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ORIGINAL ARTICLE

Breast pump suction patterns that mimic the human infant during breastfeeding: greater milk output in less time spent pumping for breast pump-dependent mothers with premature infants

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Objective: The objective of this study was to compare the effectiveness, efficiency, comfort and convenience of newly designed breast pump suction patterns (BPSPs) that mimic sucking patterns of the breastfeeding human infant during the initiation and maintenance of lactation.

Study Design: In total, 105 mothers of premature infants ⩽34 weeks of gestation were randomly assigned to 1 of 3 groups within 24 h post-birth. Each group tested two BPSPs; an initiation BPSP was used until the onset of lactogenesis II (OOL-II) and a maintenance BPSP was used thereafter.

Result: Mothers who used the experimental initiation and the standard 2.0 maintenance BPSPs (EXP-STD group) demonstrated significantly greater daily and cumulative milk output, and greater milk output per minute spent pumping.

Conclusion: BPSPs that mimic the unique sucking patterns used by healthy-term breastfeeding infants during the initiation and maintenance of lactation are more effective, efficient, comfortable and convenient than other BPSPs.
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Keywords: lactation; premature infants; breast pump-dependent women; breast pump suction patterns; human milk feedings

Introduction

Human milk from the infant's own mother reduces the risk of costly and handicapping morbidities in premature infants in a dose-response manner, with higher doses of human milk providing the greatest protection.[1,2] High doses of human milk are especially important during the first 28 days post-birth when feedings are introduced and advanced.[2,3] However, mothers of premature infants are dependent on a breast pump for the initiation and maintenance of lactation, and many of these women experience problems with providing sufficient amounts of milk during this time.[2,4,5] Despite the frequency of this problem, very few studies have examined features of breast pumps or breast pump suction patterns (BPSPs) in this population.[6] This lack of research is especially concerning because mothers of premature infants are often breast pump-dependent for weeks or months before their infants can feed at breast and pumping is no longer necessary.

In mothers of healthy-term infants, effective sucking and milk removal by the infant have a major role in regulating milk volume.[7–11] Thus, it seems logical that BPSPs for mothers of premature infants should mimic the sucking rates (number of sucks per minute) and rhythms (organization of burst–pause patterning) used by healthy-term infants during the initiation and maintenance of lactation. One BPSP (Standard 2.0; Medela, McHenry, IL, USA) has been developed based on extensive research of sucking patterns of infants during established breastfeeding (e.g., after the completion of lactogenesis II).[12,13] This BPSP has two phases, based on sucking patterns used by breastfeeding infants during a single feeding. The first (stimulation) phase mimics the rapid sucking rate used by the infant before milk ejection, whereas the second (expression) phase simulates the slower sucking rate that occurs after milk ejection.[14] This two-phase BPSP was also demonstrated to be effective, efficient, comfortable and convenient in a randomized clinical trial of breast pump-dependent mothers of premature infants who had initiated lactation and established an adequate milk volume.[6]

However, in the first days post-birth, the healthy-term infant does not suck in a biphasic pattern, because only minimal amounts of milk are available for removal before the onset of lactogenesis II.[15,16] The infant responds to the limited availability

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and slow flow of milk with a rapid sucking rate and an irregular sucking rhythm,[14,17–19] however, no previous BPSP has attempted to simulate this unique sucking pattern. We hypothesized that this early ‘initiation’ sucking pattern does more than just ‘get the milk out’, and that its intense application to the mammary gland in the early days post-birth may have a role in programming the initiation and maintenance of an adequate milk volume. The purpose of this study was to compare the effectiveness, efficiency, comfort and convenience of new combinations of BPSPs designed to mimic the sucking patterns used by healthy-term infants to initiate and maintain lactation.

Methods

Design

Development of BPSPs. We sought to design BPSPs for breast pump-dependent mothers that mimic those used by the healthy-term infant during the initiation and maintenance of lactation. Thus, the BPSPs that were compared in this study were developed based upon classic research in the physiology of lactation as well as the physiology of non-nutritive and nutritive infant sucking. This research demonstrates that the healthy human infant adapts the sucking rate, rhythm and pressure to the milk flow rate.[14,18,19] Specifically, during non-nutritive sucking or when milk flows slowly, the infant sucks rapidly, because little or no milk is extracted. Thus, the swallow-induced airway closure is infrequent and breathing is minimally affected.[14,18] However, as the milk flow rate increases, the infant must swallow the extracted milk and regulate the closure and re-opening of the airway to integrate swallowing and breathing.[14,18] As a result, the sucking rate slows considerably.[14,17–19] Thus, during established lactation, a breastfeeding infant sucks rapidly before milk ejection and more slowly after milk ejection because of the extra time required for swallowing and breathing once milk begins to flow regularly.[14,18]

The standard BPSP. This two-phase BPSP (Standard 2.0, Medela) consists of an initial (2-min) stimulation phase of rapid suction events (120 per minute) that correspond to sucking at the breast before milk ejection under low milk flow conditions. At the end of 2 min (or sooner if overridden by the breast pump user), this rate slows to approximately 60 events per minute to mimic nutritive sucking with regular milk flow. Both the stimulation and expression phases of the standard BPSP cycle continuously with no pause events. The standard BPSP was developed before its use in this investigation, and involved an exhaustive study of its effectiveness, efficiency, comfort and convenience in healthy-term infants of mothers with an established milk supply.[12,20,21] Similarly, a previously published randomized clinical trial demonstrated that it was effective, efficient, comfortable and convenient in breast pump-dependent mothers of premature infants with an adequate milk supply.[6]

The experimental initiation BPSP. This new BPSP (Preemie +, Medela) was designed to mimic the rapid sucking rate and irregular sucking rhythm used by healthy-term infants during breastfeeding before the onset of lactogenesis II,[17–19] when only small amounts of milk are available for removal.[15] The new initiation BPSP included periods that mimic non-nutritive sucking (120 sucks per minute), low milk flow rate sucking (90 sucks per second) and average nutritive milk flow rate (60 sucks per second) sucking.[19] These varying sucking rates and rhythms were interspersed with brief, unpredictable pauses in suction similar to those that occur during breastfeeding before the OOL-II.

The experimental maintenance BPSP. This new BPSP began with a 2-minute stimulation phase identical to the current Standard 2.0 (standard; STD) BPSP. However, the expression phase of this pattern incorporated a different suction curve in which the rate varied (35–54 cycles per minute) as a function of the amount of vacuum selected by the mother. The nadir of this vacuum curve was reached more quickly than with the STD BPSP, mimicking the sucking rate and rhythm of a ‘hungry’ breastfeeding infant during conditions of rapid milk flow such as that which occurs immediately following milk ejection in mothers with an established milk supply.[14] When the milk flow rate is rapid, infants exert less suction pressure and suck more slowly to swallow large boluses of milk and to reopen the airway to breathe.[14,18] These sucking characteristics of infants were programmed into the expression phase of the experimental maintenance BPSP.

The experimental initiation and the new maintenance BPSPs were developed and field-tested over the course of 18 months by having breast pump-dependent mothers of premature infants systematically evaluate evolving versions of the BPSPs. This process was supervised by lactation research nurses and an engineer with expertise in BPSP programming. Suction pressures, rates, rhythms and other pumping characteristics were adjusted and evaluated until mothers consistently reported that the new BPSPs were effective, efficient, comfortable and convenient.

Research design. A randomized clinical trial design was used to compare the effectiveness, efficiency, comfort, and convenience of the new initiation and maintenance BPSPs with the standard BPSP in the Symphony breast pump in breast pump-dependent mothers of premature infants. A randomized block design was used to assure a representative sample of mothers with infants <27 and $\geqslant 27$ weeks' gestation in each study group to reduce the potential that the degree of prematurity affected lactation outcomes.[4,22] The randomized block design also ensured that within every block of three infants, one infant was randomly assigned to each group so that environmental and clinical conditions within the neonatal intensive care unit were consistent among the groups.

Mothers were blinded to the assigned BPSPs. There were three study groups. The mothers in EXP-EXP used the experimental initiation BPSP until the OOL-II, and then switched to the experimental maintenance BPSP for the remainder of the study. Mothers in EXP-STD used the experimental initiation BPSP until the onset of the OOL-II, and then switched to the standard maintenance BPSP for the remaining study. Mothers in STD-STD used the standard BPSP for both the initiation and maintenance phases and served as the control group for this study.

All BPSPs were embedded in identical appearing cards that were coded only by number and inserted into the breast pump. All mothers were given an initiation card at the onset of the study, and all were switched to a maintenance card with the OOL-II.

Sample and setting. This study was conducted in a Level III neonatal intensive care unit in the Midwestern United States. Criteria for sample selection included infant gestational age $\leqslant 34$ weeks, anticipated neonatal intensive care unit stay of $\geqslant 15$ days and maternal decision to initiate lactation. All mothers who met the inclusion criteria were approached for the study and 128 mothers agreed to participate. No mothers were excluded on the basis of pre-existing medical conditions, perinatal complications or other lactation-related risk factors. Of the 128 mothers who were enrolled, 105 (82.0%) completed the study with usable data, defined as at least nine consecutive days from the onset of the study of complete milk output records. Supplementary Figure 1 details the study design, randomization and completion rates of study subjects. The completion rate among the groups was not significantly different (EXP-EXP = 33/42 (78.6%); EXP-STD = 34/43 (79.1%); STD-STD = 38/43 (88.4%), $\chi^2 = 1.77$, df = 2; $P = 0.413$). There were no statistically significant differences among the groups with respect to any maternal and infant characteristics that might have influenced the dependent variables in this study (Supplementary Table 1). The project was approved by the Institutional Review Board of the research setting.

Measures

Effectiveness of the BPSPs. The effectiveness of BPSPs was evaluated by three variables: OOL-II; daily maternal milk output; and percentage of mothers that achieved a total daily milk output of $\geqslant 350$ and $\geqslant 500$ ml.

The OOL-II was defined as the time at the onset of the first of two consecutive pumping sessions for which the total milk output was $\geqslant 20$ ml. Four characteristics of the OOL-II were measured: hours from the time of birth until OOL-II; hours from the first pumping until OOL-II; number of pumping sessions from birth until the OOL-II; and the total number of minutes spent pumping until OOL-II. These data were calculated from the mothers' daily milk output records.

Daily milk output was measured volumetrically and recorded by mothers for each pumping session during the study period using the 'My Mom Pumps for Me!' milk output records, which have been used in other BPSP studies.[6]

Daily milk outputs of $\geqslant 350$ and $\geqslant 500$ ml were calculated to determine the percentage of mothers who achieved the minimum output needed to achieve exclusive human milk feeding for premature infants at the time of neonatal intensive care unit discharge (350 ml per day),[23] and a milk output that approximates that of a mother who exclusively breastfeeds a healthy-term infant at 4 to 7 days post-birth (500 ml per day).[5,11,23–25]

Efficiency of the BPSPs

The efficiency of the BPSPs was evaluated using three variables: number of pumping sessions; number of minutes spent pumping; and milk output per minute spent pumping (calculated from total milk output and total minutes spent pumping). These variables were obtained from the maternal milk output records for each study day.

Maternal perceptions of effectiveness, efficiency, comfort and convenience

Maternal perceptions of effectiveness, efficiency, comfort and convenience were measured by questionnaires that contained Likert-type and multiple-choice items derived from previous studies of BPSPs.[6] Each questionnaire contained 13 to 18 Likert-type and multiple-choice items. The Time 1 questionnaire measured mothers' perceptions of the initiation pattern, and was completed within 72 h after giving birth. This questionnaire contained items such as 'How do you rate the overall comfort of this pattern?' and 'How do you rate the number of times that the pattern changes rhythm during each pumping?'. The Time 2 questionnaire measured mothers' perceptions of the maintenance pattern as well as their perceptions of differences between the initiation and maintenance patterns. This questionnaire, which was completed within 96 h after mothers changed from the initiation to the maintenance pattern, asked mothers how strongly they agreed with statements such as 'The suction or pull of this pattern is better than the one before' and 'The new pattern is better than the one before at getting my milk out quickly.' The Time 3 questionnaire measured mothers' perceptions of the maintenance pattern, and was completed at the end of the study. This questionnaire asked mothers questions such as, 'How easy is it to know when you have used the pumping pattern long enough to remove your milk?' and 'How do you rate the length of time that your nipple is pulled into the tunnel of the breast shield?'

Procedure

Mothers were approached for inclusion in the study within 24 h after birth if they and their infants met the inclusion criteria. The study was explained, and written informed consent was obtained. At the time of enrollment, mothers began use of the breast pump according to the randomization plan, and received standardized pumping instructions and guidance. All mothers were taught to use simultaneous (e.g., pumping both breasts at the same time) milk expression. Similarly, appropriate pumping pressures and correctly fitted breast shields were individualized for each mother at this time. Mothers were instructed to use the breast pump eight times daily for 15 min each pumping until the milk output was at least 20 ml from the two breasts combined. Thereafter, they were instructed to pump until they no longer saw milk droplets for at least two consecutive minutes, ensuring the available milk had been removed as completely as possible. Mothers were taught to measure their pumped milk output volumetrically and were shown how to record these volumes in the milk output record. Mothers were given an initiation BPSP card to be used in the Symphony pump, according to their randomized group assignment. This card was used for all pumping sessions until the OOL-II.

Mothers completed the Time-1 questionnaire within 72 h after enrollment. If mothers experienced the OOL-II before hospital discharge, they were given the maintenance card at that time. If mothers were discharged before the onset of lactogenesis II, they were provided with the maintenance card at the time of hospital discharge with specific instructions about changing from the initiation to the maintenance card once they had experienced two consecutive pumping sessions with a total milk output of $\geqslant$20 ml for each session. Mothers completed the Time-2 questionnaire within 96-h of switching from the initiation to the maintenance BPSP. The Time-3 questionnaires were completed at the end of the study.

Data analysis

Data were analyzed using Microsoft Excel (Redmond, WA, USA) and SPSS (version 15.0, Chicago, IL, USA). The data for each variable were examined using univariate analyses. Categorical data were compared using χ^2-analysis. Continuous, normally distributed data were compared using analysis of variance. A *posteriori* comparisons were performed on continuous data using Bonferroni tests. Ranked data and non-normally distributed data were compared using Kruskal–Wallis tests. A *posteriori* comparisons on these data were performed using Mann–Whitney U tests. A Type I error of 5% was used for all tests of statistical significance.

Results

Effectiveness of the BPSPs

The Onset of Lactogenesis II. Of the 105 mothers, 3 (2 EXP-EXP and 1 STD-STD) failed to achieve the OOL-II by day 14, and were excluded from analyses related to the OOL-II. None of the four measures for the OOL-II was statistically different among the groups (Figure 1). However, all four measures suggested an earlier and more efficient (e.g., fewer pumpings, fewer minutes spent pumping) OOL-II for the EXP-STD mothers.

Daily maternal milk output. Mean daily maternal milk output is depicted in Figure 2c. During the initial 5 days of the study,

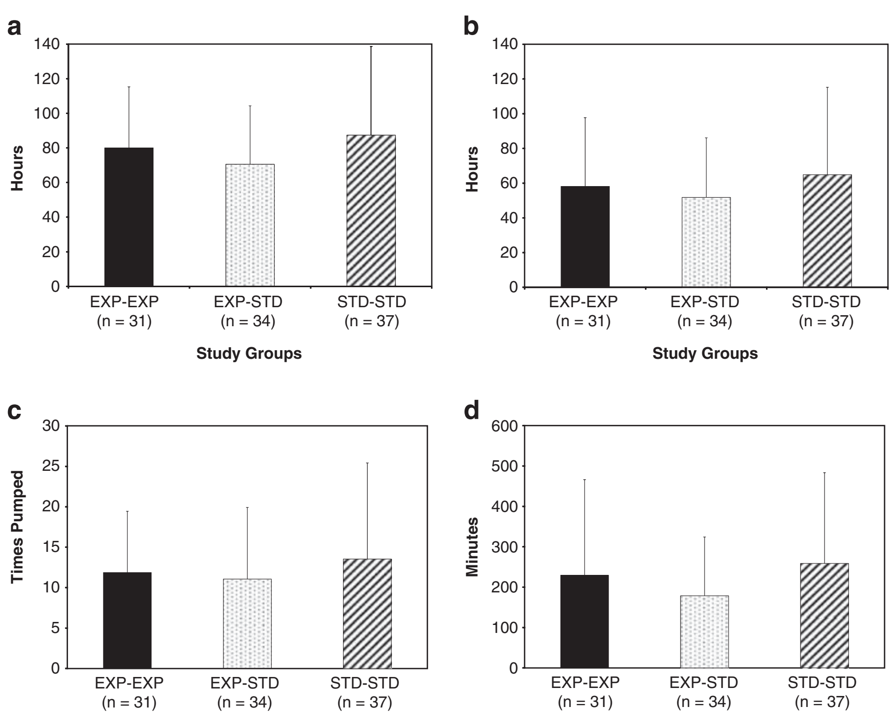

Figure 1 Measures of the onset of lactogenesis II. (**a**) Hours from birth until onset of lactogenesis II (mean ± s.d.); (**b**) hours from first pumping to onset of lactogenesis II (mean ± s.d.); (**c**) number of pumping sessions until onset of lactogenesis II (mean ± s.d.); (**d**) total minutes of pumping until onset of lactogenesis II (mean ± s.d.).

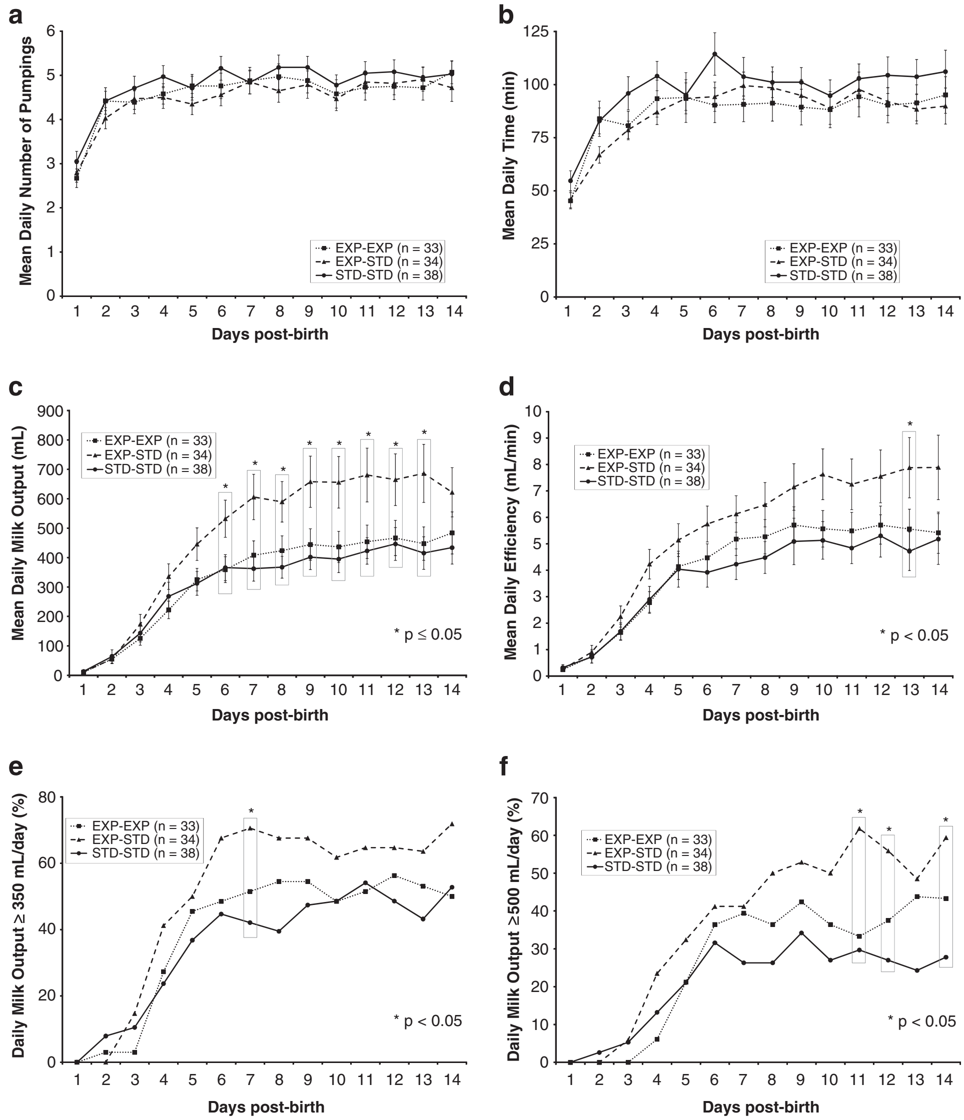

Figure 2 Daily measures of effectiveness and efficiency. (**a**) Daily number of pumpings (mean ± s.d.); (**b**) daily pumping time (mean ± s.d., in min); (**c**) daily milk output (mean ± s.d., in ml); (**d**) daily efficiency (mean ± s.d., in ml per min); (**e**) percentage of cases with daily milk output ⩾350 ml per day; (**f**) percentage of cases with daily milk output ⩾500 ml per day.

there were no significant differences among the groups. However, starting on day 4, mean daily milk output for EXP-STD mothers (335.4 ml) started to trend higher than for EXP-EXP (222.2 ml) and STD-STD mothers (268.3 ml). These differences became statistically significant starting on day 6, and remained significantly higher through day 13. A *posteriori* comparisons, when significant, demonstrated that milk output for EXP-STD mothers was higher than for the other groups.

Mean cumulative maternal milk output for the study period is depicted in Figure 3c. Starting on day 4, mean cumulative milk output began to trend higher for EXP-STD mothers (575.8 ml), when compared with EXP-EXP (413.3 ml) and STD-STD (488.8 ml) mothers. Starting on day 8, EXP-STD mothers demonstrated significantly greater cumulative milk output, and this difference continued through the remainder of the study.

Percentage of mothers in each group with daily maternal milk output ⩾350 and ⩾500 ml per day. Figures 2e and f depict the percentage of mothers in each group with daily milk outputs ⩾350 and ⩾500 ml, respectively. A greater percentage of EXP-STD mothers achieved both the 350 ml and 500 ml thresholds when compared with EXP-EXP and STD-STD mothers. These differences were statistically significant for the ⩾350 ml threshold on day 7, and for the ⩾500 ml threshold on days 11, 12 and 14.

Efficiency of the BPSPs

Daily minutes spent pumping. There were no statistically significant differences among the groups in either the mean daily number of pumpings or in the minutes spent pumping (Figures 2a and b) or in the mean cumulative number of pumpings or

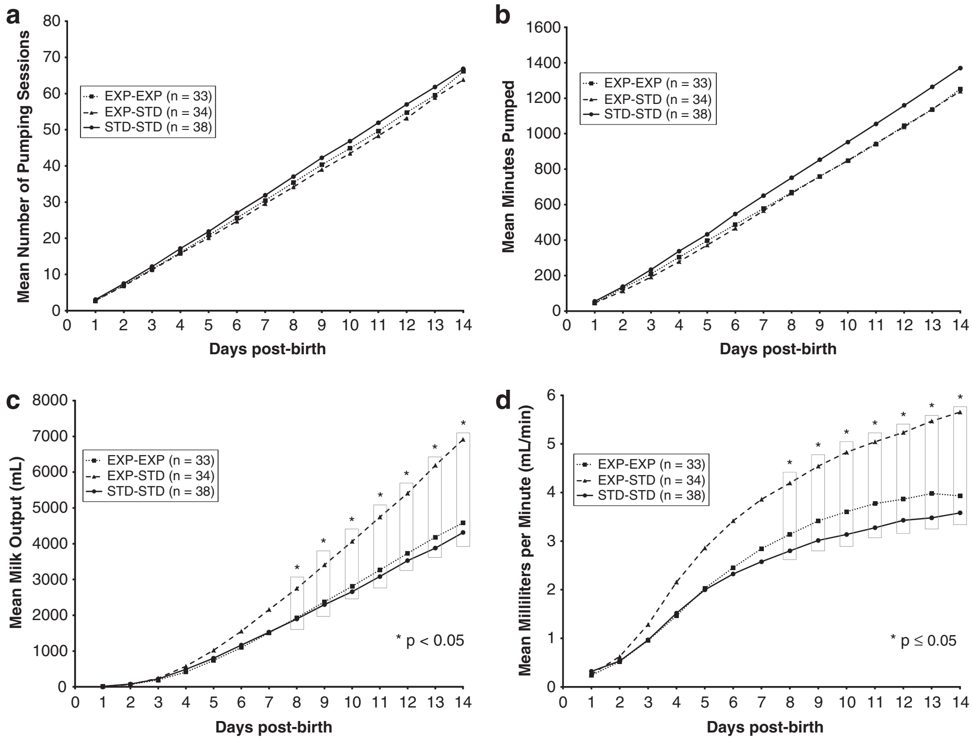

Figure 3 Cumulative measures of effectiveness and efficiency. (**a**) Cumulative number of pumping sessions; (**b**) cumulative number of minutes pumped; (**c**) cumulative milk output (ml); (**d**) cumulative efficiency (ml per min).

minutes spent pumping (Figures 3a and b) throughout the study. However, the STD-STD mothers trended consistently toward more daily and cumulative minutes spent pumping than did the EXP-EXP or EXP-STD mothers.

Milk output per minute of pumping time. This measure was calculated by dividing the total daily milk output by the total daily minutes spent pumping. Milk output per minute of pumping time was higher for EXP-STD mothers than for EXP-EXP or STD-STD mothers, a trend that emerged on day 4 post-birth and was significantly higher on day 13 (Figure 2d). Cumulative milk output per minute of pumping time demonstrated a similar trend (Figure 3d), and was significantly higher for days 8 through 14.

Mothers' perceptions of effectiveness, efficiency, comfort and convenience

The only statistically significant difference in the Time-1 questionnaires revealed that STD-STD mothers perceived that the initiation BPSP they used did not have enough changes in rhythm when compared with EXP-EXP and EXP-STD mothers. For the Time-2 questionnaire, eight statistically significant differences were noted, all of which indicated that EXP-EXP mothers did not perceive the new experimental maintenance BPSP as 'comfortable', especially when compared with the experimental initiation BPSP that these mothers had used. Only one statistically significant difference was noted in the Time-3 questionnaires, which revealed that EXP-EXP mothers did not like the 'suction strength' of the new experimental maintenance BPSP.

Discussion

Mothers who are breast pump-dependent must substitute the sucking stimulus and milk removal functions of the healthy-term infant with a breast pump. This is the first study to compare the effectiveness, efficiency, comfort and convenience of combinations of BPSPs that mimic human infant sucking patterns during the immediate post-birth period as well as later in lactation. The findings of this study indicate that the combination of the EXP-STD BPSPs is superior to the other combinations of BPSPs for breast pump-dependent mothers with premature infants. We hypothesize that the new EXP initiation BPSP provides uniquely human sucking stimulation to the mammary gland during the critical post-birth period when lactation is initiated. This stimulatory effect is optimized when followed by the STD maintenance BPSP, which was developed and tested extensively for its effectiveness, efficiency, comfort and convenience after the OOL-II.

The complex transition from the initiation to the maintenance of lactation is a critical period and its successful completion has been linked to subsequent milk output and/or duration of lactation in human and animal studies.[11,26–29] The primary trigger for lactogenesis II for all mammals is the withdrawal of circulating progesterone following the birth of the placenta, because progesterone inhibits prolactin-regulated milk synthesis.[16,26] Thereafter, prolactin release by the anterior pituitary is suckling-induced, and prolactin concentrations are directly related to the intensity of the suckling stimulus.[26]

The mammary gland is extremely sensitive to the effects of prolactin in the early post-birth period.[26,29,30] During this critical window, prolactin upregulates genes that promote rapid proliferation and differentiation of the secretory cells in the mammary gland, prevents apoptosis of secretory cells and stimulates closure of the tight junctions in the mammary epithelium.[16,26,29–31] Although these processes are known to be essential for the transition from the initiation to the maintenance of lactation, recent evidence suggests that they also have a programming role with respect to long-term milk output.[29–32] Several studies in dairy cows have clearly demonstrated this programming mechanism by randomly assigning animals to either frequent (four times daily) or control (two times daily) milking during the first 3 weeks post-birth. After the 3-week period, both groups of cows were milked twice daily. Results revealed that animals in the early frequent milking group produced significantly greater milk throughout lactation.[29–31] Laboratory findings demonstrated that frequent milking during this critical period resulted in higher concentrations of prolactin and greater secretory cell number and differentiation, optimizing milk yield throughout lactation.[29–31]

In our blinded, randomized clinical trial, the three groups of mothers and infants did not differ significantly on any of the characteristics that might potentially influence maternal milk output, such as parity, delivery mode, infant gestational age, previous breastfeeding experience or presence of maternal medical complications. Similarly, the three groups of mothers received identical pumping instructions, lactation care and access to nonpharmacological interventions, such as skin-to-skin care, from the same set of clinicians. The findings also reveal that the three groups of women pumped a similar number of times and minutes daily. Thus, common extraneous variables cannot explain the greater maternal milk output noted in the EXP-STD mothers.

We conclude that the mechanism for the greater effectiveness, efficiency, comfort and convenience in the EXP-STD mothers is the combination of the two BPSPs used by these women. Specifically, the EXP initiation BPSP provided an intensive rapid-rate stimulus and burst–pause pattern that is uniquely human, as other infant mammals do not demonstrate this rapid non-nutritive sucking pattern.[33] Additionally, the EXP initiation BPSP mimics sucking that occurs during early breastfeeding, but not bottle-feeding in healthy term infants.[18,19] Once the 'milk comes in', infants change the sucking pattern to reflect the availability of milk. Specifically, they suck rapidly until milk ejection occurs, and then switch to a slower, more rhythmic suck in order to accommodate swallowing and breathing after milk ejection.[14,18,19] This biphasic pattern is replicated in the standard BPSP, and was used by EXP-STD mothers in our study after the OOL-II.

By 4 to 7 days post-birth, exclusively breast-fed infants consume approximately 500 to 600 ml of milk daily.[11,24,25,28] In our study, EXP-STD mothers achieved a comparable mean daily milk output by day 6 and maintained it through day 14, whereas mean milk output for EXP-EXP and STD-STD mothers did not reach 500 ml per day during the entire 14-day study period. Additionally, the EXP-STD mothers achieved a mean daily milk output that was considerably higher than that previously reported for breast pump-dependent mothers of premature infants in early lactation.[4,28]

In summary, this research suggests that the use of BPSPs that mimic the sucking patterns of healthy-term infants during the initiation and maintenance of lactation are more effective, efficient, comfortable and convenient in breast pump-dependent mothers with premature infants. Additionally, these findings add to the anatomical and biochemical evidence that the initial post-birth sucking patterns may serve a function beyond extracting milk, and appear to have a role in the programming of critical processes during the transition from the initiation to the maintenance of lactation.

Conflict of interest

Dr Meier and Dr Engstrom have received research funding and honoraria for projects from Medela. The other authors declare no conflict of interest.

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Supplementary Information accompanies the paper on the Journal of Perinatology website (http://www.nature.com/jp)