Effect of the Premature Infant Oral Motor Intervention on Sucking Capacity in Preterm Infants in Turkey

A Randomized Controlled Trial

Selver Guler, PhD, RN; Zerrin Cigdem, PhD, RN; Brenda S. Lessen Knoll, PhD, RN;
Tulay Ortabag, PhD, RN; Yavuz Yakut, PhD, PT

ABSTRACT

Background: Preterm infants have oral feeding difficulty that often delays discharge, indicating a need for evidence-based interventions for oral–motor development.

Purpose: To test the Premature Infant Oral Motor Intervention (PIOMI) on the development of oral–motor function, feeding, and anthropometric outcomes using sucking manometry.

Methods: A single-blind randomized experimental design was conducted with a sample of 60 preterm infants from 2 neonatal intensive care units between May 2019 and March 2020. The experimental group received PIOMI for 5 min/d for 14 consecutive days. Sucking capacity, anthropometrics (weight and head circumference), bottle feeding, breast/chest feeding initiation, and length of hospital stay were measured. The Yakut Sucking Manometer (PCT/TR2019/050678) was developed specifically for this study and tested for the first time.

Results: The experimental group had a statistically significant percent increase over controls in sucking power (69%), continuous sucking before releasing the bottle (16%), sucking time (13%), and sucking amount (12%) with partial η^2 values of interaction between the groups of 0.692, 0.164, 0.136, and 0.121, respectively. The experimental group had a higher increase in weight (89%) and head circumference (81%) over controls ($F = 485.130$, $P < .001$; $F = 254.754$, $P < .001$, respectively). The experimental group transitioned to oral feeding 9.9 days earlier than controls ($t = -2.822$; $P = .007$), started breast/chest feeding 10.8 days earlier ($t = 3.016$; $P = .004$), and were discharged 3.0 days earlier.

Implications for Research/Practice: The PIOMI had a significant positive effect on anthropometrics, sucking capacity, readiness to initiate bottle and breast/chest feeding, and a 3-day reduction in length of hospital stay.

Key Words: feeding, oral stimulation, PIOMI, preterm infant, sucking capacity

Author Affiliations: *Department of Nursing, Faculty of Health Sciences, Sanko University, Gaziantep, Turkey (Dr Selver Guler); Departments of Nursing (Dr Cigdem) and Physiotherapy and Rehabilitation (Dr Yakut), Faculty of Health Sciences, Hasan Kalyoncu University, Gaziantep, Turkey; Department of Nursing, Faculty of Health Sciences, Gedik University, Istanbul, Turkey (Dr Ortabag); and School of Nursing, Illinois Wesleyan University, Bloomington (Dr Knoll).*

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The authors declare no conflicts of interest.

Ethical approval was provided by the Institutional Review Board of Hasan Kalyoncu University Faculty of Health Sciences, Research Ethics Committee (2019/29) in advance of implementation. Written informed consent was obtained from the patients/guardians.

This study was prospectively registered at ClinicalTrials.gov, registration: NCT04835155.

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Correspondence: *Selver Guler, RN, Department of Nursing, Faculty of Health Sciences, Sanko Üniversitesi, Gazimuhtar Paşa Bulvarı No. 36—27090 Şehitkamil, Gaziantep, Turkey (selvergulerr@gmail.com).*

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Preterm infants' survival rates have increased in recent years due to the advancement of technology and improvements in treatment and care.[1] However, the immature oral motor structures and lack of neuro-organization still result in delays to feeding readiness and the transition from gavage to oral feeding. Because the attainment of full oral feedings is often one of the final benchmarks for discharge from the neonatal intensive care unit (NICU), a delayed transition can result in a prolonged length of hospital stay (LOS). The extended separation of mother and infant can interfere with breast/chest feeding and lead to both short and long-term sequela in the infant.[2-4] A prolonged LOS also results in significant increases in cost for additional inpatient hospital care.[4]

The literature has shown various interventions to support the development of oral–motor feeding skills of preterm infants, including nonnutritive sucking (NNS), feeding position, and oral motor therapy programs.[6-11] Many of the randomized controlled trials (RCTs) tested a specific therapy called the Premature Infant Oral Motor Intervention (PIOMI)[12] and found significant improvements in feeding outcomes and

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LOS. However, most RCTs measured PIOMI's effect on bottle feeding, recommended further study to assess for a similar impact on breast/chest feeding, and none directly measured sucking.

The PIOMI was chosen for this study because it is the only oral motor program designed specifically for preterm infants as young as 29 weeks post–menstrual age (PMA)[12,13] and the only program with a standardized training method and published intervention fidelity.[14] The PIOMI is an 8-step therapy lasting only 5 minutes, including 2 minutes of NNS. Gentle stroking and compression are applied to the cheeks, lips, gums, tongue, and palate. The therapy provides the targeted stimulation to the perioral structures, stimulation which is otherwise missing in the environment of the NICU. The therapy is specifically designed to replicate the in utero sensory–motor experiences that facilitate the development of sensory–motor pathways that directly affect feeding and coordination of sucking, swallowing, and breathing.[12] These neuronal connections are strengthened or weakened by repeated transmission of information based on experience and the environment.[15] The ideal in utero sensory–motor experience builds upon the stimulation provided by a mouthful of amniotic fluid, which provides strength building through gentle resistance to the tongue and the cheeks. A floating tongue also provides tactile stimulation to the cheeks, palate, lips, and gums, as does the amniotic fluid itself. Even the external orofacial structures benefit from the warm tactile stimulation of the amniotic fluid while in utero, including allowing hands to float and brush against the lips and the face. Each sensation experienced is directly affecting the sensory neurons to establish connections that are needed for successful feeding.[16,17] This warm in utero stimulation is in sharp contrast to the dry NICU environment where there is no longer amniotic fluid in or around the mouth. The building of tongue and cheek strength against fluid is no longer facilitated, nor is range of motion of the tongue or tactile input from a floating tongue or extremities. In addition, medical interventions including suctioning, intubation, taping, and naso/orogastric tube placement are negative inputs that are disruptive to oral sensory–motor development and can result in oral aversions.[18-20]

Nonnutritive sucking alone and combined with oral stimulation has been found to mature the oral motor–sensory system and improve not only bottle feeding but also breast/chest feeding.[21] Many RCTs have shown PIOMI to improve oral feeding outcomes such as readiness to feed,[22-28] oral motor function,[24,28-31] breast/chest feeding,[31,32] and a faster transition to full oral feeding.[7,12,24,27-38] which often results in decreased LOS. Other RCTs have shown PIOMI's positive effect on NNS scores,[37] behavioral state,[30] and higher scores on the Infant Neurological International Battery (INFANIB) even sustained at 3 and 6 months after discharge.[26] However, there are no studies that have quantitatively tested PIOMI specifically on sucking capacity using pressure manometry. In addition, although most oral motor studies include the outcome of weight, results vary with some studies demonstrating increased weight gain with PIOMI[28,30,33] while others have not shown this effect.[26,38] No studies were found that measured PIOMI's effect on head circumference.

PURPOSE

The aim of this research was to evaluate the effect of PIOMI (when provided during the 29th- and 30th-week PMA) on the infant's sucking capacity (sucking power [mm Hg], sucking time without releasing the bottle [s], total sucking time [s], and suction amount [mL]). Additional variables included the anthropometrics of weight (g) and head circumference (cm), readiness to initiate breast/chest feeding, transition to oral feeding, and LOS.

HYPOTHESIS

Subjects who receive PIOMI once per day for 14 consecutive days will have greater sucking capacity (power, time, and amount), faster transition from tube feedings to oral feedings, earlier initiation of breast/chest feeding, increased weight and head circumference, and a shorter LOS over controls.

What This Study Adds

- The first study testing the effect of PIOMI on a neonatal population in Turkey.
- The first study testing PIOMI's effect directly on sucking via pressure manometry.
- The novel patented Yakut Sucking Manometer (patent: PCT/TR2019/050678) was tested for reliability.
- Dose-response evidence for a 14-d duration of PIOMI, as opposed to the 7- or 10-d durations in the current literature.
- Evidence on the positive effect of PIOMI on readiness to breast/chest feed.

METHODS

Design and Setting

This study used a single-blind randomized experimental design. Random assignment to groups was performed by a research assistant using the online software at https://www.randomizer.org. The primary nurses were blinded to groups, and the parents stepped out during therapy to assist in blinding.

The data were obtained for 11 months between May 2019 and March 2020 in the NICUs of 2 different hospitals in the Gaziantep province of Turkey. There are a total of 90 beds across both units and these units are generally 90% occupancy and greater.

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Ethical Approval

Approval for this research was obtained from Hasan Kalyoncu University Faculty of Health Sciences, Research Ethics Committee (2019/29). Written informed consent was obtained from the parents of all subjects.

Sample

Inclusion and Exclusion Criteria

Eligibility was determined by the neonatologist based on the following inclusion criteria: (1) infants born at 26 to 29 weeks of PMA; (2) vital signs stable and within normal limits for at least 24 hours; (3) required respiratory support limited to an oxygen hood, continuous positive airway pressure, and/or nasal cannula up to 2-L flow; (4) Apgar scores at 1 and 5 minutes of 4 or above; and (5) intraventricular hemorrhage limited to grade 1 or 2.

Exclusion criteria included (1) congenital defect, (2) necrotizing enterocolitis, (3) neonatal abstinence syndrome, (4) fetal alcohol syndrome, and (5) receiving ventilator support.

Sample size was determined through a power analysis using the G*Power (v3.1.7) program. For a power (1-ß) of 0.80, a minimum of 36 cases were needed, 18 per group. The target population was preterm infants born between 26 and 29 weeks of PMA, who met inclusion criteria, and who were then enrolled between 29 and 30 weeks of PMA. Infants born before 26 weeks were not included because of the likelihood of extreme neurological comorbidities that would confound the study. The upper limit of 29 weeks of PMA at birth was necessary to begin the study intervention by 29 weeks, the earliest point at which it is safe, tolerated well, while leveraging early neuroplasticity.[12]

The sample included 60 preterm infants with 30 each in the experimental and control groups. Two subjects were withdrawn from the study due to death or needing ventilator support, both of which were unrelated to the intervention. If a subject was withdrawn, the next subject enrolled replaced that subject to maintain the same-group sizes. Sample demographics of PMA at birth, type of delivery, sex, Apgar scores, and birth weight were collected via a chart audit prior to the start of the study.

Intervention

The intervention was administered by the same researcher across all subjects for intervention fidelity. The researcher was trained to criteria by Dr Knoll, the founder of PIOMI, through a video-recorded demonstration on a live preterm infant. Competency was validated by Knoll using the PIOMI Reliability Rating Tool[14] on the correct order of steps, correct technique at each step, and correct time spent at each step. Day 1 of the study was the first day that the infants received PIOMI and considered study entry. The researcher consulted the primary nurse before each intervention to ensure that the infant was clinically stable. The medical record was reviewed for any changes in health or medications that may affect subject eligibility. The primary nurse was blinded to group assignment, and PIOMI was performed in the absence of the parent for additional blinding (no curtain could be pulled to obscure view). The researcher positioned the infant in a semi-recumbent position while swaddled in a blanket, with the chin slightly tucked. The first 6 steps of the intervention were applied beginning on the cheeks, then moving to the lips, and proceeding inward to the oral cavity to target the gums, tongue, and palate. These steps were each limited to either a 15- or 30-second time frame. The final 2 steps elicited a suck and supported 2 minutes of NNS either on a pacifier or the researcher's finger. The intervention is completed in 5 minutes. The researcher applied PIOMI to the experimental group once per day for 14 consecutive days, 15 to 20 minutes before either the 09:00 or 12:00 scheduled feeding. Once the intervention was complete, the infant was prepared by the primary nurse for its subsequent feeding.

Subjects in the control group were given a sham intervention, which was to stand at the bedside to obtain sucking measures and anthropometrics but not provide oral motor therapy. Again, the parents stepped out of the room to assist in blinding.

Dependent Variables

Sucking Capacity

Sucking capacity included measures of sucking power, sucking time, and sucking amount. Sucking power (mm Hg) was measured only during NNS prior to feedings. Two events of nutritive sucking time (s) were measured during bottle feedings: (1) sucking time without releasing the bottle and (2) total sucking time. Finally, sucking amount (mL) was measured as volume consumed during the feeding. Sucking capacity (excluding volume) was measured by the Yakut Sucking Manometer (Figure 1) using a pressure manometer embedded into a silicone nipple and measurements cross-validated by both the researcher and the primary care nurse. The manometer was developed by Professor Dr Yavuz Yakut specifically for use in this study (international patent number PCT/TR2019/050678). Reliability of the manometer was assessed before using it for this study by Dr Yakut testing sucking power (mm Hg) on 10 preterm infants who had transitioned to full oral feedings, and who had written parental consent and approval by the neonatologist. Each infant sucked on the manometer nipple for a minimum of 1 minute of successful NNS on 2 separate occasions with a 5-minute interval in between. During both

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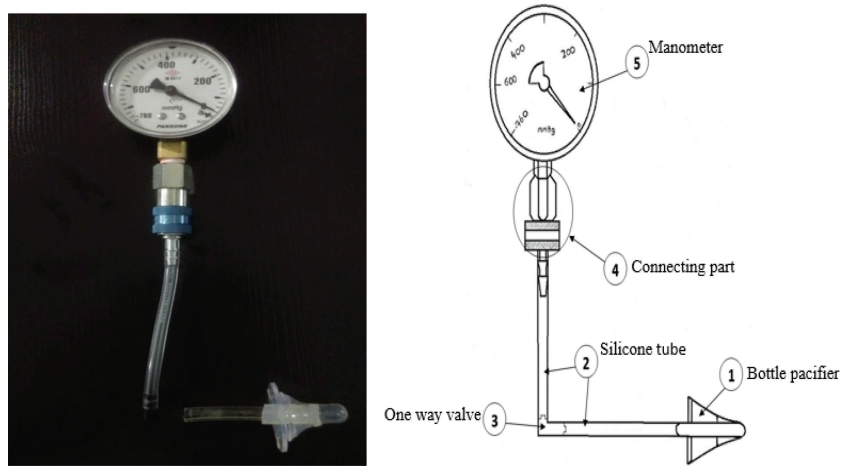
FIGURE 1



Manometer measuring suction power and a method for measuring suction power.

measurements, the highest value the infant could reach within the first minute was documented. The average sucking power at the first measure was 102 ± 22.38 mm Hg, and 104.5 ± 13.83 mm Hg at the second measure. The test retest reliability coefficient between the 2 applications was calculated by the intraclass correlation coefficient(2.1) and found to be 0.912. An intraclass correlation coefficient value of 0.75 indicates good reliability, and above 0.90 is excellent.[39] The obtained intraclass correlation coefficient value of above 0.90 showed that the manometer was acceptable for use in our study.[40] Dr Yakut then trained the researcher on how to use the manometer and supervised the first applications to ensure competency.

On day 1 of the study, the baseline NNS power in both groups was measured before any intervention. Each infant sucked on the manometer nipple for nonnutritive sucking and the highest value the infant could reach within the first minute was documented. On the following 8th, 11th, and 14th days of intervention, sucking times and amounts were measured. Sucking time without releasing the bottle was measured from initial sucking motion to first release of the bottle nipple. Total sucking time was measured from initial sucking motion to the point where the infant stopped sucking for at least 30 seconds, including any brief starts and stops, which signified the end of the feeding period. Sucking amount was the total amount (mL) consumed at that feeding. Infants were monitored during sucking measurements for any negative physiological/behavioral cues of intolerance (apnea, bradycardia, desaturation below 90%, crying, tachycardia, facial color change). If 1 negative cue was observed, the measurement was suspended until the infant returned to normal.

Feeding Transition

Bottle Feeding

Feeding transition is defined as the time it takes to progress from tube feedings to the first bottle feeding. This transition was calculated from a standardized starting point for all subjects, starting from the day PIOMI was initiated (all subjects still being tube fed) to the day when the first bottle feeding was offered, and the infant demonstrated the ability to safely manage the feeding. No formal feeding readiness tool was used, so readiness to begin bottle feeding was determined by the neonatologist and the primary nurse by observing standard feeding readiness cues (waking, rooting, sucking) and assessing the infant's ability to coordinate nutritive sucking, swallowing, and breathing without excess spilling while maintaining physiologic stability (no gagging, choking, apnea, bradycardia, or color changes).

Initiation of Breast/Chest Feeding

The initiation of breast/chest feeding was calculated as the number of days from the day PIOMI was initiated to the first day the infant demonstrates a successful breast/chest feeding. Readiness to breast/chest feed was determined by the neonatologist in consultation with the primary nurse, who was blinded to groups. The neonatologist uses a protocol in Turkey where all preterm infants attempt the first oral feedings with a bottle before attempting breast/chest feeding. Once the infant has established success with bottle feeding, breast/chest feeding attempts are started. This breast/chest feeding attempt may begin as soon as 1 day later for a strong bottle feeder to more than a week later with a struggling bottle feeder.

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Anthropometrics

Anthropometrics were collected on the 1st and 14th days of the study and on the day of discharge. Measures included length for baseline homogeneity of groups, followed by weight and head circumference at baseline and throughout the study. A flexible measuring tape was used for length and head circumference. Weight at study entry was the most recent weight recorded within the prior 24 hours.

Length of Hospital Stay

Length of hospital stay was measured from the first day of study entry (the day PIOMI was initiated) to the day of discharge. This standardized the starting point for all subjects regardless of birth PMA.

Statistical Analysis

SPSS (Statistical Package for the Social Sciences) for Windows 22.0 was used for data analysis. Descriptive statistical methods (frequency, mean, and standard deviation) and χ^2 test were used for comparison of variables, and the independent sample t test was used for comparisons of 2 groups assuming a normal distribution. Shapiro-Wilk and Kolmogorov-Smirnova tests confirmed the assumption of normality for weights, length, head circumference, and suction capacity measurements in both groups. Repeated-measures 2-way analysis of variance test was used to measure the effect of PIOMI application on anthropometrics and sucking capacity of infants in both groups. To determine the increase associated with the PIOMI intervention, partial η^2 values of the interaction between the groups were calculated by applying the "Bonferroni" correction. The confidence level was 95% with significance level of $P < .05$.

RESULTS

Homogeneity of Groups

There was no statistically significant difference between the groups for sex, PMA at birth, 1- and 5-minute Apgar scores, or in the baseline anthropometrics (Table 1).

Sucking Capacity

The mean sucking power (Figure 2) increased in both groups as the measurement day progressed from day 1 to day 14. However, this increase was higher in the PIOMI group, and the difference was statistically significant ($F = 130.094$, $P < .001$). The partial η^2 value of the interaction between groups was found to be np2 = 0.692, with the Bonferroni correction indicating a 69% increase in the infant's sucking capacity after receiving PIOMI (Table 2).

Increases in both measurements for sucking time (time of sucking without releasing the bottle and total sucking time) and in sucking amount (mL) on the 8th, 11th, and 14th days were statistically significant in both groups ($F = 11.337$, $P < .001$, $F = 9.148$, $P = .001$, and $F = 7.951$, $P = .002$, respectively). The partial η^2 values of the interaction between groups were 0.164, 0.136, and 0.121, respectively. In the PIOMI group, the increase in infants' sucking time without leaving the bottle was 16% more than in controls, there was a 13% greater increase in total sucking time, and a 12% greater increase in sucking amount in the PIOMI group (Table 2). There were no negative physiological/behavioral cues of intolerance observed during the sucking measurements that required suspension or delay of measurement.

Feeding Transition

Bottle Feeding

After PIOMI had begun, the infants' first day of oral feeding (revealing oral feeding readiness) was 31.8 ± 13.6 days in the experimental group versus 41.7 ± 13.6 days in the control group. The PIOMI group initiated oral feeding 9.9 days earlier than controls and that difference was statistically significant ($t = -2.822$; $P = .007$) (Table 3).

Initiation of Breast/Chest Feeding

The infants who received PIOMI started breast/chest feeding almost 10 days earlier than those in the control group. The mean first day of breast/chest feeding was 37.1 ± 13.6 days in the experimental group compared with 47.9 ± 14.1 days in the control group, which was a statistically significant difference ($t = 3.016$; $P = .004$).

Anthropometrics

Weights measured on the 1st and 14th days and the day of discharge were found to be statistically significant regardless of which group (experimental or control) the infants were in ($F = 485.130$, $P < .001$). However, the mean weight increase (see Supplemental Digital Content Figure 1, available at: http://links.lww.com/ANC/A170) in the experimental group from the 1st day to the 14th day and to the day of discharge was significantly higher than in the control group ($F = 485.130$, $P < .001$). The partial η^2 value of the interaction between groups was np2 = 0.893, and a Bonferroni correction indicated that 89% increase in weight appears to be due to receiving PIOMI (Table 2).

A 2-factor analysis of variance found that the increase in head circumference measured from the 1st to the 14th days of the application and the day of discharge was statistically significant in both groups ($F = 254.754$, $P < .001$). However, the mean head circumference increase (see Supplemental Digital Content Figure 2, available at: http://links.lww.

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TABLE 1. Baseline Characteristics, Apgar Scores, and Anthropometrics at Birth

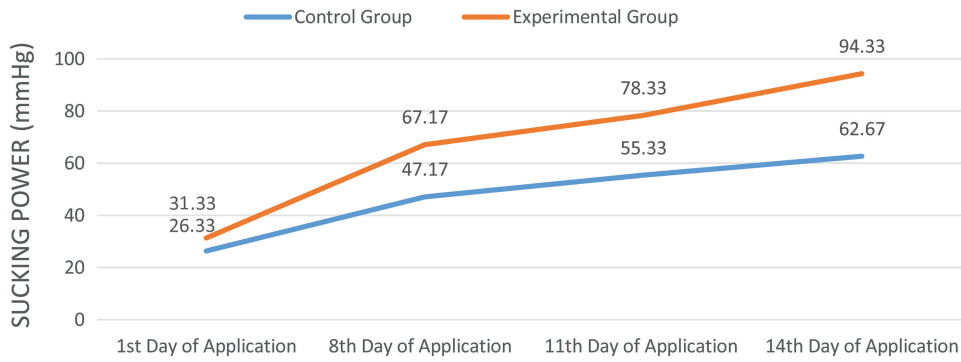
Characteristics	Experimental Group (n = 30) n	%	Control Group (n = 30) n	%	Total n	%	χ^2 P
Gender							
Female	14	23.3	15	25.0	29	48.3	.067
Male	16	26.7	15	25.0	31	51.7	.796
PMA at birth							
26	3	5.0	1	1.7	4	6.7	3.694
27	6	10.0	4	6.7	10	16.7	.449
28	7	11.7	4	6.7	11	18.4	
29	6	10.0	8	13.3	14	23.3	
30	8	13.3	13	21.7	21	35.0	
Apgar scores							
1st min							
4-6	24	46.7	28	40.0	52	86.7	2.308
7-10	6	3.3	2	10.0	8	13.3	.129
5th min							
4-6	9	15.0	10	16.7	19	31.7	.077
7-10	21	35.0	20	33.3	41	68.3	.781

Baseline Anthropometrics at Birth

Characteristics	Experimental Group (n = 30) Mean ± SD (Minimum-Maximum)	Control Group (n = 30) Mean ± SD (Minimum-Maximum)	Statistical Analysis, t P
Weight, g	1267.0 ± 276.6	1266.7 ± 233.6	−.005
	800-1900	850-1700	.996
Length, cm	40.9 ± 2.8	41.2 ± 3.1	.363
	36-48	34-47	.718
Head circumference, cm	26.7 ± 2.0	27.2 ± 1.8	1.137
	23-30	23-32	.260

Abbreviations: Apgar, Appearance-Pulse-Grimace-Activity-Respiration; P, probability; %, frequency; PMA, post–menstrual age; t, independent sample t test.

FIGURE 2



Sucking power (mm Hg).

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TABLE 2. Two-Factor Analysis of Variance on Anthropometrics and Sucking Capacity in the Experimental and Control Groups (N = 60)

Source of Variance	Sum of Squares	SD	Mean Squares	*P*	*F*	np²
Anthropometrics						
Weight, g (1st and 14th d, and Day of Discharge)						
Time	49723417.500	3	16574472.500	<.001	485.130	0.893
Time × Study group	252597.083	3	185987.825	.110	2.464	0.041
Error	5944710.417	174	34165.002			
Head Circumference, cm (1st and 14th d, and the Day of Discharge)						
Time	1133.434	3	377.811	<.001	254.754	0.815
Time × Study group	37.894	3	23.765	.001	8.517	0.128
Error	258.050	174	1.483			
Sucking Capacity						
Sucking Power, mm Hg (1st, 8st, 11th, and 14th d)						
Time	80973.333	3	26991.111	<.001	130.094	0.692
Time × Study group	5551.250	3	2456.928	<.001	8.919	0.133
Error	36100.417	174	207.474			
Continuous Sucking Before Releasing the Bottle, s (8th, 11th, and 14th d)						
Time	884.844	2	442.422	<.001	11.337	0.164
Time × Study group	158.978	2	93.148	.143	2.037	0.034
Error	4526.844	116	39.025			
Total Sucking Time, s (8th, 11th, and 14th d)						
Time	27610.633	2	13805.317	.001	9.148	0.136
Time × Study group	10043.878	2	6261.200	.051	3.328	0.054
Error	175051.489	116	1881.456			
Sucking Amount, mL (8th, 11th, and 14th d)						
Time	114.902	2	57.451	.002	7.951	0.121
Time × Study group	7.645	2	5.179	.537	0.529	0.009
Error	838.139	116	7.225			

Abbreviation: np², partial eta square.

com/ANC/A171) in the experimental group from the 1st to the 14th days and the day of discharge was significantly higher in the PIOMI group than in the control group ($F = 254.754$, $P < .001$). The partial η^2 value of the interaction between groups was np2 = 0.815, and a Bonferroni correction indicated that

TABLE 3. Transition to Oral Feeding, Day of First Breastfeeding, and Length of Hospital Stay

Characteristics	Experimental Group (n = 30) Mean ± SD (Minimum-Maximum)	Control Group (n = 30) Mean ± SD (Minimum-Maximum)	Statistical Analysis, *t* *p*
No. of days following start of PIOMI treatment			
First day of oral feeding	31.8 ± 13.6 12-57	41.7 ± 13.6 8-67	2.822 .007
Day of first breastfeeding	37.1 ± 13.6 17-63	47.9 ± 14.1 13-75	3.016 .004
Length of hospital stay	58.2 ± 17.9 21-96	61.2 ± 13.5 26-87	.726 .471

Abbreviations: P, probability; PIOMI, Premature Infant Oral Motor Intervention; t, independent sample t test.

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the 81% increase in head circumference appears to be due to receiving PIOMI (Table 2).

Length of Hospital Stay

There was 3-day reduction in LOS in the experimental group. Although this difference is clinically significant for both cost savings and time of parental separation, it did not reach statistical significance ($t = 0.726$; $P = .417$) (Table 3).

DISCUSSION

Being born prematurely disrupts the neurological development of feeding mechanisms in the preterm infant brain. Sucking behaviors are known to be a window into the neurobehavioral organization of the preterm infant brain.[41,42] The purpose of this study was to measure the impact of an oral motor therapy on the sucking mechanisms specifically, as well as anthropometrics and LOS. Oral motor therapy is one of the most effective interventions used in the NICU to temper the negative perioral sensory–motor experiences by offering positive perioral experiences in hopes of modulating delays in the transition from tube feeding to oral feeding.[7] The results of our study support earlier findings of improved feeding outcomes and reduced LOS and provided new data on outcomes not previously studied: (1) improved sucking measured via manometry after PIOMI and (2) evidence that PIOMI may result in earlier initiation of breast/chest feeding.

Although most oral motor studies use feeding volume and transition to full oral feedings as the primary outcomes, our study directly measured sucking during both NNS and feedings and at both periods had significantly improved sucking over controls. No studies were found that directly measured PIOMI against the sucking capacity with a manometer. Boiron et al[43] tested a similar oral motor stimulation using a sucking manometer and showed significant improvement in NNS of preterm infants. Skaaning et al[45] measured sucking via intra-oral vacuum after parents applied PIOMI for 14 days and not surprisingly found that the infants who demonstrated a stronger suck were more likely to breast/chest feed. Medoff-Cooper et al[41] measured sucking patterns (bursts and pauses) with a manometer demonstrating that maturation of sucking patterns is an indicator for neurobehavioral development of the preterm infant brain. Use of an objective measure such as manometry can provide direct and accurate data to evaluate sucking patterns for both bottle and breast/chest feeding. Manometry could be used concurrently with therapy to evaluate both the formative and summative effects of PIOMI or other types of oral motor stimulation.

This study also measured sucking during the entire feeding. Many oral motor studies measure volume and assess only the amount consumed within the first 5 minutes of a feeding.[7,12,23] This study did not designate a 5-minute feeding limit for the data point but instead 2 two infant-driven indicators to capture the initial sucking time and the total sucking time at the completion of a feeding.

One of the most impactful findings of this study is related to the exponential sucking improvement over time in those subjects who received PIOMI compared with the linear (and much diminished) improvement over time in controls.[7,12,23,27] For example, although baseline sucking capacity started out higher in the PIOMI group, the subsequent increases in capacity did not follow a parallel course of improvement with the control group but instead the gap increased as each time of measurement moved forward. In the PIOMI group, the nonnutritive sucking power increased by 3 times the initial value over time and almost doubled in the 3 nutritive parameters: continuous sucking, total sucking time, and sucking amount. The longer PIOMI was applied, the larger the improvement over controls. This is consistent with the findings by Lessen Knoll et al,[7] in which volume consumed revealed the same type of exponential increase the longer PIOMI was applied compared with the natural developmental trajectory of a control group. Similarly, Osman et al[28] conducted a dose-response study and found that the more days PIOMI was provided, ranging from 1 to 16 days, the better the outcomes (transition to full feedings and LOS). These authors conclude that when infants start PIOMI in the early prefeeding period before a bottle or breast is ever introduced, they start their first oral feeding with strengthened oral motor pathways, which build the scaffolding for more developed feeding skills. Therefore, as these initial successful feedings progress, infants are reinforcing efficient pathways, as opposed to infants without therapy reinforcing inefficient pathways.

This study's findings of a 3-day reduction in LOS in the PIOMI group were consistent with the reduced LOS found in other PIOMI studies[7,12,27,31,33] ranging from 2.5 days to 9.5 days shorter in infants receiving PIOMI. In other studies, subjects who received similar programs of oral motor therapy were discharged between 6 and 10.9 days earlier than controls.[45,46] This reduction in length of stay substantially reduces overall cost of care, risk of nosocomial infections, and separation between the infant and its caregivers.

This study design included weight gain/loss following oral motor therapy to evaluate the assumption that additional caloric demand from stimulation results in weight loss, and if so, whether that weight loss is then mediated by the increase in feeding efficiency and volume. In our study, PIOMI was found to increase weight of infants in the experimental group over controls. Consistent with other

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studies using oral motor interventions, the greatest positive effects on weight gain occur after the second week of therapy. These results provide strong rationale of why it may be beneficial to continue PIOMI for at least 14 days, as was done in this study.

The other anthropometric measure in our study was head circumference. Dogan and Celebioglu[2] also measured head circumference as an outcome variable after 14 days of oral motor therapy and found no statistically significant difference at 36 weeks of PMA or at discharge between groups. In our sample, the head circumference in both groups naturally increased over time. However, although the average head circumference in the PIOMI group was lower on the 1st day, the increase was higher on the 14th day compared with the control group and was significantly higher than controls at discharge. Again, the greatest difference revealed itself 2 weeks after the therapy began. The effect on head circumference may indicate an increased brain volume, which potentially indicates a positive effect not only on physical growth but also on cognitive, social, and emotional development. A more direct measure of neurobehavioral improvement after PIOMI was seen in the work by Jaywant and Kale[30] using the Anderson Behavioral State Scale demonstrating better neurobehavioral organization in the infants who received PIOMI over controls. Subjects' behavioral states demonstrated improved state scores as early as days 1 to 4 of feeding. Li et al[26] also assessed neurobehavioral status after PIOMI using the Infant Neurological International Battery (INFANIB) to assess the longer-term effect of PIOMI postdischarge and found that infants in the PIOMI group had higher scores (eg, oral motor control and neurobehavioral regulation) on the INFANIB at 3 months and 6 months of age over controls.

Limitations

This study was not blinded to the primary physicians ordering feedings, which could have resulted in a bias when determining readiness to feed. The sample was taken from 2 different NICUs; therefore, a difference in the culture of feeding progression could not be controlled for, except through randomization to groups. In addition, there was no standardized feeding readiness tool used for bottle feeding or breast/chest feeding to provide consistency across the 2 units. Although the primary nurse and parents stepped out for blinding to the intervention, no curtain blocked the view from other staff who may later be responsible for feedings.

There were also some measurement limitations. A flexible measuring tape was used for the length, which is not as accurate as a length board and could have caused variation in measurement. Also, the Yakut Sucking Manometer was a novel invention, thus untested prior to the reliability testing as part of this study. However, the principles of pressure manometers are well understood and there are similar sucking manometers that have demonstrated reliable measures for preterm infant sucking,[41] which lends construct validity. An additional variable that may have impacted sucking was the use of human milk versus formula, which can affect the willingness of the infant to initiate suck and continue to suck. The ratio of human milk to formula for each feeding or among groups was not recorded and may have impacted readiness to feed. The use of human milk fortifier could also be a confounding variable for the anthropometrics.

CONCLUSION AND RECOMMENDATIONS

There have been several studies that have demonstrated that the feeding improvements after PIOMI are exponential over time when compared with controls. The results of our study using sucking manometry after PIOMI now add data showing an exponential improvement in sucking skills. This trajectory requires an early start to therapy, and the frequency and duration require a daily presence at the bedside from 29 weeks to discharge to maximize the impact. Therapy should be provided by nurses, therapists, and parents trained through the standardized training program. The involvement of parents is a key aspect of the neuroprotective care models used in modern NICUs and has been shown to improve neonatal outcomes.[47] Future PIOMI studies should involve parents in both therapy administration and in feedings, such as in the study by Skanning et al,[44] in which parents performed PIOMI 2 times per day for 14 days starting at 32 weeks of PMA and subsequently breastfed. Majoli et al[47] demonstrated that parents can successfully learn PIOMI and apply it with no difference in outcomes compared with when applied by professionally trained staff. Moreover, parent satisfaction was rated very high due to their involvement in such an impactful aspect of their infant's care.

We recommend that PIOMI be provided once per day from 29 weeks of PMA for 2 weeks and increase to 2× per day at 31 weeks when infants can tolerate additional therapy.[48] Premature Infant Oral Motor Intervention should continue to be provided until discharge and include parents in the training through the standardized training program. Future dose-response studies should test when the effect of PIOMI is maximized through variations in frequency and duration. Studies examining the effects of PIOMI should include neurodevelopmental outcomes using behavioral state tools and infant neurological batteries and include follow-up postdischarge for longer-term effects on general

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Summary of Recommendations for Practice and Research	
What we know:	• Sucking-swallowing-respiratory coordination is not yet developed in 29-30 wk of PMA preterm infants. • Because of the underdeveloped oral motor structures of preterm infants, the transition to oral feeding is delayed. • The extrauterine environment does not provide the sensory oral motor stimuli needed to develop effective sucking and feeding skills.
What needs to be studied:	• What type of oral motor therapy results in improved development of sucking and feeding? • How long should oral motor therapy continue in order to improve the transition from tube feedings to oral feedings? • Does PIOMI have a positive effect on chest/breastfeeding? • Do objective measures of sucking power lend evidence to the positive effect of PIOMI?
What can we do today:	• Premature Infant Oral Motor Intervention should be applied as early as 29-30 wk of PMA for faster transitions to full bottle feedings. • PIOMI should be provided to improve earlier initiation of successful chest/breastfeeding. • The suction capacity of the preterm infant can be effectively measured with the Yakut Suction Manometer.

neurobehavioral organization and development. Studies are also needed that test possible benefits of PIOMI on more vulnerable NICU populations such as those with cardiac or neurological diagnoses and postsurgical patients. Finally, the Yakut Sucking Manometer was used safely in our study, and we recommend continued testing in future studies.

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