Imalac

Nurture Breast Massager
Preliminary Clinical Study Results

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Nurture by Imalac

Nurture by Imalac is a breast massage system for nursing and pumping mothers that provides gentle compression massage, replicating hands-on pumping.

The Nurture system includes:

- Hands-free, progressive motion breast massage
- Flattering, no underwire nursing, pumping AND massage bra
- Adjustable settings for pressure, speed, and hold time
- Easy to use controller with free, mobile app
- Compatible with most standard breast pumps

Imalac's current study of Nurture is testing:

1. Does Nurture increase the caloric content of milk expressed?
2. Does Nurture increase the total volume of milk expressed?
3. Does Nurture increase the rate at which milk is expressed?

To answer these questions, mothers who are exclusively pumping, completed five days (5) of pumping sessions: Day one (1) and day two (2) without Nurture, day three (3) to get accustomed to using Nurture and days four (4) and five (5) using Nurture. Participants were asked to pump for a minimum of three (3) times a day until the user determined their breasts were empty. At each session, participants noted pump time, volume of milk expressed from both the left and right breast, and they took a sample of the expressed milk at the end of each session. Complete breast expression was at the discretion of the subject. Each session was completed at approximately the same time on subsequent days. At the end of the five (5) day period an Imalac staff member picked up the device and milk samples. The caloric content of the expressed milk was then evaluated in Imalac's lab using a creamatocrit.

This is the third phase of product testing, following adjustments to the study protocol to ensure accuracy, adjustments in data collection methods in order to reduce the risk of the spread of COVID-19, and adjustments in the device itself.

In total, 16 exclusively pumping mothers completed 296 pumping sessions (149 pump only and 147 pump with Nurture). Imalac compared the fat content of expressed milk (grams/liter), total volume of milk expressed (ounces), and rate of expression of milk (ounces per minute) to when mothers wore Nurture verses when they did not wear Nurture. To date Imalac's findings are as follows across all participants:

- **75% of participants experienced an increase in total fat expressed per session with Nurture.** Mean calories expressed increased by an average of 26% per pump.
- **94% of participants experienced an increase in volume expressed with Nurture**. Mean volume in ounces increased by an average of 1.03 ounces per pump, an increase of 25% per pump.
- **88% of participants experienced an increase in rate of expression with Nurture.** Mean rate of expression (ounces/minute) increased, on average, by 30% per pump.

Time savings while pumping based on this rate of expression are shown in Table 1.

Table 1. Estimated time savings with Nurture based on rate of expression.

Example of Time Spent Pumping over One Day (minutes)	Estimated Pumping Time with Nurture (minutes)
30	21
60	42
90	63
120	84

A woman who pumps 3 times a day, 30 minutes per pump, for 6 months will spend approximately 16,200 minutes pumping. With Nurture that same woman would save 4,860 minutes (81 hours) or more than three and a half full days of time spent pumping in a year. Among women studied who showed an improvement in their rate of expression, pumping efficiency increased 35% which would reduce pumping time over the 12-month period by 94.5 hours.

Overall, the results suggest that nurture increases the caloric content of the milk expressed and increases the total volume of milk expressed per minute.

Methods

Exclusively pumping mothers were asked to complete their normal pumping schedule for two days without wearing the Nurture device. At a minimum, women were required to complete three (3) pumping sessions per day. Women recorded the start and stop times for each pumping session, photographed the pumping bottle (for each breast) at the end of each pumping session showing the volume markings on the bottle. The women took a 10 mL sample from each bottle (both left and right breast) after each completed pump and placed milk in a designated vial to be frozen until testing. After completing two days of data collection while not wearing Nurture women then spent the next consecutive three days pumping while wearing Nurture. Day three was considered a training day allowing the women to familiarize themselves with the Nurture device. Days 4 and 5 were testing days. Women repeated the same steps of recording pumping session start and stop times, photographing both milk collection bottles for the left and right breast to show the volume of milk expressed, and took a 10 mL sample from each bottle at the end of each pumping session.

Estimation of Fat Content from Expressed Milk

Small amounts of milk (50 to 100 microliters) were removed from each provided sample and collected into microhematocrit tubes. The tubes were centrifuged using the Creamatocrit Plus™ machine developed by EKF Diagnostics. Using the Creamatocrit Plus, fat content (g/L) was estimated based on the following equation:

$$Fat\ \left(\frac{g}{L}\right) = [5.37 * Creamatocrit\ (\%)] + 5.28$$

Statistical Analysis

Each woman served as her own control for data analysis. The average fat content, volume expressed in total across both breasts, and rate of expression on Days 1 and 2 (without Nurture) was compared to the

average fat content, volume expressed across both breasts, and rate of expression of Days 4 and 5 (with Nurture). The mean difference in the outcome between days when wearing Nurture versus days not wearing Nurture was calculated by pump session (e.g. mean difference in outcome between wearing and not wearing Nurture at Pump 1, Pump 2, Pump 3, etc.), respectively. Thus, for each woman a minimum of two measurements for Pump 1, Pump 2, etc. of each outcome was taken. The absolute difference at the subject and pump number and a percentage difference (difference divided by without Nurture estimate) were calculated. While women were required to pump a minimum of 3 times per day, they were able to pump as many times per day as they felt necessary.

Results

In total, 16 women successfully completed the study activities. Participants completed an average of 9.31 pumping sessions without Nurture over the course of 2 days and an average of 9.18 pumping sessions with Nurture over the course of 2 days (excluding the 3rd day, which is designated for mothers to get comfortable with the device). 18.75% completed 3 pumping sessions with and without Nurture, 31.25% completed 4 pumping sessions with and without Nurture, and 50% completed 5 or more pumping sessions with and without Nurture.

Total Fat Expressed

Patient-level average percentage and absolute differences in fat (grams) expressed per session are shown in Table 2. Overall, 75% of women expressed more grams of fat per session when using the Nurture device. The average increase in fat expressed across all participants was 26%, or 1.78 grams. Among only those who experienced an increase (12 participants), the average increase was 37%, or 2.57 grams. A gram of fat contains 9 calories, more than carbohydrates and proteins (4 calories). The highest increase in fat expressed was seen in participant 67731, who experienced a 160% increase in fat expressed per session, or 3.54 additional grams per pump. This measurement is not standardized by time but is a reflection of the increase in nutritional value of the total volume of each pump with Nurture compared to without.

Table 2. Average percent and absolute differences in fat expressed per session.

Participant	Average Absolute Difference (g)	Average Percentage Difference
67731	3.54	160%
22027	4.70	45%
19134	-0.43	-12%
13007	-0.26	-4%
47087	0.29	3%
87173	1.89	22%
112497	0.89	8%
252954	2.65	12%
17238	1.46	10%
91267	0.04	0%
58890	1.04	11%
62625	5.73	22%
95471	4.85	22%
11230	1.33	11%
22275	-1.76	-8%

42448	2.53	122%
SUCCESSFUL	**2.57**	**37%**
ALL	**1.78**	**26%**

Volume of Expressed Milk

Patient-level average percentage and absolute differences in volume (ounces) expressed per session are shown in Table 3. Overall, 94% of women experienced an increase in the total volume (across both breasts) of expressed milk when wearing Nurture. The absolute average increase in ounces of expressed milk increase across all pumps was 1.03 ounces per pump session, an increase of 25%. Among women who experienced an increase the average increase was 1.15 ounces per pump, or 27%. The greatest increase in volume was seen in participant 42448, who increased an average of 118% per pumping session with Nurture.

Table 3. Average percent and absolute differences in volume expressed per session.

Participant	Average absolute difference (oz)	Average percentage difference
67731	2.33	82%
22027	2.08	23%
19134	0.36	13%
13007	-0.93	-14%
47087	0.56	9%
87173	0.56	15%
112497	0.32	7%
252954	3.06	42%
17238	0.81	12%
91267	0.34	6%
58890	0.94	25%
62625	2.18	19%
95471	1.25	11%
11230	1.18	18%
22275	0.54	6%
42448	1.08	118%
SUCCESSFUL	**1.15**	**27%**
ALL	**1.03**	**25%**

Rate of Expression

Patient-level average percentage and absolute differences in rate of percentage (ounces/minute) are shown in Table 3. Overall, 88% of women experienced an increase in the rate of expression of milk when wearing Nurture. The absolute average increase in ounces of expressed milk increase across all pumps was 0.07 ounces per minute, an increase of 30%. Among women who experienced an increase the average increase was 0.08 ounces per pump or 35%.

Table 3. Average percent and absolute differences in rate of expression per session, comparison without Nurture and with Nurture.

Participant	Average absolute difference (oz/min)	Average percentage difference
67731	0.06	28%
22027	0.08	23%
19134	0.02	28%
13007	-0.03	-14%
47087	0.16	118%
87173	0.03	14%
112497	0.03	13%
252954	0.45	70%
17238	0.09	27%
91267	0.01	4%
58890	0.05	19%
62625	0.09	25%
95471	0.02	5%
11230	-0.03	-5%
22275	0.03	7%
42448	0.05	113%
SUCCESSFUL	**0.08**	**30%**
ALL	**0.07**	**35%**

Discussion

Significance of 26% fat expressed increase

Across 16 exclusively pumping participants, Imalac discovered an average 26 percent increase in total fat (grams) expressed per pump. Of those 12 participants (75%) experiencing an increase, their average increase was 37%. The significance of an increase of this quality can be illustrated by what percentage of that infant's daily intake may be obtained with Nurture versus without Nurture. This is a measurement that requires assessment by individual participant, due to the varying ages and genders of infants in this study; infants have different caloric needs based on their age and gender. Caloric needs also differ by pre-term versus term infants; at this time we are only assessing infants born at term. In addition to this, the total nutritional value of the milk expressed per session is a more accurate measurement of the benefit of Nurture when compared to the measurement of fat content in grams per liter; it illustrates how much of their daily caloric need is being expressed per session, regardless of time. It is notable that even considering this measurement, there was still a slight decrease in average amount of time spent pumping by each mother: 44% of mothers experienced a decrease in time spent pumping, and of those who did experience a decrease, the average decrease was -15% (minutes).

For example, Participant 67731 experienced a mean 160% percent increase in fat expressed when comparing each pump across the 4 days of sample collection **(Table 4)**. On days one and two (no Nurture used), she expressed a total of 18.08 and 27.57 percent of her infant's estimated daily caloric

need (~522 calories – 1-3 month male), respectively. On days four and five (pumped with Nurture), she expressed 36.24 and 82.66 percent of her infant's estimated daily caloric need **(Table 4).**

Table 4. Comparison of fat calories expressed with and without device, Participant 67731

	No Device		Device	
	Day 1	Day 2	Day 4	Day 5
Volume (oz.)	16.25	17.75	27.5	34.5
Fat expressed (g)	10.49	15.99	21.02	47.94
Calories of fat expressed	94.41	143.91	189.18	431.46
% daily need	**18.08%**	**27.57%**	**36.24%**	**82.66%**

Participant 67731 pumped 6 times per day on each day of the study. On her most successful day, day 5 (with Nurture), she was expressing on average 14% of her infant's daily caloric need. On her least successful day, day 1 (without Nurture) she was expressing only 3.01% of her infant's daily caloric need per session. Without supplementation or a previously stored milk supply, it would require an unrealistic time spent pumping to express their daily need without Nurture. With Nurture, the needed number of sessions is 7, which is an obtainable number of pumping sessions per day for a mother, decreasing or even eliminating the need for formula supplementation or a built-up stored supply of milk.