

# EVALUATION OF MILK PRODUCTION WITH A MULTI-USER, ELECTRIC DOUBLE PUMP WITH A SOFT FLANGE IN MOTHERS OF VLBW NICU INFANTS: A PILOT STUDY

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## Background

Human milk is now the standard of care in the NICU.<sup>1,3</sup> The cost of not using human milk is high, both in increased healthcare costs and short-term and long-term infant morbidity and varies in a dose-response manner.<sup>4-9</sup> In addition, pumping and providing milk for her baby contributes to the physical and emotional recovery of the mother.<sup>10</sup>

Unfortunately, if a mother delivers prematurely, it is often very difficult to establish and maintain a full milk supply through discharge and beyond.<sup>5,7,8</sup> As most preterm infants are too small or too ill to nurse directly at breast, mothers in the United States often use a breast pump for weeks to months before their infants can be breastfed. Many mothers are unable to provide the early milk (colostrum) to enable early feedings for their infant, and many more suffer a decline in milk production during their infants' prolonged hospital course.<sup>9</sup>

Because of the physiology of human lactation, the first few days postpartum are crucial in establishing a full milk supply.<sup>2</sup> Even though a tiny preterm infant may only consume 10 ml per 24 hours, it is important to establish a full milk supply within the first 7 to 10 days, so adequate milk is available later when the infant is ready to nurse. Early, frequent, and effective breastfeeding or pumping appears to be the most important factor in establishing normal lactation.<sup>2,4,9,10</sup>

Healthy postpartum breastfeeding mothers usually reach a volume of 600 ml (2oz) per 24 hours by 4-7 days postpartum.<sup>11,13</sup> Research is minimal regarding the actual milk output after delivery at various gestational ages. However, milk output at one week is strongly predictive of milk output at 6 weeks post delivery.<sup>12</sup>

## Methods

> Non-blinded, prospective trial of P.J.'s *Comfort*® electric breast pump using a convenience sample compared to recent historical controls (Hill 2005) in a similar population of mothers of preterm infants (≤ 31 weeks gestation) in a Community Level III NICU during a 24 month period between Oct 2007 and Nov 2009.

> P.J.'s *Comfort*® electric breast pump is an automatic cycling, variable speed and pressure, hospital grade, WHO Code-compliant, FDA-approved multi-user pump capable of double-pumping (pumping both breasts at the same time) with a soft collapsible silicone flange and carries a 3 year-warranty. It retails for \$500-\$600, considerably less than other multi-user, hospital grade pumps (\$1,200-\$1,400).

> Eligibility Criteria: (Same as Hill, 2005)  
 > Nonsmoking, English or Spanish-speaking, ≥ 18 yrs old, who could be reached by telephone  
 > Intended to provide breastmilk and started pumping within 12 hrs post-partum  
 > Delivered a preterm infant weighing ≤ 1,500 g or ≤ 31 weeks gestation

> Exclusion Criteria: (Same as Hill, 2005)  
 > History of thyroid or other endocrine disorders, breast surgery  
 > Oral steroids or inhalers  
 > Postpartum complications such as hemorrhage or pregnancy-induced hypertension  
 > Multiple pregnancy greater than twins

> Mothers approached prenatally or immediately post-partum and informed consent obtained  
 > Study approved by Sharp HealthCare Institutional Review Board  
 > Mothers given a P.J.'s *Comfort*® breast pump, a personal double-pumping kit, tote and cooler and a log book to record pumping sessions.  
 > After instruction, all mothers demonstrated their knowledge of how to use the pump and their understanding of the study protocol.  
 > Instructed to pump 8 to 10 times per 24 hrs for minimum of 15 minutes, or for 2 minutes after last drops once milk volume increases (lactogenesis II).  
 > Demographic questionnaire and clinical data form completed

## Objectives

We hypothesized that using the P.J.'s *Comfort*® electric breast pump, mothers would be able to establish an adequate milk supply, comparable to larger, more expensive breast pumps, but with a compressible silicone flange.

We also hypothesized that mothers' milk volumes would be inversely proportional to gestational age at birth.

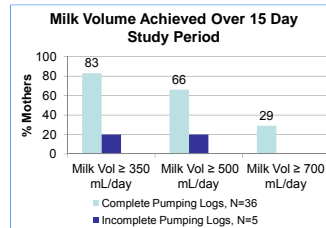
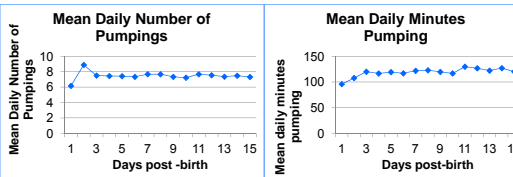
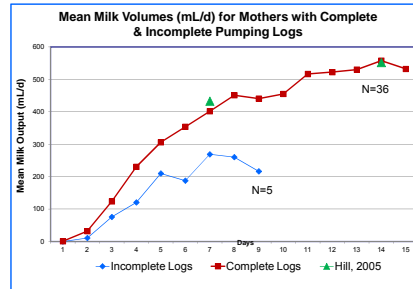


## Demographics

| Table 1: Characteristics of Study Group and Comparisons | Current Study<br>N=41 (%) | Hill et al. 2005<br>N=95 (%) |
|---|---------------------------|------------------------------|
| Decision to breastfeed made prior to pregnancy          | 71.8                      | 64.2                         |
| Income ≥ US \$50,000                                    | 52.8                      | 42.1                         |
| Prior breastfeeding experience                          | 50.0                      | 21.1                         |
| Maternal Ethnicity                                      |                           |                              |
| Black/African American                                  | 30.0                      | 31.6                         |
| White, non-Hispanic                                     | 26.6                      | 54.7                         |
| Hispanic  | 41.5                      | 8.4                          |
| Other   | 1.9                       | 5.3                          |
| Type of Delivery  |                           |                              |
| Vaginal   | 22.5                      | 42.1                         |
| Cesarean  | 77.5                      | 57.9                         |
| Multiple gestation                                      | 20.4                      | NA                           |
| Live with father of baby                                | 87.5                      | 74.7                         |
| Private insurance                                       | NA                        | 70.5                         |
| WIC Participant   | NA                        | 30.0                         |
| Prenatal breastmilk discussion in hospital              | 86.7                      | NA                           |
| Mouth care with expressed colostrum                     | 38.6                      | NA                           |
| Prenatal steroids 2-7 days prior to delivery            | 92.5                      | NA                           |
| Parity-Nuliparous                                       | 25.0                      | NA                           |
|   | <b>Mean ± SD</b>          | <b>Mean ± SD</b>             |
| Infant gestational age, wk                              | 27.8 ± 2.17               | 27.7 ± 2.0                   |
| Infant birth weight, g                                  | 1074 ± 317.3              | 1019 ± 267.3                 |
| Mother's age, y   | 30.4 ± 6.7                | 28.5 ± 6.2                   |
| Mother's education, years                               | 14.3 ± 2.4                | 14.7 ± 2.2                   |
| Father's education, years                               | 16.2 ± 13.7               | 14.6 ± 2.4                   |

**Conflict of Interest Declaration:** The study was partially funded by Limerick, Inc., manufacturers of P.J.'s *Comfort*® breast pump. In that study subjects were given a P.J.'s *Comfort*® breast pump to keep. The primary investigator (NEW) received no funding for the study.

## Results



## Results

- > Study done before NICU mothers were instructed on hand expressed and "power pumping"
- > 51 enrolled: 36 complete pumping logs; 5 incomplete logs; 10 no logs (4 infants died)
- > Mothers with a complete pumping log were older (31.2 v. 24.8 years, p=0.04)
- > Mothers with complete pumping logs:
  - ◊ Mean time to first pumping: 9.5 hrs. (range 4.1 to 12 hrs)
  - ◊ Mean number of pumpings per 24 hrs: 7.4 (range 1-9; more than previously published)
  - ◊ Mean minutes pumping per 24 hrs: 118 min/24 hrs
- > Mean number of pumpings and mean minutes pumping per 24 hrs was not correlated with milk volume
- > Milk volume was correlated with prior breastfeeding experience (p=0.037)
- > Milk volume was not correlated with infant's gestational age
- > Milk volume was not correlated with income
- > Milk volumes:
  - ◊ 83% of mothers achieved ≥ 350 mL/d
  - ◊ 66% of mothers achieved ≥ 500 mL/d
  - ◊ 29% of mothers achieved ≥ 700 mL/d
- > Of the 6 mothers who did not reach a milk volume of ≥ 350 mL/day, 5 were either obese or overweight
- > Comments regarding comfort, ease of use and pump features were all very positive – perhaps leading to more pumpings per 24 hrs than previously reported.

## Conclusions

- > Mothers of preterm infants in the US are dependent on a breast pump to establish and maintain a full milk supply.
- > Many women experience difficulties in providing enough milk for early trophic feeds and later exclusive human milk feedings for their infants.
- > Milk volumes obtained with P.J.'s *Comfort*® breast pump were equal to those reported by Hill et al. 2005, in a similar population, and equal to or better than a more recently published study (Meier et al. 2011).
- > P.J.'s *Comfort*® multi-user pump is a viable alternative to larger, more expensive pumps for establishing an adequate milk supply in mothers of VLBW infants in the NICU.
- > As techniques for milk expression are investigated and improved, it is our hope that the opportunity (and burden) of providing milk will be made easier for mothers of preterm infants.

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