longer-term use as compared with avoidance.

Some crossover occurred in the cup versus bottle intervention; however, this would tend to lessen rather than exaggerate differences between groups. Nurses also were not masked to intervention groups in this part of the study and could have offered differential assistance to couplets. Chart review data, however, showed no differences between the cup and bottle groups for feeding indications, composition of feedings, or numbers of supplements given. The biological mechanism whereby cupfeeding preserves breastfeeding may ultimately be shown to result from a reduced volume of feeding.

Scientific investigation of the effect of early artificial sucking experiences on the ability of newborns to breastfeed successfully is of profound importance to maternal and child health worldwide. Although there are numerous recommendations to avoid exposing breastfed infants to artificial nipples through the use of pacifiers or bottle-feedings, the effects of these exposures have only recently been subjected to evaluation using rigorous scientific methods. Exposures to artificial nipples remain commonplace in nurseries throughout the world.⁴⁹ This study provides important information about the detrimental effects of early pacifier use on the duration of breastfeeding. For families who wish to use pacifiers, we recommend that they avoid introducing a pacifier until 4 weeks' postpartum, when breastfeeding is more likely to be established.

In addition, we have demonstrated the physiologic

stability of healthy term infants during cupfeeding²⁸ and helped to identify a population of infants who may benefit greatly from this technique. We believe that this information will help to enhance the breast-feeding success of mothers who choose to breastfeed their infants. We believe that this study confirms the importance of recommendations made in the Baby Friendly Hospital Initiative, the content of which should be promoted as the standard of care in all maternity settings.

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Randomized Clinical Trial of Pacifier Use and Bottle-Feeding or Cupfeeding and Their Effect on Breastfeeding

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