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Evaluating milk flow patterns using the high flow rate period during breast pumping

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ABSTRACT

Problem: Breast pumping practices have scope for improvement.
Background: Breast milk weight measurement can be used to evaluate milk flow pattern dynamics during breast pumping.
Aim: To determine inter-individual differences in milk flow patterns and their practical implications based on high milk flow rate period (HFP) data among Japanese women expressing breast milk using an electric pump.
Methods: This cross-sectional, observational study analysed data from 19 women (33.0 ± 3.9 years) nursing 1–6-month-old infants and with previous breast milk expression experience. Breast milk was weighed continuously during a 15-min single-breast electric pumping session. The HFP features and flow rate time (≥0.1 g/s) were analysed to determine each individual's milk flow pattern.
Findings: The total expressed breast milk was 69.8 ± 42.5 g with a maximum individual flow rate of 0.5 ± 0.2 g/s. The breast milk yielded during the HFPs was 43.1 (34.4–81.3) g, accounting for 82.5 % (69.9–89.5 %) of the total expressed breast milk. HFP occurred 0–3 times during the 15-min session. Multiple discrete and continuous milk flow patterns were observed. Among those with discrete HFP, the HFP interval was 221 (68–371) s. Breast milk fat content changes and subjective residual milk measurements implied sufficient milk removal. A strong positive correlation was noted between HFP length and total breast milk expression volume.
Discussion: Individual differences in milk flow patterns were observed among the women using HFP. Milk flow patterns were consistent with previous reports.
Conclusion: Milk flow pattern data can be used to guide individualised lactation support.

Introduction

Breast milk is considered the optimal nutrition for preterm newborn infants. Mothers are encouraged to commence lactation when preterm infants are hospitalized in the neonatal intensive care unit (NICU) or when mother-infant separation does not allow for direct breastfeeding. Lactation should be initiated as early as possible (Murase et al., 2014; Parker et al., 2021; Parker et al., 2012; Parker et al., 2020) and performed at least eight times per day or every 2–3 h (Hill et al., 2005; Lawrence and Lawrence, 2021; Ru et al., 2020). However, expressing breast milk impacts maternal psychological and physical well-being owing to the absence of the infant, hand and breast pain, expressing equipment cleaning and disinfection, and sleep disruption (Fujimoto and Yokoo, 2009; Takiguchi and Kanaizumi, 2023).

An efficient expression method is important to achieve sufficient milk supply, maximize pumping time, and reduce maternal fatigue. While several methods for breast milk expression are used, method selection depends on the time since birth or the individual mother and infant (Becker et al., 2016). Among them, breast pumping using an electric breast pump is recommended when frequent breast expression is required to establish and maintain milk supply, owing to its efficiency and fatigue-reducing effects (Fujimoto and Yokoo, 2009; Meier et al., 2016; Ru et al., 2020). However, there is scope for improvement in the practice of breast pumping (Felice et al., 2017). Since previous studies have used a wide range of conditions and variables, such as regarding breast pump type and maternal pumping purpose, the results have been inconsistent and are difficult to compare, leading to a lack of data for helping mothers achieve their breastfeeding goals (Becker et al., 2016).

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Moreover, studies addressing patterns of breast milk flow rate among Japanese women have been limited. Thus, further geographic and demographic research is needed to establish accurate and detailed breastfeeding support practices.

Milk ejection is essential for efficient breast milk expression, but the timing and magnitude of this reflex differ among mothers owing to the anatomical characteristics of the mammary glands and ducts and differences in the reactivity of the oxytocin receptors in mammary gland cells, which cause each mother's flow rate pattern to be unique and consistent throughout the infant nursing period (Gardner et al., 2015; Prime et al., 2011). Moreover, an efficient breast milk pumping method is important to achieve sufficient lactation, reduce the time needed for pumping, and reduce maternal fatigue. Individualized lactation support is necessary to increase the breast milk supply (Mitoulas et al., 2002) and when selecting a suitable breast milk expression method. Thus, understanding the unique and consistent characteristics of maternal milk flow patterns is essential when providing such support. Prime et al. (2009) reported unique maternal milk flow patterns based on continuous weight measurements of milk expressed during pumping sessions, which facilitated continuous and non-invasive evaluation of milk ejection dynamics during lactation. However, because this method requires the expressed breast milk to be placed near the floor for measurement, the setup was unhygienic. Furthermore, problems such as breast milk being unable to flow into the collection bottle at a fixed rate naturally and occasionally accumulating within the collection tube led us to conclude that improvements were necessary. In addition, there was the problem of mothers being required to maintain an upright posture to enable good flow.

Prime et al. (2012) have shown that individual-specific flow patterns can be ascertained by detecting flow peaks using a continuous measurement method for weight. Although time series analysis of the peak milk weight data is the most accurate method for estimating ejection reflex occurrence, the peaks often occur in succession, are not clearly separated, and require advanced processing for detection. Hence, a more practical simplified method for observing individual milk flow patterns is needed for use in clinical practice to measure when the ejection reflex mediates increases in milk flow rate, even if precisely identifying the onset is not possible.

Therefore, this study aimed to describe milk flow patterns using high flow rate period (HFP) data during continuous milk flow weight measurement in Japanese women breast pumping using an electric breast pump. The modified measuring device was originally built to allow the mother to pump in a comfortable position while accurately measuring the flow rate. Individual flow patterns were identified by investigating the timing characteristics of relatively high flow rates during pumping instead of detecting the milk flow peaks.

Statement of significance:

Problem or issue	Individual patterns of breast milk flow rate during pumping may be useful for providing clinical support, but an easier method for evaluating each milk flow pattern is needed.
What is already known	Milk ejection is essential for efficient breast milk expression, but the timing and magnitude of this reflex differ among individuals. Moreover, each individual's flow rate pattern is unique and consistent throughout the breastfeeding period.
What this paper adds	Milk flow patterns similar to previous reports were observed by measuring the high flow rate periods.

Participants, ethics, and methods

Study design

This cross-sectional, observational study was conducted at a research facility of Pigeon Corporation in Japan between March–December 2021. The expressed breast milk weight was measured in real time while participants used an electric breast pump on a single breast for 15 min. This study was approved by Showa University Research Ethics Review Board (approval number: 3150) and performed after obtaining written informed consent from the participants. All procedures were conducted in accordance with the Declaration of Helsinki.

Setting and participants

Data were collected from 28 women who were breastfeeding, with or without supplementing with formula, 1- to 6-month-old infants at the time of the study, had not yet introduced solid foods, and had previous breast milk expression experience. The participants were recruited via a monitor system operated by the research institute, allowing neighborhood residents to engage in research activities at their own free will publicly. The participants were recruited throughout the study period. When a woman expressed interest in the study, a researcher made contact via telephone and arranged the observation dates once the participant provided consent for participation.

Measures

Breast pumping and measurement of expressed breast milk weight

The participant expressed milk from one breast for 15 min using an electric breast pump (Breast Milk Assist Pro Personal, Pigeon, Tokyo, Japan). This experiment used an electric breast pump designed to express a volume of breast milk equivalent to one feeding rather than a pump for removing excess breast milk or reducing excessive breast fluid. Although it is a personal-use breast pump, it has the same suction pressure as hospital-grade models. It is equipped with adjustable increments, fast cycle suction to stimulate the nipples, and suction for breast pumping. It is capable of pumping from both breasts simultaneously. The breast pump provided several different suction rhythms, but the suction strength and speed were set to a constant rhythm for this experiment. The participants were not exclusively breast pump-dependent mothers (Meier et al., 2016), and they reported sequential pumping as their typical breastfeeding method. The participants selected the breast side to pump, which usually expressed breast milk more easily. In previous studies, the pumping times varied as mothers continued pumping until the milk flow slowed or ceased, or a time set by the researchers (Becker et al., 2016). To compare flow rate patterns with those reported in previous studies (Prime et al., 2011; Prime et al., 2009), the pumping time was set to 15 min in the present study. Pumping began with a fast-cycle suction to stimulate the nipple. After breast milk expression or 120 s of stimulation, the 15-min session began. Suction pressure was gradually increased to the highest pressure at which the mother did not feel discomfort to maximize the efficiency of breast milk expression (Kent et al., 2008). As optimal suction pressure varies during breast pumping, the participant was permitted to adjust this accordingly. The breast pump was connected to an electronic balance via silicone tube (Fig. 1). A tubing pump, placed in the middle of the tube, facilitates effective feeding and allows the mother to express breast milk in a comfortable position without being conscious of the measurement. The weight of the expressed breast milk was continuously recorded at a rate of 5.2 Hz.

Breast milk expression effectiveness and residual milk

The breast pumping effectiveness was evaluated in two ways. The change in breast milk fat content was analysed using the creamatocrit (CrCt) method (Collares et al., 1997; Czank et al., 2009; Mizuno et al., 2009), which required approximately 1–5 mL of breast milk manually expressed before (foremilk) and immediately after (hindmilk) the breast pumping session. The samples were stored and later thawed for analysis. Before CrCt measurement, the samples were centrifuged at 12,000 g for 15 min at 4 °C (Sorvall ST 8R, Thermo Fisher Scientific, Waltham, MA, USA). Residual milk was measured using a 10-point visual analogue scale (VAS), whereby the women subjectively assessed the amount of milk present before and after pumping, from empty to full (left and right

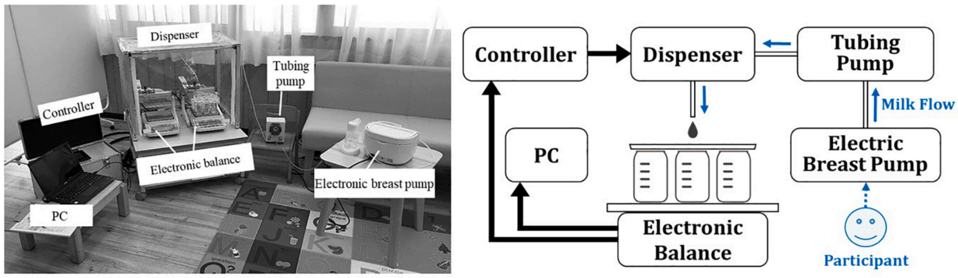

Fig. 1. Milk flow measurement system and the lactation room layout.
The breast milk, expressed through a breast pump, flows into a bottle (KR50, Pigeon, Tokyo, Japan) placed on an electronic balance (GX-2002A, A&D Company, Ltd., Tokyo, Japan), connected via silicone tube. The breast milk weight is continuously measured, with the data transmitted to a computer (PC). A tubing pump (TP-10SA, AS ONE, Osaka, Japan), placed in the middle of the tube, ensures a constant flow rate, preventing uneven flow and pooling in the tube. All components in contact with the breast milk comply with the Food Sanitation Act. The electronic breast pump shown differs from the one used in the present study.

on the VAS, respectively).

Procedure

The participants presented to the research facility according to the infant nursing and breast milk expression times. To account for circadian changes in the composition of breast milk, we conducted breast pumping during the daytime, and measurements were completed between 10:00 am and 2:00 pm.

The researcher explained the study procedure to the mothers in writing and orally, and participant characteristic data were obtained via interview. Afterwards, the observer attached the electric breast pump to the mother while the infant was in view. Before and after the pumping session, the participants recorded their subjective measurement of residual milk using the VAS, and foremilk and hindmilk samples were collected. After the 15-min session, the participants were permitted to pump or breastfeed on the contralateral breast. Breast milk samples were frozen until CrCt analysis was performed.

Analysis

The cumulative volume of expressed breast milk and flow rate (g/s) changes were analysed using the expressed milk weight data (Fig. 2). The time series data for expressed breast milk weight was resampled at 1 Hz. The 10-s moving average was used to create flow rate curves.

High flow rate period

The HFP was defined as the time during which the flow rate was ≥0.1 g/s. If the threshold value was not exceeded for 10 s, the period was not considered an HFP. If the interval between adjacent HFPs was <10 s, the two HFPs were considered the same HFP, and the interval was included in the HFP time (Fig. 2).

Statistical analysis

Continuous variables (the weight of expressed breast milk, flow rate characteristics, subjective residual milk, and CrCt) are expressed as mean ± standard deviation when normally distributed and median (interquartile range) when not normally distributed. Pearson's product-rate correlation coefficient was used to examine the relationship between each HFP indicator and milk expression volume.

The foremilk and hindmilk CrCt and the subjective residual milk measurements before and after breast milk expression were compared using a paired *t*-test. Statistical significance was set at $p < 0.05$. The *t*-test effect sizes were measured using Cohen's *d*. All data were analysed using SPSS version 28.0 (IBM Corp., Armonk, NY, USA).

Results

Among the 28 participants, 9 were excluded from the analysis, including 3 who had insufficient milk supply for breast pumping, 4 whose hindmilk could not be collected, and 2 whose milk was not recorded correctly. Therefore, the data of 19 participants were included in the analyses (Table 1).

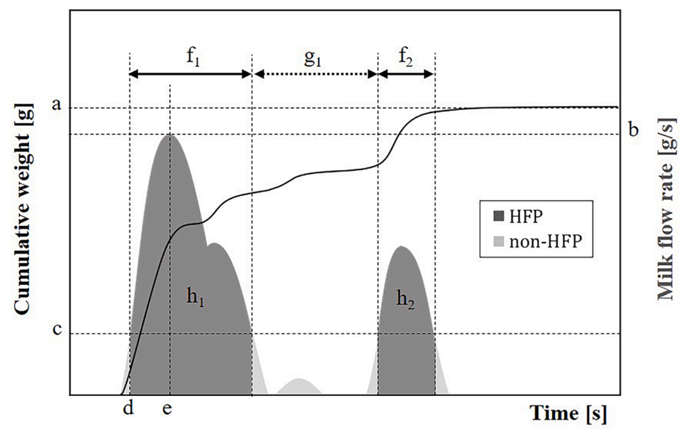

Fig. 2. Flow rate change curve and analysis indices.
The high flow rate period (HFP) characteristics displaying the cumulative weight of expressed breast milk on the left *y*-axis, milk flow rate on the right *y*-axis, and time on the *x*-axis are shown. HFP is defined as a flow rate ≥ the threshold value (0.1 g/s) for 10 s (dark grey). If the interval between adjacent HFPs is less than 10 s, these two HFPs and the interval between them are considered a single HFP. Expressed Breast Milk Amount Variable. (a) Total expressed breast milk amount over a 15-min period [g]. Maximum Flow Rate Variables. (b) Maximum intra-individual flow rate [g/s]; e. Maximum flow rate generation time [s]. HFP Characteristics Variables. (c) HFP threshold value [g/s]; h. Number of HFP count; d. HFP start time [s]; $\Sigma f_i + \Sigma g_i$. Total HFP length including non-HFPs [s]; Σf_i. Total HFP length excluding non-HFPs [s]; Σh_i. Breast milk amount expressed in HFP [g]; $(\Sigma h_i/a) \times 100$. Percentage relative to total expressed breast milk amount [%].

In total, 14 participants (73.7 %) pumped the right breast, and 5 (26.3 %) pumped the left breast. The mean elapsed time since the last direct breastfeeding was 110 min (60–150 min). The mean required stimulation time at the start of the pumping session was 29 s (15–64 s). The total expressed breast milk was 69.8 ± 42.5 g.

The flow rate ranged from 0.0 g/s to 1.1 g/s, with a maximum individual flow rate of 0.53 ± 0.23 g/s, which occurred at 278.2 ± 200.3 s from suction initiation. All participants had an interval with a flow rate of 0.0 g/s, indicating that no milk expression occurred at some point during each pumping session.

The number of HFPs ranged from 0–3 during the pumping sessions (Table 2). The first HFP began 48.5 s (27.0–252.8 s) after the start of pumping, and the total HFP time was 207.1 ± 107.7 s. Among participants with ≥2 HFPs, the mean HFP interval was 221 s (68–371 s). The longest HFP interval was 505 s. The HFP duration, including non-HFPs, was 355.7 ± 242.3 s. The mean amount of breast milk expressed during

Table 1
Participant characteristics.

Characteristic	Value
Participant age, years[a]	33.0 ± 3.9
Birth order of nursing child	
First	7 (36.8)
Second	9 (47.4)
Third	3 (15.8)
Infant age, months	4.0 (2.0–4.0)
Gestational age, weeks	38.5 ± 1.2
Infant birth weight, g	3088.3 ± 427.4
Breastfeeding frequency, times/day	7.0 (5.0–8.0)
Infant nutrition	
Breast milk nutrition	14 (73.7)
Mixed nutrition	5 (26.3)
Breast pump used	
Manual	13 (68.4)
Electric	6 (31.6)
Pumping frequency per week	
Almost everyday	7 (36.8)
Between two and five times	8 (42.1)
Once or less	4 (21.1)

Note. Values are presented as number (percentage), mean ± standard deviation, or median (interquartile range).
[a] Missing data for two participants.

Table 2
High flow rate period characteristics.

Variable	Value
HFP count	
0	1 (5.3)
1	7 (36.8)
2	4 (21.1)
3	7 (36.8)
HFP start time, s[a]	48.5 (27.0–252.8)
HFP interval, s[b]	221.0 (68.0–371.0)
Total HFP length, s	
Excluding non-HFPs	207.1 ± 107.7
Including non-HFPs	355.7 ± 242.3
Breast milk amount expressed during HFP, g	43.1 (34.4–81.3)
Total breast milk amount expressed during HFP, %	82.5 (69.9–89.5)

Abbreviations: HFP, high flow rate period.
Note. $N = 19$. Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range).
[a] $n = 18$. One participant had no HFPs when the threshold of flow rate ≥0.1 g/s was used.
[b] $n = 11$. Eleven participants had ≥2 HFPs.

the HFPs was 43.1 g (34.4–81.3 g), accounting for 82.5 % (69.9–89.5 %) of the total expressed breast milk.

Flow peaks for milk ejections occurred based on flow rate changes and the HFPs (Fig. 3). In some participants, multiple peaks were included in a single HFP (Fig. 3b, c, e, and f).

One participant had no HFP during the pumping session (Fig. 4a). However, if the relative HFP standard was used, HFPs were identified, suggesting milk ejections occurred during the pumping session (Fig. 4b). The Pearson product-moment correlation coefficients between total milk expression volume and peak flow for the first HFP start time and total HFP length (excluding non-HFPs) showed that total HFP length was strongly positively correlated only with total milk production ($r = 0.856$, $p < 0.001$).

The mean CrCt of the hindmilk (13.8 ± 6.0 %) was significantly higher than that of the foremilk (5.0 ± 2.0 %; $t_{(18)} = 7.830$, $p < 0.001$, $d = 22.683$). The residual milk after breast milk expression (5.9 ± 6.8 %) was significantly lower than that before breast milk expression (46.6 ± 23.4 %; $t_{(18)} = -6.618$, $p < 0.001$, $d = 5.805$).

Discussion

While successful lactation is important to reduce pumping time and maternal fatigue, studies addressing the most efficient breast pumping methods based on individual milk ejection patterns are limited. This study investigated the individual breast milk flow patterns during breast pumping using modified continuous breast milk weight measurements and HFPs described previously (Prime et al., 2009). To analyse the milk flow pattern during a 15-min single-breast pumping session, we identified HFPs. Multiple milk flow patterns were observed, including discrete and continuous patterns consistent with previous reports (Prime et al., 2011). More than 50 % of participants exhibited a discrete milk flow pattern. The median HFP interval was 221 s (68–371 s), while the longest was 505 s. Coupled with the breast milk fat content changes and maternal subjective assessment of residual milk using VAS, our results suggested that the milk was ejected efficiently during the pumping session, even in participants with multiple HFPs.

Continuous breast milk weight measurement during pumping is an effective non-invasive method for determining an individual's unique flow pattern through flow peak frequency and timing analysis, representing milk ejection (Prime et al., 2009; Ramsay et al., 2006). However, a preliminary study found that breast milk stagnation occurred in the tube when the device was positioned a certain way. Hence, a tubing pump was installed centrally to actively transport the breast milk, enabling the weight and flow rate to be continuously measured without disturbing the mother.

The flow rate data were analysed using HFP variables to describe individual milk flow patterns. We observed that the peaks often occurred in succession and were not clearly separated, indicating that advanced processing was needed for detection to estimate ejection reflex occurrence accurately. Therefore, we described individual patterns by HFP analysis using clear, predetermined criteria to enable mothers and caregivers to understand patterns of breast milk flow rate. Several HFP patterns were observed in this study, including one continuous HFP, three or more HFPs, a continuous long HFP with multiple peaks, and an increasing flow rate at regular intervals (Fig. 3). Unfortunately, a direct comparison with data from previous studies cannot be made, given the differing study protocols. Likewise, the HFP cannot be directly compared to the ejection reflex. Nonetheless, the patterns described using the HFP had similar discrete-continuous flow peaks and individual frequency differences to previously reported patterns (Prime et al., 2011).

The number of HFPs detected in this study was reasonable. Typically, the number of HFPs, which may include multiple milk flow rate peaks that occur continuously, should be less than the number of milk ejection reflexes, which occurs approximately 3.4 ± 1.4 times during a 15 min pumping session (Prime et al., 2012). Notably, the interval between HFPs was longer than previously reported milk ejection intervals (Prime et al., 2011), which may be because the HFP interval captures minimal or almost no milk ejections rather than the intervals of continuous milk ejections during which milk expression continues. Thus, although it is difficult to determine the exact number of milk ejections, the HFP interval is clinically useful for understanding the timing of milk expression and determining the optimal pumping method and time. For example, mothers may pause breast pumping if lactation stops, especially when the time until the next milk ejection is long. Alternatively, untimed pumping is defined as the time until breast milk leaking from at least one breast is no longer observed (Auerbach, 1990). However, as the time allotted for direct breastfeeding should not be restricted, the breast milk expression time should be adjusted to match each mother's pace of breast milk expression. This flexibility in timing reduces maternal burden and may establish an optimal breast milk expression method tailored to their individual needs, such as a desire to express more milk or to express hindmilk thoroughly.

Additionally, by defining HFP at a threshold relative to an individual's milk flow rate, the individual's pattern can be determined

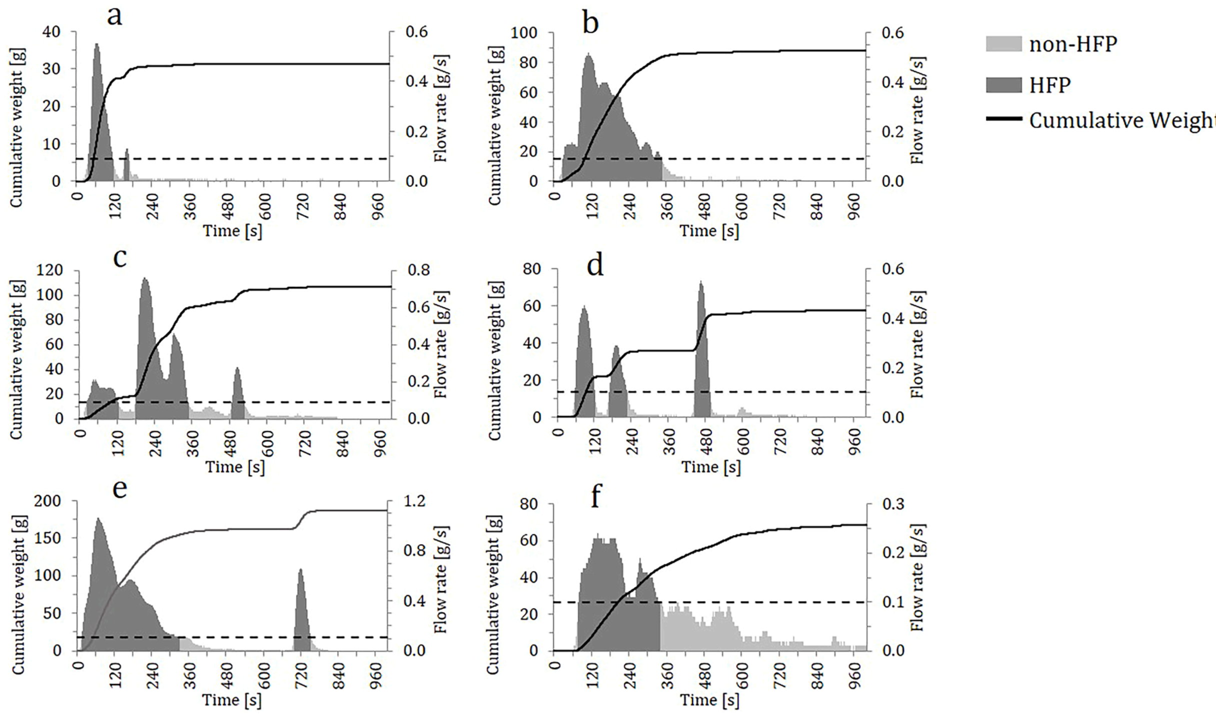

Fig. 3. Changes in breast milk amount and flow rate.
Flow rate change curves with one high flow rate period (HFP) (b, f), two HFPs (a, e), and three or more HFPs (c, d) are shown, with individual differences in HFP appearance, frequency, and duration. After the expressed breast milk amount decreased once, a second HFP was observed approximately 10 min after the start of breast milk expression (e). Breast milk expression continued after the end of the HFP, and the flow rate fluctuated at regular intervals throughout the pumping session (f).

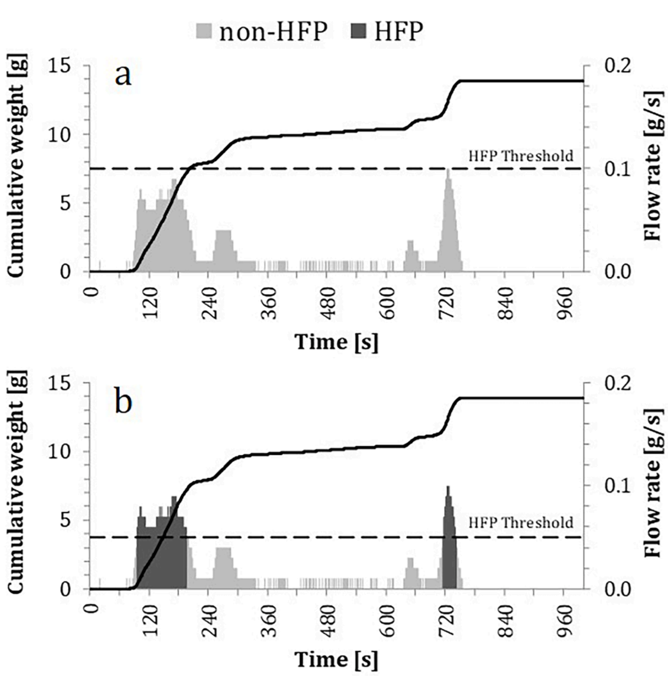

Fig. 4. HFPs in a participant with a low amount of expressed breast milk.
When the high flow rate period (HFP) threshold of 0.1 g/s is used, the participant experienced no HFPs (light grey) (a). When a relative standard threshold for HFP was set according to the individual flow rate distribution, two HFPs are observed (dark grey) (b).

even when the milk flow rate is low (Fig. 4). In this study, one participant had a very low breast milk expression and no HFPs (threshold flow rate of 0.1 g/s). However, when a relative HFP value was set, two HFPs were observed. Thus, using uniform and relative threshold values according to the expressed breast milk yield effectively determines individual milk flow patterns. Hence, the results of the current study can be considered an adequate description of individual breast milk flow patterns during breast pumping.

Simultaneous bilateral breast pumping, combining manual milk expression with a breast pump, and using photos of infants or music have been identified as effective methods for stimulating the breast milk ejection reflex and more efficiently expressing breast milk (Becker et al., 2016). The evaluation of HFP-based breast milk pumping presented in this study suggests that, in addition to conventional methods for improving milk pumping efficiency, we could consider interventions that take HFP and non-HFP intervals into account. For example, there may be suction pressures and suction rhythms appropriate for HFP intervals, as well as those appropriate for non-HFP intervals. In addition, pumping per HFP seems possible to prevent over- or under-pumping, and pumping methods that maximize an individual's milk pumping efficiency should be suggested.

Understanding inter-individual breast milk flow pattern variability allows for developing an optimal breast milk expression method for each individual. When expressing breast milk for the first time, women are often unaware of the different expression methods and ultimately use breast pumps according to the advice of hospital staff. However, based on the results of the current study, individualized guidance is warranted, and future studies to improve breast milk expression efficiency and reduce maternal stress are necessary. Such studies may focus on suction types that match the individual's flow rate pattern and the appropriate choice of breast pump, pumping times, or suction strength. Overall, achieving a standardized evaluation of individual milk flow patterns can be used to support each breastfeeding mother.

This study had several limitations. First, differences in breast pumping equipment, method, or purpose were not examined. Second, the impact of sequential breast pumping was not investigated. A comparative study addressing double-breast and sequential pumping techniques is needed to assist mothers who cannot directly breastfeed their infants for a certain period due to NICU hospitalization or separation. Lastly, as HFP frequency and duration are relative to milk yield, further studies are necessary to determine the intra-individual consistency throughout the lactation period and during direct breastfeeding.

This study shows individual differences in pumping patterns with electric breast pumps and suggests that HFP evaluations may help to improve pumping efficiency. However, whether electric breast pumps alone can achieve sufficient milk expression remains. It has been suggested that expressing milk using only a breast pump is insufficient for establishing breastfeeding, indicating the importance of combining it with manual breast pumping (da Silva et al., 2021; Morton et al., 2012; Morton et al., 2009). Furthermore, because pumping can result in too much or too little breast milk being produced, it may not be effective for women who already have insufficient lactation. Because different breast pumping methods differ in effectiveness (Meier et al., 2016), in actual clinical practice, a combination of various methods will need to be evaluated in various situations. We believe this study presents an effective proposal for one such method.

Conclusion

This novel study illustrated that individual milk flow patterns could be determined by observing HFPs during continuous milk weight measurement and observed milk flow rate patterns similar to milk ejection patterns previously reported. There was a strong positive correlation between HFP length and milk expression volume. Understanding individual milk flow patterns can facilitate individualized breast pumping support and help determine an appropriate breast pumping schedule once optimal breast pumping session efficiency is achieved. The results of this study can be used as the basis for further research to improve breast pumping efficiency and breast milk production through the identification of breast pumping methods that correspond with specific milk flow patterns.

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CRediT authorship contribution statement

Yoko Idei: Formal analysis, Investigation, Project administration, Writing – original draft. **Yukifumi Ochiai:** Formal analysis, Methodology, Writing – original draft. **Kanae Yoshibe:** Investigation. **Sumiko Kuroishi:** Conceptualization, Writing – original draft, Writing – review & editing. **Mariko Takase:** Formal analysis. **Katsumi Mizuno:** Conceptualization, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

K.M. and M.T. received payment from Pigeon for advice and consultation, respectively.

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