UNIVERSITY OF ALBERTA

THE EFFECT OF FEEDING METHOD ON THE OXYGEN SATURATION OF THE PREMATURE INFANT

BY

© SANDRA JEAN YOUNG

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- Cell 0379
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- Ophthalmology 0381
- Pathology 0571
- Pharmacology 0419
- Pharmacy 0572
- Physical Therapy 0382
- Public Health 0573
- Radiology 0574
- Recreation 0575
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Home Economics 0386

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- Organic 0490
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- Polymer 0495
- Radiation 0754

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Physics
- General 0605
- Acoustics 0986
- Astronomy and Astrophysics 0606
- Atmospheric Science 0608
- Atomic 0748
- Electronics and Electricity 0607
- Elementary Particles and High Energy 0798
- Fluid and Plasma 0759
- Molecular 0609
- Nuclear 0610
- Optics 0752
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- Solid State 0611

Statistics 0463

Applied Sciences

Applied Mechanics 0346
Computer Science 0984
Engineering
- General 0537
- Aerospace 0538
- Agricultural 0539
- Automotive 0540
- Biomedical 0541
- Chemical 0542
- Civil 0543
- Electronics and Electrical 0544
- Heat and Thermodynamics 0348
- Hydraulic 0545
- Industrial 0546
- Marine 0547
- Materials Science 0794
- Mechanical 0548
- Metallurgy 0743
- Mining 0551
- Nuclear 0552
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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled "THE EFFECT OF FEEDING METHOD ON THE OXYGEN SATURATION OF THE PREMATURE INFANT" submitted by SANDRA YOUNG in partial fulfillment of the requirements for the degree of MASTER OF NURSING.

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DEDICATION

To Colin, who somehow always knew I could do it.

ABSTRACT

This study focussed on the problem of ventilatory stability during oral feeding of the premature infant. The problem was investigated using a quasi-experimental, interrupted time-series design. Oxygen saturation levels for premature infants during breastfeeding and bottlefeeding, were analyzed using visual analysis and repeated measures analysis of variance for two within-subjects measures.

The sample consisted of 10 premature neonates of 32-36 weeks gestation, and no greater than 37 weeks postconceptual age. Each subject served as their own control. Infants were breastfed and bottlefed during two separate, sequential feeding sessions. The order of the feeding sessions was determined via use of a random numbers table.

The findings of the visual analysis revealed that the premature infants experienced greater frequency of desaturations during bottlefeeding as compared to breastfeeding. However, repeated measures analysis of variance indicated that there was no significant difference between oxygen saturation levels during breastfeeding as compared to bottlefeeding.

Consequently, premature infants were not found to be more physiologically stressed during breastfeeding as compared to bottlefeeding, which calls into question the commonly held assumption that breastfeeding is more physiologically stressful than bottlefeeding.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Breastmilk is the optimal nutrition for infants, including neonates of 32 weeks gestational age or older (International Lactation Consultant Association, 1991). Yet, premature infants admitted to a neonatal intensive care setting, whose mothers intend to breastfeed, are usually fed formula or breastmilk by bottle prior to starting to breastfeed. Following a demonstrated tolerance of bottlefeeding, a gradual transition to breastfeeding, or a combination of breast and bottle feeding, is then made. This practice is based on a clinical assumption that breastfeeding is more physiologically stressful than bottlefeeding for premature infants. No research has been found in the literature which supports this practice. Furthermore, early bottlefeeds "...can impede later attempts to breastfeed" (Stine, 1990, p.167).

Statement of the Problem

There are only three studies in the literature that compare breastfeeding and bottlefeeding and the relationship between feeding method and oxygen saturation in the premature infant (Blaymore, Ferguson, Anderson, Solomon, Voltas, Oh, & Vohr, 1993; Meier, Engstrom, Estrada, & Mikulajcik, 1991; Snell, 1991). Each of the previously stated studies analyze oxygen saturation levels in either two minute (Blaymore et al, 1993), or five minute averaged intervals (Meier et al, 1991; Snell, 1991). Variability in oxygen saturation levels may have been missed because of these averaging techniques. Therefore, the relative physiological stability of the premature infant during breastfeeding and bottlefeeding requires further investigation using continuous oxygen saturation measurement via pulse oximetry.

Purpose

The following study was conducted in order to examine one aspect of the physiologic stability of the neonate during nutritive sucking. The study investigated oxygen saturation levels in premature infants during breastfeeding and bottlefeeding.

Research Questions

The following research questions guided the research study. 1) What is the difference in oxygen saturation levels in premature infants during breastfeeding as compared to bottlefeeding? The null hypothesis to be tested for the first research question was as follows:

there will be no difference in oxygen saturation levels in premature infants during breastfeeding as compared to bottlefeeding. 2) What are the differences in oxygen saturation between baseline and treatment, and post-treatment phases for two methods of nutritive sucking. The null hypothesis to be tested for the second research question was as follows: there will be no difference in oxygen saturation between baseline, treatment, and post-treatment phases.

Definition of Terms

For the purposes of this study, the following variables were defined: premature infant, breastfeeding, bottlefeeding, nutritive sucking, ventilation, and oxygen saturation.

Premature Infant

A premature infant was defined as any infant born prior to 36 weeks gestation, as confirmed by a Newborn Maturity Rating and Classification, which examines neuromuscular and physical maturity (Ballard, Kazmaier, & Driver, 1977). For the purpose of this research study, the terms infant and neonate are used interchangeably. It is recognized that the definition of neonate includes any live birth to 28 days of life; and the definition of infant includes the period from 29 days of life to one year of age.

Breastfeeding

Breastfeeding was defined as the method of oral feeding whereby the infant actively sucks directly from the breast of the mother and swallows breastmilk.

Bottlefeeding

Bottlefeeding was defined as the method of feeding expressed breastmilk using a Ross Gradufeed bottle and a Ross Premature, Standard, or NUK Nipple Unit.

Nutritive Sucking

Nutritive sucking, as opposed to non-nutritive sucking, was defined as when the neonate sucks at the bottle or breast and swallows breastmilk. Non-nutritive sucking was not investigated in this study. Non-nutritive sucking involves sucking on an artificial nipple, such as a soother, and is not associated with swallowing milk.

Ventilation

Ventilation was defined as the exchange "...of gas per unit time into and out of the alveoli to effect oxygen uptake and carbon dioxide elimination" (Nugent, 1991, p.106). The interaction between ventilation and perfusion bridges the gap between ventilation and oxygen saturation. The ventilation-perfusion ratio "...reflects the relationship between alveolar ventilation and capillary perfusion..." (Nugent, 1991. p.20).

Oxygen Saturation

Oxygen saturation was defined as the total oxygen content of the blood displayed as a percent by a Nelcor 200 pulse oximetry monitoring device. Oxygen saturations between 90-94% were considered normoxemic for the sample consisting of premature neonates (Henderson, 1988). Therefore oxygen saturations of <90% were interpretted as constituting a period of desaturation for analysis purposes. An oxygen saturation level of <85% was considered clinically significant and warranted intervention by the researcher.

Furthermore, hypoxemia was defined as deficient oxygenation of the blood. Hypoxemia can lead to hypoxia, or deficient oxygen delivery to the tissues. The degree of hypoxemia is measured directly from an arterial blood sample. Conversely, the pulse oximetry device allows for a noninvasive measurement of the oxygen saturation of the hemoglobin molecule.

The Physiological Model

A physiological model based on physiological and clinical knowledge was used in this study. The model served as the foundation from which the research questions were generated. A graphic representation of the physiological model appears in Figure 1.

Figure 1. Physiological model

Nutritive Sucking in Premature Infants

Coordination of the

Suck-Swallow-Breathe Reflex

Ventilation-Perfusion Ratio Match

Normoxemia

Thus a relationship between nutritive sucking, ventilation, and oxygenation served as the theoretical basis for the study. An uncoordinated suck-swallow-breathe reflex in the premature neonate may potentially lead to airway obstruction. Obstruction of the airway with milk may consequently decrease ventilation resulting in a ventilation perfusion mismatch. Therefore decreased oxygen is delivered to the blood which causes hypoxemia, leading to decreased oxygen to be delivered to the tissues which causes hypoxia. The pulse oximetry device utilizes spectrophotometric principles to analyze the transmission of light through oxygenated tissue which leads to a reading of <90% during a period of desaturation.

Significance of the Study

The research study provides information related to the stability of the premature infant during two different modes of oral feeding through an investigation of oxygen saturation levels. This information may be employed by health care professionals in the Neonatal Intensive Care Unit (NICU) in the evaluation of present nursery feeding routines.

CHAPTER 2

REVIEW OF THE LITERATURE

Literature from nursing, medicine and the biological sciences located through a computerized search of CINAHL, Medline, and PSYCHLIT data bases from 1984 through to 1994 was reviewed. Appropriate studies before 1984 were found through repeated references made in more recent publications. Although there is an increasing volume of literature relating to the dynamics of breastfeeding and bottlefeeding in both term and premature infants, there is a relative paucity of research that examines the relationship between feeding method and ventilatory stability in the premature infant.

The following literature review concentrates on the nature of feeding and ventilation in premature and term infants during the first month of life. The discussion of the literature addresses the following issues: 1) specific phases during oral feeding that are associated with a greater degree of ventilatory disruption, 2) the differences in sucking patterns during breastfeeding and bottlefeeding, 3) the relationship between sucking, swallowing and breathing during oral feeding in the neonate, and 4) the physiological stability of the premature infant during nutritive sucking.

Significant Phases in Oral Feeding

There are important differences between specific phases of an oral feeding that may potentially affect the physiological stability of the neonate. The following review identifies the significance of the first five minutes of nutritive sucking.

The First Five Minutes

Meier, Engstrom, Estrada, and Mikulajcik (1991) reported a greater mean decline in oxygen saturation levels during the first five minutes of bottlefeeding, as compared to the same time period of breastfeeding in premature infants. Similarly, Hill (1992) noted a significant inverse relationship between the volume of formula swallowed and the respiratory rate in premature infants within the first three minutes of bottlefeeding. The importance of the first five minutes of oral feeding is further highlighted by the following studies. Case-Smith, Cooper and Scala (1989) found that premature infants consume one-half of the total prescribed formula volume of 30-45 ml within the first five minutes. Medoff-Cooper, Weninger, and Zukowsky (1989) demonstrated that premature infants tend to tire after the first five minutes of oral feeding. Perhaps this tiring phenomenon could be further explained by the findings of Selley, Ellis, Flack, and Brooks (1990). They analyzed sucking, swallowing and breathing patterns in 20 term infants, and determined that for every suck the infant would extract 0.19 ± 0.11 milliliters (mls) of formula. Therefore, these researchers considered that the infant would suck approximately 300 times in a five minute period in order to consume 60 mls.

Shivpuri, Martin, Carlo, and Fanaroff (1983), recorded a feeding pattern during bottlefeeding in premature infants which consisted of an initial period of continuous sucking for approximately 30 seconds in which the infants would consume 22-32% of the total volume, followed by intermittent sucking for the remainder of the feeding. This feeding behavior has also been observed in term infants during bottlefeeding (Mathew and Bhatia, 1989; Mathew, Clarke, Pronske, Luna-Solarzano, and Peterson, 1985).

Post-Feed

Hill (1992) measured oxygen saturation (SaO2), pulse rate, and respiratory rate in 21 premature infants during bottlefeeding in an attempt to quantify a maximum duration for nipple feeding based on physiological indicators rather than clinical judgement. The results of this study are somewhat consistent with Meier (1988), in that the greatest ranges in mean SaO2 levels occurred throughout the postfeed period (98.00 $\pm$ 12.67, 98.00 $\pm$ 12.72, and 98.00 $\pm$ 8.93, at 3 minutes, 6 minutes, and 9 minutes post-feed respectively). During feeding SaO2 levels remained consistently above 90.65% and there were no significant differences in SaO2 levels before, during and after the feeding. There are two possible explanations for the lack of a significant difference ($p>.05$) between baseline, feeding and postfeed periods. First, the standard for normoxemia which was established as ranging between 80-95% is a broad range. Second, a three minute interval data collection technique was employed rather than continuous monitoring. Both of these factors may have increased the possibility that significant changes in SaO2 levels were not detected. More research is needed in which SaO2 levels are measured more frequently, and a narrower normoxemic range of 90-94% (Henderson, 1988) is used.

Bottlefeeding Versus Breastfeeding

The dynamics of sucking have been studied in relation to bottle feeding (Mathew, 1991) and breastfeeding (Righard & Alade, 1992). However in a review of the literature pertaining to nutritive sucking in the premature and term neonate, nineteen studies referred to sucking during bottlefeeding, and only two referred to sucking during breastfeeding exclusively. Five more studies compared different aspects of sucking during bottlefeeding and breastfeeding. Studies aimed at quantifying nutritive sucking patterns in premature infants have concentrated on bottlefeeding (Palmer, Crawley, & Blanco, 1993; DeMonterice, Meier, Engstrom, Crichton & Mangurten, 1992; Medoff-Cooper, 1991). Instruments devised to study the dynamics of breastfeeding are infrequent (Drewett & Woolridge, 1979), although DeMonterice and colleagues (1992) do argue that the Whitney strain gage could be utilized in the breastfeeding infant as well as the bottlefeeding infant.

Studies that examined different responses to breastfeeding and bottlefeeding in the neonate have conflicting findings. Bu'Lock, Woolridge, and Baum (1990) did not detect differences in the feeding behavior of healthy term and preterm infants fed expressed breastmilk or formula. In contrast, Mathew and Bhatia (1989) observed higher frequencies of sucking in term infants during breastfeeding as compared to bottlefeeding. A greater prolongation in expiration, and a reduction in respiratory rate was recorded during bottlefeeding with either formula or expressed breastmilk. Bradycardia occurred in two infants during bottlefeeding and none during breastfeeding; oxygen saturation levels fell below 90% in more infants during bottlefeeding than during breastfeeding. Matthew and Bhatia (1989) concluded that the differences in sucking and breathing patterns between breastfeeding and bottlefeeding are related to the method by which the nutrient is delivered rather than the nutrient itself. Mathew (1991) has also shown that milk flow generated during bottlefeeding contributes to a decrease in ventilation in premature infants.

Differences in feeding patterns have also been noted in the types of nipple units used in bottlefeeding. In an evaluation of artificial nipples conducted by Mathew (1988), the rate of milk flow varied widely between different types of nipples and within the same type of nipple. The NUK nipple type had a higher flow as compared to standard nipples. Nipples designed for premature infants required fewer sucks for a prescribed volume, as compared to the standard nipples, and more sucks than the NUK nipples. Mathew (1988) concluded that although certain nipples were designed for certain populations, the variability in flow rates makes clinical application problematic. Furthermore, Mathew (1988) questions the basis for higher flow nipples for use with premature infants, in relation to the limited respiratory control exhibited in this population (Mathew, Sosa, & Cowen, 1987). In a subsequent study by Mathew, Belan, and Thoppil (1992), sucking patterns using term, preterm, and NUK artificial nipples, were compared in term and preterm infants. No statistically significant differences were noted in sucking frequency or pressure, flow rate, or total feeding time between the preterm or term infants. Flow rates for the three nipple types in term infants ranged from 0.22 to 0.26 mls per second (Mathew et al, 1992). These rates are comparative to flow rates of approximately 0.2 mls/suck on a full breast and 0.05mls/suck on an emptied breast (Bowen-Jones, Thompson, and Drewett, 1982).

In summary, the differences between breastfeeding and bottlefeeding patterns in the premature infant, relate primarily to the greater interruption in breathing patterns that occurs during bottlefeeding. Consequently, literature on the relationship between the physiological stability of the premature infant and the mode of nutritive sucking was reviewed.

Suck-Swallow-Breathe Reflex Maturation

A fundamental developmental milestone for the premature infant is the maturation of the suck-swallow-breathe reflex, which affords the infant physiological stability during nutritive sucking. It has been established that the coordination of the suck-swallow-breathe reflex occurs at approximately 32-34 weeks gestation and matures with increasing gestational age (Gryboski, 1969). By approximately 37 weeks postconceptual age, increasing coordination in the suck-swallow-breathe reflex is established (Bu'Lock, Woolridge, & Baum, 1990). Although sucking and swallowing may occur by as early as 32 weeks, respiratory effort is generally poorly coordinated in relation to feeding (Bu'Lock, Woolridge, & Baum, 1990).

There exists some controversy over the difference between the maturation of the suck-swallow-breathe reflex in breastfed versus bottlefed infants (McCoy, Kadowaki, Wilks, Engstrom, & Meier, 1988). Although 34 weeks gestation is described as the threshold period for the maturation of the suck-swallow-breathe reflex, minimal substantiation for this claim is provided in the research studies. Furthermore some studies suggest that the maturation of the reflex may occur earlier in breastfed infants as compared to bottlefed infants because the research findings indicate less ventilatory interruption during breastfeeding in infants as young as 32 weeks gestational age (Meier, 1988; Meier & Anderson, 1987; Meier & Pugh, 1985).

In an investigation of apnea and bradycardia during feeding in ten infants, one full-term and the remainder preterm, Guilleminault and Coons (1984) found that apneic episodes were related to uncoordinated sucking and breathing. This lack of coordination in sucking, swallowing and breathing was present during breastfeeding, and bottlefeeding regardless if the fluid fed was expressed breastmilk, formula or sterile water. Apneic periods ranging from 4-45 seconds were associated with significant decreases in transcutaneous oxygen pressure values (tcPO2) and bradycardia. Shorter apneic periods were interrupted by rapid breaths which did not always improve tcPO2 values, and often resulted in a further decline in tcPO2 values.

Bu'Lock, Woolridge, and Baum (1990) found significant differences between the development of the suck-swallow-breathe reflex in 14 infants of 33-40 weeks gestation using real-time ultrasonography. The highest incidence of abnormal tongue movements during sucking was noted among infants between 33-34 weeks gestation. Whereas term infants generally showed a 1:1:1 ratio of the suck-swallow-breathe sequence, infants of 33-34 weeks gestation typically sucked up to 4 times per swallow. Also the premature infants demonstrated alternate patterns of feeding, whereby periods of apnea would occur during feeding alternated with breathing bursts when feeding was interrupted.

Building upon previous postulation and the initial work by Sumi (1963) in kittens; Wilson, Thach, Brouillette and Abu-Osba (1981) investigated the suck-swallow-breathe reflex from the premise that premature human infants may breathe and swallow simultaneously, or exhibit the swallow-breath. These researchers also found an association between apnea and swallowing in the premature infant. When swallowing interrupted inspiration, there was a brief period of 0.12 seconds, when respiratory effort continued in spite of inspiratory airflow interruption. The researchers assumed this phase was synonymous with the swallow-breath phenomenon. It should be noted however that the changes in respiratory status may have been influenced by the invasive monitoring techniques utilized in this study, such as pharyngeal catheters, and flowmeters inserted into both nostrils. Further reference is made to the swallow-breath in a visual analysis of audio tapes made of infant swallowing during feeding by Vice, Heinz, Giuriati, Hood, and Bosma (1990). Swallow breaths depicted a distinct pattern whereby swallowing changed over time from being inaudible, to becoming an expiratory grunt and inspiratory gasp (Vice et al, 1990).

Results of one study by Gryboski (1969), and another study by Koenig, Davies and Thach (1990) conflict with the findings of Vince et al (1990). Gryboski (1969) studied the sequence of sucking, swallowing and breathing during bottlefeeding and reported that inspiration and expiration were inhibited during swallowing. Similarly, Koenig et al (1990), demonstrated that sucking did not interfere with minute ventilation during non-nutritive sucking. However, an inhibition in the initiation of breathing and decreased ventilation was noted during bottlefeeding, due to airway closure associated with swallowing in term and premature infants (Koenig et al, 1990). One limitation of the study by Koenig et al, (1990) is that data were generated from eight term and five premature infants and were analyzed together. Any unique differences related to sucking and breathing that might have occurred between the two groups of term and preterm infants were not examined. A second limitation is that the insertion of catheters into the nares and pharynx of each infant may have interfered with normal suck-swallow-breathe patterns in both groups of infants.

Shivpuri, Martin, Carlo, and Fanaroff (1983) describe themselves as the first group to examine the effect of bottlefeeding on minute ventilation and tcPO2 values in premature infants. In a comparison of two groups of infants, one of 34-35.9 weeks and the other 36-38 weeks postconceptual age, a greater decrease in tcPO2 levels related to a decrease in minute ventilation, was noted in the more immature group during continuous sucking. Also, during intermittent sucking, minute ventilation and tcPO2 partially recovered in the 36-38 week group. Although recognizing the limitations of transcutaneous oxygen monitoring in relation to time delay, the researchers speculated that the decrease in tcPO2 levels and delayed recovery was due to the immmaturity of chemical respiratory control in the younger group.

During polygraphic monitoring of 150 premature infants, all of whom were greater than 36 weeks postconceptual age, Rosen, Glaze, and Frost (1984), noted 16 infants who demonstrated hypoxemia associated with nutritive sucking. However, all of the infants admitted to this study were being investigated for apnea, and those infants who exhibited hypoxemia related to bottlefeeding were shown to have either abnormal Computed Tomography scans or abnormal ultrasound examinations of the head. The generalizability of these results are limited, yet the authors caution that ventilatory disturbances associated with feeding may be undetected in the clinical setting when infants are disconnected from monitoring equipment during feeding.

The aforementioned studies have concentrated on the relationship between sucking and swallowing, sucking and ventilation, and/or swallowing and ventilation; whereas the following studies will view the problem in a more interconnected fashion. These studies will closely approximate the topic of the proposed study in an examination of the relationship between prematurity, oxygenation and oral feeding.

Oxygenation of the Premature Infant

During Nutritive Sucking

Utilizing a within-subject design, Meier (1988) compared the effects of bottlefeeding versus breastfeeding on temperature regulation and tcPO2 in five premature infants. As a general trend, tcPO2 increased following breastfeeding and decreased following bottlefeeding. Although the study findings of greater ventilatory interruption during bottlefeeding as compared to breastfeeding were consistent with previous research (Meier & Anderson, 1987); the small sample size demands that the study be replicated. Although the use of repeated measures contibutes to the power of the study, the five infants could potentially be unique to the general premature infant population, and thus the generalizability of this study is limited.

A further limitation of the study by Meier (1988), is the use of the tcPO2 monitoring device as a measurement instrument of the oxygenation status of the neonate. The readout will be delayed for approximately 20-30 seconds due to an electrochemical reaction, as compared to the instantaneous readout of pulse oximetry. Therefore, use of pulse oximetry for continuous monitoring of oxygen saturation may allow the researcher to correlate with greater accuracy changes in feeding in relation to the infant's oxygenation status. Of direct relevance to the proposed research endeavor, Hay, Brockway, and Eyzaguirre (1989) demonstrated that nipple feeding negatively skewed the transcutaneous oxygen partial pressure measurement correlations with oxygen saturation measurements; and pulse oxygen saturation measurement was not affected by gestational age.

Meier, Engstrom, Estrada, and Mikulajcik (1991) have conducted a replication of Meier's (1988) research in which ten premature infants, whose gestational or postconceptual ages are not specified, served as their own controls during breastfeeding and bottlefeeding in a longitudinal study. Temperature and oxygen saturation (SaO2) levels were measured continuously and graphed at one minute intervals. In this study the number of breastfeeding sessions (34), outweighed the number of bottlefeeding sessions (11), because the infants were unable to safely bottlefeed as early as they were able to safely breastfeed. In Meier's (1988) earlier study, no explanation is provided for the different number of measurements associated with breastfeeding (39) versus the number of measurements associated with bottlefeeding (32).

In a similar study of ten premature infants of 27-32 weeks gestation, Snell (1991) utilized an alternating treatment repeated measures design to test the hypothesis that oxygen saturation levels would not be significantly different during the early initiation of breastfeeding versus bottlefeeding. The hypothesis was supported. No statistically significant differences in oxygen saturation levels were found using repeated measures analysis of variance.

Finally, Blaymore, Ferguson, Anderson, Solomon, Voltas, Oh, and Vohr (1993) compared the physiological effects of breastfeeding and bottlefeeding in twenty very low birth weight infants of <1500 grams. Five breastfeeding sessions and five bottlefeeding sessions were assessed per infant. The researchers found no significant difference in oxygen saturation during breastfeeding versus bottlefeeding ($p = 0.056$), but did find a lower incidence of periods of oxygen desaturation during breastfeeding (21%) versus bottlefeeding (38%); ($p < 0.025$).

Summary

Three main gaps exist in the research to date regarding the relationship of oral feeding and respiratory stability in the premature infant. First, although there are a substantial number of studies which investigate the ventilatory stability of the premature infant during bottlefeeding (Hill, 1992; Vince et al, 1990; Hay et al, 1989; Rosen et al, 1984; Shivpuri et al, 1983; Wilson et al, 1981; Gryboski, 1969), there are fewer studies that examine similar dynamics in the premature infant during breastfeeding (Meier, 1988; Meier et al, 1987; Meier et al, 1985).

Second, only three studies compare breastfeeding and bottlefeeding and the relationship between feeding method and oxygen saturation in the premature infant (Blaymore et al, 1993; Meier et al, 1991; Snell, 1991). Finally, some of the studies utilized invasive monitoring techniques which may have interfered with the dependent variable itself, ventilatory stability (Koenig et al, 1990).

The commonly held assumption that bottlefeeding is less physiologically stressful for the premature infant as compared to breastfeeding is not supported in the research literature. Therefore, the relative physiological stability of the premature infant during breastfeeding requires further investigation using pulse oximetry.

CHAPTER 3

METHOD

A quasi-experimental, interrupted time-series design was utilized in the study (Cook & Campbell, 1979). Each subject served as their own control for the purpose of comparison of the treatments. One breastfeeding session and one bottlefeeding session per infant was studied sequentially on the same day. Thus an alternating treatment method, or ABA ABA design, was executed (see Table 1). The use of a quasi-experimental time series design permitted the researcher to conduct physiologically based research with premature infants within the natural setting of the NICU. In addition, the alternating treatment design allowed the researcher to rule out random fluctuations in oxygen saturation levels from changes caused by the introduction of the independent variable, with greater confidence, than a simple AB AB design would have revealed.

The independent variables, or treatment variables were breastfeeding and bottlefeeding. In both cases, a feeding session was initiated in accordance with the feeding routine specified for each infant. The dependent variable was oxygen saturation level.

Table 1

Diagram of Treatment Phases

A	B	A
Baseline	Treatment	Post-Treatment
A-N (pre)	Bottle or Breast	A-N (post)
10 minutes or discontinued if infant cried $\geq$ 2 minutes		10 minutes or discontinued if infant cried $\geq$ 2 minutes

Sample

A convenience sample of ten infants were recruited from the University of Alberta Hospitals Level III NICU, the Misericordia Hospital Level II Intermediate Care Nursery (ICN), and the Grey Nuns Hospital Level II ICN. The study was conducted over a period of four months from April 1994 - July 1994.

No formal power testing was utilized to determine sample size because a standard deviation of pulse oximetry values is specific to the sample being studied, and can only be determined using invasive means. Thus, a sample size of 10 was employed because it was a feasible number to recruit during the specified data collection period, and previous infant feeding studies using similar numbers of subjects revealed significant findings (Blaymore et al, 1993; Meier, 1991).

Selection Criteria

Initially, all infants were to be healthy infants of 34-36 weeks gestation at birth, and no greater than 37 weeks postconceptual age. Infants of less than 34 weeks were to be excluded. However, access to subjects was limited, and upon consultation with the thesis committee members, infants of 32-36 weeks gestational age and no greater than 37 weeks postconceptual age, were admitted into the study.

All subjects demonstrated a stable temperature and stable cardiorespiratory status, as determined by the primary nurse caring for the infant, and as noted in the nursing documentation. All infants were being nursed in an open cot, and on full oral feeds at the time of the study. All infants had demonstrated coordination of the suck swallow breath reflex in prior feeding sessions. All infants maintained an oxygen saturation level of greater than or equal to 90% during the baseline measurement period. Henderson (1988) recommended maintaining oxygen saturation levels between 90-94% in premature infants in order to prevent the complications associated with hypoxemia and hyperoxia.

In order to control for factors which might alter ventilatory stability and subsequently affect the oxygen saturation levels, neonates were excluded from the sample if they met any of the following criteria: presence of a congenital anomaly, dependency on supplemental oxygen via nasal cannula, oxygen hood, nasal prongs, or intubation within the last twelve hours; persistent tachypnea with a respiratory rate equal to or greater than 80 breaths per minute, or prescriptions for aminophylline or doxapram medication administration within the previous five days.

Mothers were not admitted into the study if they presented with any of the following conditions: maternal physical or mental illness, human immunodeficiency virus infection, active infection incompatible with breastfeeding or known medication/illicit drug use administration incompatible with breastfeeding as per the American Academy of Pediatrics Committee on Drugs (1989).

Recruitment

Mothers of all infants who qualified for participation in the study were initially approached by the nursing staff and given a brief outline of the study. If the mother was interested, the nurse would notify the researcher, who met with the mother to explain the study in detail.

Informed Consent

Prior to recruitment of subjects, ethical clearance was obtained from the University of Alberta and the participating hospitals. The consent form (see Appendix A), was presented to the mother and any questions the mother had were addressed by the researcher. The mother was informed of the purpose of the study, the study protocol, and the right to withdraw from the study at any time. The mother was informed that refusal to participate in the study would not affect the care provided to the infant in the NICU. Proxy consent for participation in the research study was obtained from the mother on behalf of the infant. As the mother would also act as a participant in the study through the expression of breastmilk for bottlefeeding, and actively breastfeeding the infant, consent for participation in the study was obtained from the mother as well.

Data Collection

The timing of the data collection period was negotiated between the mother and the researcher. One breastfeeding session and one bottlefeeding session were measured sequentially. The order of the feeding session was determined by a random numbers table. An odd number resulted in a bottlefeeding followed by a breastfeeding. An even number resulted in a breastfeeding followed by a bottlefeeding. Six of the babies were bottlefed first and four of the babies were breastfed first.

The initiation of a feeding session was determined by the feeding schedule ordered for the infant by the physician. During a breastfeeding session no supplemental bottlefeedings were provided. Alternatively, during a bottlefeeding session, breastfeeding was not offerred. Thus the problem of carry-over effect was minimized (Munro & Page, 1993, p.17).

Demographic information pertaining to the sample was collected from the chart (see Appendix B). The demographic information included the sex of the infant, the birthweight and current weight of the infant, as this has often been used as a criteria for the initiation of oral feeding in the NICU setting (Meier, 1988); gestational and post-conceptual age. Other information collected included the following: the type of feeding that preceded the experimental feeding, the volume of milk per bottlefeed, the type of nipple used per bottlefeed, and any environmental factors noted during the measurement period.

Breastfeeding

To ensure that mothers were comfortable with breastfeeding, each infant was breastfed on two previous occasions prior to the measurement period. One mother used a Medela Nipple Shield during the breastfeeding session. To minimize the effects of nipple confusion, all infants were well established with breastfeeding prior to the introduction of the bottle nipple (Newman, 1990).

All of the mothers were informed that assistance with positioning the infant at the breast was available to the mother by the researcher, an International Board Certified Lactation Consultant, upon request. However, none of the mothers required assistance with positioning. All of the infants were fed in cradle hold position.

The mothers were encouraged to breastfeed their infants in their usual manner. Eight of the infants remained bundled at the breast. Two of the mothers unbundled and undressed their babies during breastfeeding.

The breastfeeding session concluded upon the occurrence of one of two criteria; 1) when the infant had ceased actively sucking, and would not relatch and actively suck from the breast despite burping, unbundling of blankets, or disrobing within a five minute period, or 2) when the mother recognized and verbalized to the researcher that the feeding session was over.

Bottlefeeding

The type of nipple unit that was used was dependent upon the nipple unit used in previous bottlefeeding sessions. Mathew et al (1992) has previously demonstrated no statistically significant difference in sucking frequency, mean sucking pressures, and mean milk flow rates in premature infants using standard versus NUK nipple units. Six infants were bottlefed with a standard nipple unit, and four infants were bottlefed with a NUK nipple unit, as manufactured by Ross Laboratories. A NUK nipple was used during the bottlefeeding sessions for the two infants who had not been bottlefed prior to enrollment in the study. The rationale being that the NUK nipple supposedly mimics the shape of the teat created in the mouth of a breastfeeding infant (Mathew et al, 1992).

The infant was bottlefed by the researcher, a neonatal intensive care nurse with five years of experience. The infant was held by the researcher, cradled in the researcher's arm at approximately a 45 degree angle. A bottlefeeding session concluded when the prescribed volume had been ingested and the infant had been burped as required.

Infants were bottlefed within the same area of the NICU as they were breastfed. All babies admitted to the study were breastfed and bottlefed within rooming-in rooms. The lighting was half dimmed in all cases to minimize the loss of data related to light interference. Maintaining a consistent setting for feeding helped to minimize environmental differences such as air temperature, lighting, noise level, and involvement with other health care personnel.

Monitoring Procedure

The infant's oxygen saturation and heart rate were continuously monitored throughout the data collection period. The procedure consisted of attaching the pulse oximetry monitoring device to the infant's foot, with the adhesive tape of the probe itself. The probe was then protected from light with the use of an acrylic yarn sock. Cardiac leads were attached to the infant's chest and abdomen. The infant was then bundled in a single blanket and held by the researcher for the baseline period, cradled in the researcher's arm at approximately a 45 degree angle.

A Nellcor 200 pulse oximetry device set in mode II was used to measure oxygen saturation continuously. Alarm limits were set at 90-100%. Heart rate was measured continuously via a Hewlett Packard cardiac monitor (model 78342A, Hewlett-Packard, Waltham, MA). Alarm limits were set at 100-200 beats/minute. The raw data from both of these sources were stored directly at a rate of 10mm/minute via computer recording. The analogue outputs were then digitized by a DT2801-A Data Translation board. Software control of this process was through programs written in ASYST (Asyst Software Technologies Inc., Rochester, NY). A Zenith 386/33MHZ IBM compatible computer was used.

The data collection had four phases for each feeding (see Table 2). Pulse oximetry was measured for ten minutes prior to the initiation of oral feeding, in order to record a baseline of oxygen saturation levels. It has been established that a ten minute period is an appropriate allotment of time to detect changes in oxygen saturation that are attributable to the treatment (Danford, Miske, Headly, & Nelson, 1983). The research assistant entered the code (A) to open the baseline phase and entered the code (N) to close the baseline phase.

Pulse oximetry was then measured continuously throughout the feeding session. The research assistant entered the code (o) to signal when bottlefeeding started, and entered the code (r) to signal when breastfeeding started.

Upon the completion of a feeding session the infant was again bundled in a single blanket, and cradled in an upright position in the arm of the researcher at approximately a 45 degree angle. Pulse oximetry measurement continued for a ten minute post-treatment phase. The research assistant entered the code (A) to open the post-treatment phase, and enter the code (N) to close the post-treatment phase.

Throughout the monitoring period, the research assistant entered codes related to environmental stimuli (see Table 3). One of these codes was (h), used to identify a time period when handling was occuring. The final (h) entered during a feeding session, which usually corresponded to burping, was used to signify the close of a feeding session.

Table 2

Diagram of Analysis Phases

Phase I	Phase II	Phase III	Phase IV
Baseline	Bottle or Breast	Bottle or Breast	Post-Treatment
A-N (pre)	0-30 seconds	30 seconds-5 minutes	A-N (post)
10 minutes, or time span between code A and code N	start of active feeding to 30 second point	30 second point to 5 minute point	10 minutes, or time span between code A and code N

Table 3

Computer Coding

Code	Definition
A	Open a baseline or post-treatment phase
N	Close a baseline or post-treatment phase
o	Open a bottlefeeding session or to signify the continuation of bottlefeeding following removal of nipple from infant's mouth
r	Open breastfeeding or to signify the continuation of breastfeeding following relatch
i	Infant crying
m	Movement initiated by infant
h	Movement initiated by researcher or mother for repositioning or burping
p	Hicupping
v	Regurgitation
c	Signifies potential for measurement error with the pulse oximetry probe, cable, or monitor as the source

<u>Instrument: The Pulse Oximeter</u>

The Nelcor 200 pulse oximetry monitoring instrument provides a continuous and instantaneous visual readout of the percent of total oxygen saturation of the hemoglobin in the blood of the infant. The Nelcor 200 pulse oximetry monitor was the monitor available to the researcher within study sites.

<u>Reliability and validity of pulse oximetry</u>. The reliability and validity of pulse oximetry in the neonatal and pediatric population has been established (Barrington, Finer, and Ryan, 1988; Fanconi, Doherty, Edmonds, Barker and Bohn, 1985; Hay, Brockway, and Eyzaguirre, 1989; Henderson, 1988; Jennis and Peabody, 1987; and Ramanathan, Durand, and Larrazabel, 1987). In a study by Hay et al (1989), tcPO2 levels were highly correlated with arterial blood oxygen saturation levels (r=0.99). In addition, the pulse oxygen saturation values of 92 ± 3% indicated arterial oxygen partial pressure within a range of 45-100 mm Hg with 100% sensitivity and 100% specitivity (Hays et al, 1989). Barrington et al, (1988) determined that pulse oximeters are a useful adjunct to oxygen monitoring in the NICU when applied properly and when displaying an accurate indicator of the

patient's heart rate ($r=0.8$, $p<0.0001$). Henderson (1988) reported the accuracy and reliability of pulse oximetry in premature infants with respiratory distress syndome within a oxygen saturation range of 85-95%.

Limitations of pulse oximetry. At arterial partial pressure levels lower than approximately 45 mm Hg there is a significant increase in the variability of the pulse oxygen saturation and the arterial partial pressure relationship (Hay et al, 1989). Additional problems associated with the use of pulse oximetry relate predominantly with the monitor itself. Motion can cause artifact and interfere with the formation of the pulsatile wave (Mok, McLaughlin, & Pintar, 1986) and external noise can be misinterpretted, and displayed as a saturation value (Pologue, 1987). Heat lamps and radiant warmers may have the potential to effect oxygen saturation readout (Jennis and Peabody, 1987), however Zubrow, Henderson, Imaizumi, and Pleasure (1990), demonstrated that the pulse oximetry readout was not affected by phototherapy lights and radiant warmers.

The concentration of fetal hemoglobin (Hbf) has also been postulated as influencing the accuracy of pulse oximetry. Jennis and Peabody (1987) reported a 2.8-3.6%

error in pulse oximetry measurement ($p<0.001$) when fetal hemoglobin content was >50%. Conversely, Anderson (1987) concluded that the pulse oximeter accurately measured oxygen saturation independent of fetal hemoglobin and bilirubin levels. Pologue and Raley (1987) also found that any error related to fetal hemoglobin in relation to pulse oximetry accuracy was clinically insignificant.

Finally, the difficulties in establishing a reliable standard for a physiological monitoring technique such as pulse oximetry are addressed by Hodgson (1987). "Finding a standard in the study of pulse oximetry in neonates is complex. Two major factors influence measured arterial oxygen saturation in these patients: the distinction between functional and fractional saturation, and ... Hbf" (Hodgson, 1987). Moreover, Hay (1987) outlines the following factors as problematic to the accurate measurement of oxygen saturation via pulse oximetry: normal sea-level conditions, hemoglobin content, and oxygen-hemoglobin affinity.

Advantages of pulse oximetry. Barrington and colleagues (1988) refer to the safety of the pulse oximetry probe as having no potential to burn the skin, and recommend that the probe need not be repositioned following appropriate application. Additional benefits of the system are that there is an immediate readout (Barrington et al, 1988), and the method is noninvasive, easily applied and internally calibrated (Jennis and Peabody, 1987).

Therefore pulse oximetry was chosen as a means to measure the oxygenation of the infant during feeding because of the following factors: 1) the instantaneous read-out, 2) the lack of potential harm to the infant, and 3) the simultaneous read-out of heart rate with oxygen saturation.

<u>Ethical Considerations</u>

Three factors which may have presented potential harm for the neonate related to participation in the study were: prolonged crying, skin breakdown related to Nellcor probe tape, and respiratory distress related to oral feeding. These factors were contolled by utilizing the following techniques. If an infant cried for greater than two minutes despite initiating soothing techniques such as holding, rocking, and bundling, the baseline period was discontinued and the treatment phase started.

The only potential complication associated with the use of the pulse oximetry probe was the remote potential for skin breakdown related to the adhesive tape covering the sensor (Riedel, 1987). However, the short term use of the probe minimized the risk of this complication.

Upon observing any physical signs of respiratory distress or bradycardia, the feeding session was immediately interrupted, and the appropriate interventions were initiated. Upon recovery of the oxygen saturation level to 90% or greater, and the heart rate to greater than 100 beats/minute, as noted on the pulse oximetry read-out; the feeding was restarted.

Pilot Testing

Pilot testing was conducted on two infants fitting the inclusion criteria (Br1-Br2), to determine the feasibility of the proposed study, and to give the researcher some experience with the data collection instruments (Ort, 1981, p.49). Loss of calibration, and a faulty cardiac monitor cable were two sources of measurement error detected during pilot testing which resulted in abnormal values for heart rate and oxygen saturation for subjects Br1 - Br2. Therefore the data collected for subjects Br1-Br2 was excluded from the analysis. The problems discovered during pilot testing were rectified through recalibration of the instruments and the computer-instrument interface, and replacement of the cardiac monitor transducer cable.

Data Analysis

The following techniques of data analysis were employed to analyze the data: 1) descriptive statistics, 2) visual analysis, and 3) repeated measures analysis of variance. Initially, descriptive statistics were utilized to summarize and organize the data. The range and mean SaO2 levels were calculated at the end of the baseline, treatment, and post-treatment phases.

Visual analysis of the data (Tawney & Gast, 1984; Parsonson & Baer, 1978) was also undertaken. When using graphic analysis of the data, in small sample research, "...judgements, decisions, and changes can be made as the program proceeds, providing a degree of adaptability essential in applied research" (Parsonson & Baer, 1978). Continuous measurement of oxygen saturation remained unaltered as raw data and thus, there was no loss of significant information because the data were not summarized. This method provides a detailed description of the dependent variable, oxygen saturation, and allows for point by point analysis of the effect of feeding method on oxygen saturation within each subject. Within the graphic representation the following factors have been denoted: baseline, treatment, and post-treatment phases, the duration of each phase, data points for each phase, as well as the data path comprised of a solid line connecting the data points. The entire scale from 0-100%, in relation to percent of oxygen saturation, is presented along the Y-axis, and time will be presented along the X-axis.

Stability of the data was interpreted as the maintainence of oxygen saturation levels at a level of normoxemia, or >90% (Henderson, 1988), throughout the baseline and post-treatment phases. A powerful intervention was defined as when the introduction of oral feeding resulted in an abrupt change in oxygen saturation levels. Screen by screen analysis was conducted in order to determine the degree of stability of SaO2 levels during baseline and post-treatment phases, the amount of variability of SaO2 levels during treatment phases within subjects and between subjects, the trends in SaO2 during each phase, and changes in level of SaO2 between pretreatment, treatment, and post-treatment phases.

The outcome variable, oxygen saturation, was measured at the ratio level, thus inferential statistics were employed. Averages of oxygen saturation levels were taken from 0 to 10 minutes, during the baseline and post-treatment phases. Averages of oxygen saturation levels were also calculated from 0 to 30 seconds, and from 30 seconds to 5 minutes, during the feeding phase. Repeated Measures Analysis of Variance (ANOVA) was used to test the equality of mean saturation levels. There are two within subject measures: 1) time (Phase I, II, III, and IV), and 2) feeding method (breast and bottle).

CHAPTER 4

FINDINGS

Study Subjects

The study sample consisted of 6 female and 4 male infants, with an average gestational age at birth of 33.3 weeks (SD = 1.34), ranging from 32 - 35 weeks gestational age. The average postconceptual age of the infants at the time of data collection was 35.54 weeks (SD = 0.781), ranging from 34.43 - 36.7 weeks postconceptual age. The average birthweight was 2101 grams (SD = 305.5), with a range of 1785-2505 grams. On the day of data acquisition, the average weight of the infants was 2155.5 grams (SD = 220.7), with a range of 1910-2450 grams.

Four of the fifty-four infants (7.4%) of 32-36 weeks gestational age, admitted to the University of Alberta Hospitals Level III NICU, were admitted to the study. Six of ten infants (60%) born at 32-36 weeks gestational age admitted to the Misericordia Hospital Level II Intermediate Care Nursery were admitted to the study. Two of two infants (100%) born between 32-36 weeks gestational age, who were admitted to the Grey Nuns Hospital Level II NICU, were admitted to the study.

The remainder of the infants, who were born at 32-36 weeks gestational age, were excluded from the study because of the following reasons: congenital anomolies (3), congenital heart disease (4), oxygen administration (2) or aminophylline administration (4), discharge from the NICU at less than twenty-four hours (11), mother's refusal to have her infant fed from an artificial nipple related to the potential for nipple confusion (4), cerebral infarct (1), grade III intraventricular hemmorhage (1), meningomyelocele (1), asphyxia (3), narcotic dependency (1), combined care (7), parental choice to bottlefed (8), maternal breast cancer (1), Respiratory Syncytial Virus (1), >37 weeks postconceptual age upon admission (3).

The Feeding Session

The average volume of milk ingested during bottlefeeding was 48.5 mls, with a range of 15 -70 mls, although the average prescribed volume of milk per feed was 52 mls, with a range of 35-70 mls/feed.

The duration of a feeding session varied within subjects and between subjects dependent upon feeding method (see Table 4). The average duration of a bottlefeeding session was 11.534 minutes (SD = $\pm$ 3.49), with a range of 3.83-16.27 minutes. The average duration of a breastfeeding session was 20.925 minutes (SD = $\pm$ 12.806) with a range of 7.63-44.43 minutes.

A paired t-test was performed to test the differences between the mean duration of breastfeeding and the mean duration of bottlefeeding. There was a significant difference between the duration of the two types of feeding [$t(18) = -2.24$, $p<0.05$].

Table 4
Duration of Feeding Sessions

Infant	Duration of Bottlefeeding Session in minutes	Duration of Breastfeeding Session in Minutes
Br3	13.11	14.35
Br4	9.7	17.66
Br5	10.36	44.43
Br6	10.39	26.90
Br7	13.61	11.63
Br8	14.83	7.63
Br9	13.06	41.87
Br10	16.27	13.68
Br11	3.83	18.85
Br12	10.18	12.25
Mean	11.534	20.925
Standard Deviation	± 3.49	± 12.806
Range	(3.83 - 16.27)	(7.83 - 44.43)

Data Loss

During screen by screen analysis of the data for infants Br3-Br12, the offset times of all intervention codes were calculated. The offset times were then used to delineate the opening and closing of a phase. The percentage of data loss per phase was also calculated. Data loss was defined as that period of time when no oxygen saturation tracing was recorded. Table 5 lists those infants for whom data was missing. An example of the graphic display of data loss is presented in Figure 2. Excluding the data loss accumulated for subject Br8, the percentage of data loss in this study is very low, <1% per phase in six of the infants.

Through a comparison of the contents of the field notes and the offset times of the intervention codes entered by the research assistants, it was determined that all of the loss of oxygen saturation tracing was related to temporary nonfunctioning of the pulse oximeter monitor due to movement artifact. This finding is consistent with Barrington et al (1988). When the oxygen saturation levels were lost due to motion artifact these readings were excluded from the data analysis (Harrison, Leeper, & Yoon, 1990). Tabachnick and Fidell (1989) explain that " ... if only a few data points are missing in a random pattern from a large data set, the problems are usually not serious and almost any procedure for handling them yields similar results" (p.60-61).

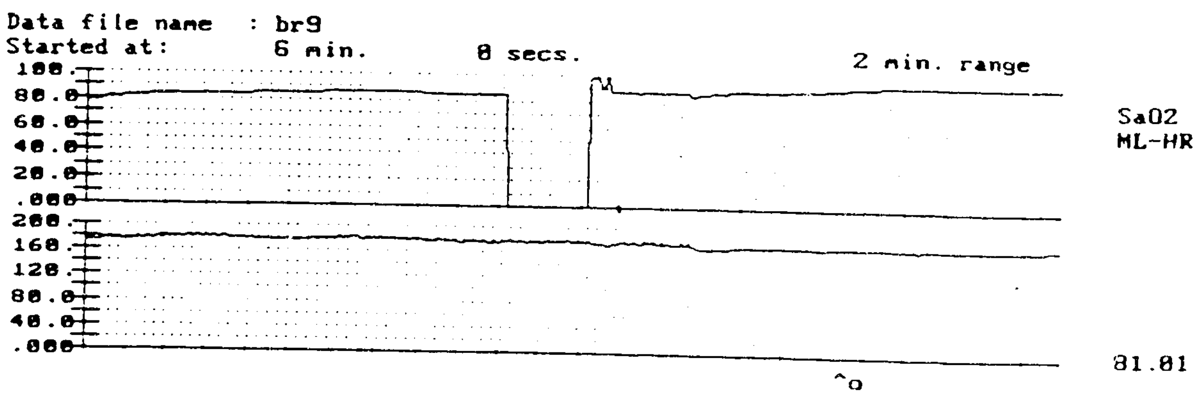
Table 5

Loss of Data in Percent During Baseline, Treatment, and Post-Treatment Phases

Infant	Feeding Method	Phase	Time in minutes	Loss of data
Br6	breast	IV	34.39 - 35.36	0.007%
Br6	bottle	I	43.32 - 44.28 49.04 - 49.61	0.095% 0.057%
Br7	bottle	I II	4.08 - 5.03 10.90 - 10.97	0.094% 0.14%
Br8	breast	I II	6.29 - 6.79 6.79 - 7.22	*100% 0.086%
Br9	bottle	III	6.85 - 7.01	0.032%
Br10	breast	I	35.25 - 35.33	0.039%
Br10	bottle	I	0.81 - 1.08	0.121%

Note. Subject Br8 was excluded from repeated measures ANOVA computations.

Figure 2. Example of graphic display of data loss



Clinical Response of the Premature Infant to Feeding Method: Results of Visual Analysis

Microanalysis of the data was performed to determine changes in the level, variablility and trend of oxygen saturation during the baseline, treatment, and post-treatment phases. A fall in the level of oxygen saturation, or desaturation, below 90% for a period of ≥20 seconds was considered significant. Table 6 displays the periods of desaturation per subject. Figures 3-18 provide a graphic representation of the periods of desaturation.

The research assistants entered a (c) to indicate one of the following occurences: loss of heart rate tracing from the cardiac monitor or ECG LOST alarm per pulse oximeter, PULSE SEARCH alarm from the pulse oximeter, loss of pulse amplitude indicator per pulse oximeter. Periods of desaturation that corresponded with an intervention code of (c) were not included in the visual analysis because the reliability of the SaO2 tracing during an alarm signal is questionable according to the manufacturer (Nellcor Incorporated, 1987). The periods of desaturation that corresponded with a (c) intervention code were not calculated as data loss. Data loss was strictly defined as that period of time when no oxygen saturation tracing was recorded.

During the first 30 seconds of feeding, or Phase II, three episodes of desaturation were recorded during bottlefeeding, as compared to two episodes of desaturation during breastfeeding. During Phase III, three episodes of desaturation were recorded during bottlefeeding as compared to zero episodes during breastfeeding. Table 8 presents the cummulative periods of desaturation per feeding. As described previously, periods of desaturation (SaO_2 less than 90%, for greater than 20 seconds) which corresponded with an intervention code such as handling, movement, or crying, were excluded from the calculation of incidences of desaturation (see Table 7). Therefore the remaining periods of desaturation included in Table 6, are more likely due to the method of feeding than any other intervening factors.

Table 6

Desaturation Periods per Subject

With No Intervention Codes

Subject	Time	Phase
Br3	5.67-6.00 6.08-7.21 11.25-12.42 15.71-16.00 44.50-44.92 46.42-46.67 68.33-68.67 74.67-76.67	I (bottle) I (bottle) II (bottle) III(bottle) I (breast) I (breast) IV (breast) IV (breast)
Br4	11.04-11.67 43.29-43.35	II (bottle) II (breast)
Br5	1.58-2.00 3.67-4.33	I (bottle) I (bottle)
Br6	3.21-3.79	II (breast)
Br11	39.0-39.79 41.04-41.33	II (bottle) III(bottle)
Br12	1.67-2.04 2.42-5.79 6.00-7.00 7.54-8.00 43.63-44.75	I (breast) I (breast) I (breast) I (breast) III(bottle)

Table 7

Desaturation Per Subject With Coding

Subject	Time	Phase	Code
Br3	37.00-37.67 42.00-42.33 50.33-50.67 66.58-67.08	I (breast) I (breast) III(breast) IV (breast)	m m,h h m
Br4	36.33-37.00 38.33-38.75 39.25-39.67 41.42-41.92	I (breast) I (breast) I (breast) I (breast)	m m h m
Br5	7.33-8.67 17.08-17.5	I (bottle) III(bottle)	h h
Br6	48.50-49.08	I (bottle)	i
Br7	9.67-10.33 60.29-60.75	I (breast) IV (bottle)	m m
Br8	16.83-17.42	IV (breast)	i
Br9	40.00-42.08 43.25-45.29	II (breast) III(breast)	h h
Br12	39.25-40.54	I (bottle)	i

Table 8

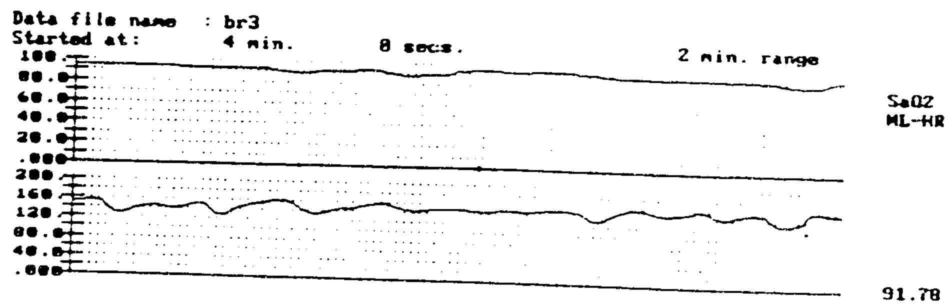
Cummulative Incidences of Desaturation per Phase

PHASE	BREASTFEEDING	BOTTLEFEEDING
I	0	0
II	2	3
III	0	3
IV	*2	0

Note. (*) denotes periods of desaturation occurring in the same infant.

Figure 3. Desaturation periods A, B and C for Br3

A



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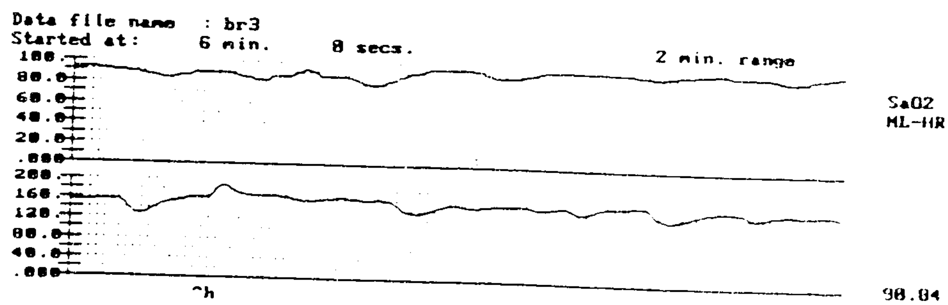


C

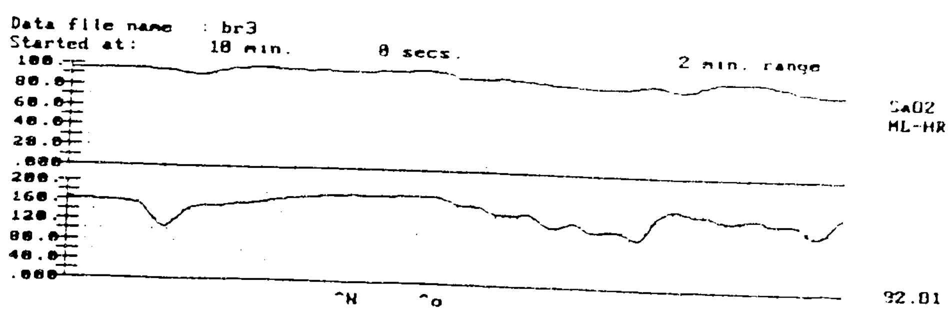
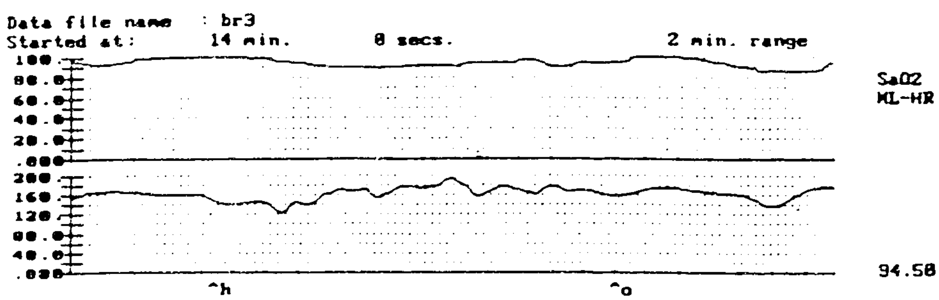
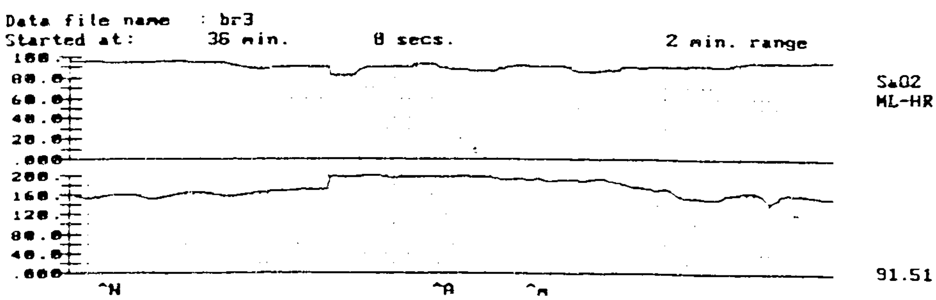


Figure 4. Desaturation periods D, E and F for Br3

D



E



F

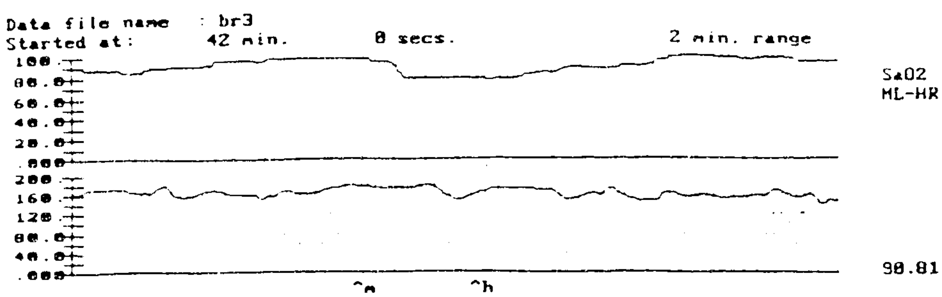
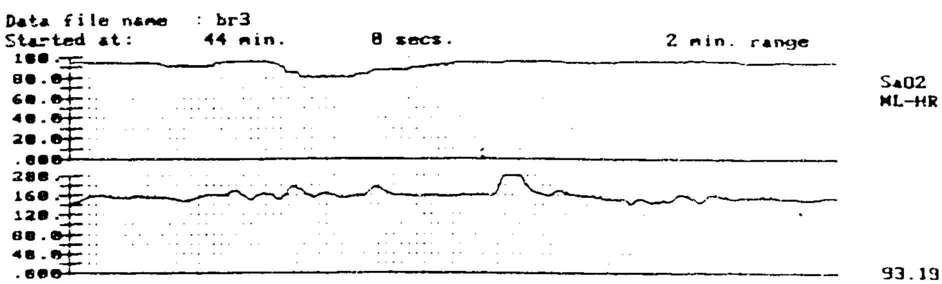
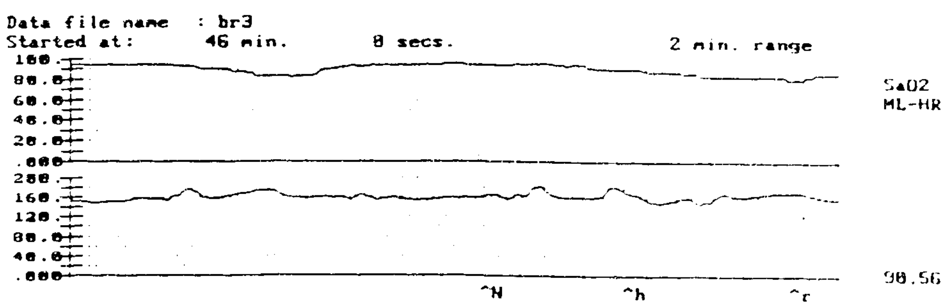


Figure 5. Desaturation periods G, H and I for Br3

G



H



I

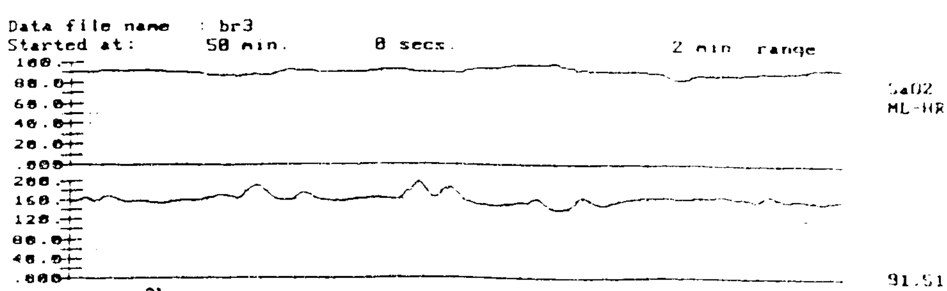
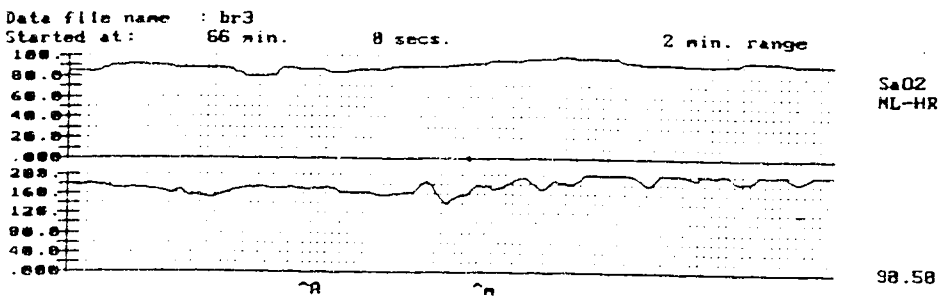
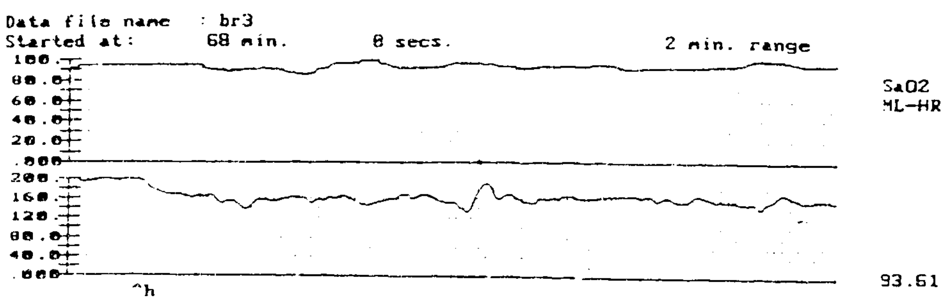


Figure 6. Desaturation periods J, K and L for Br3

J



K



L

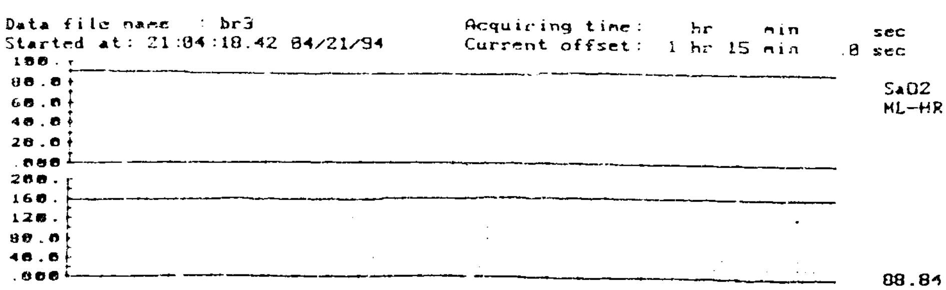
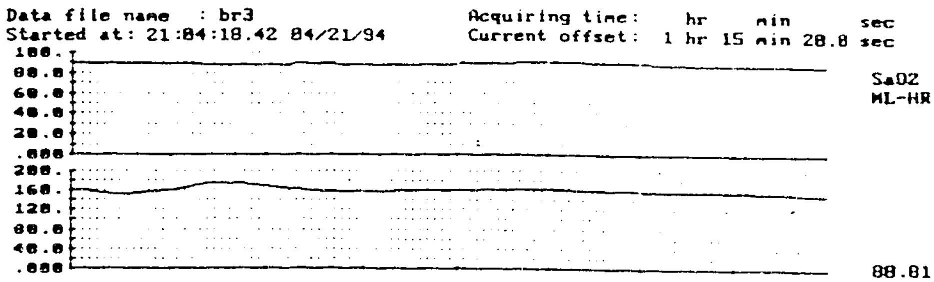
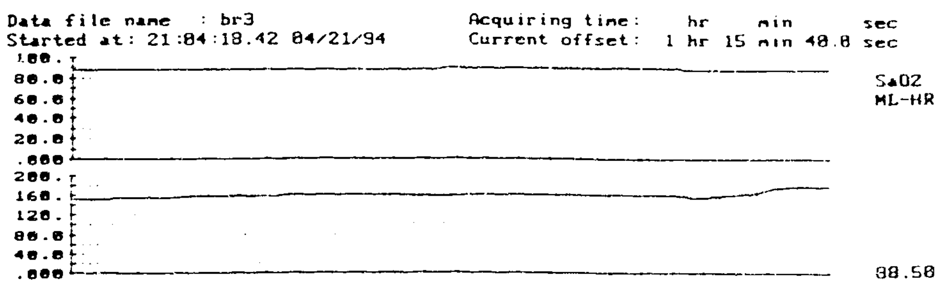


Figure 7. Desaturation periods M,N and O for Br3

M



N



O

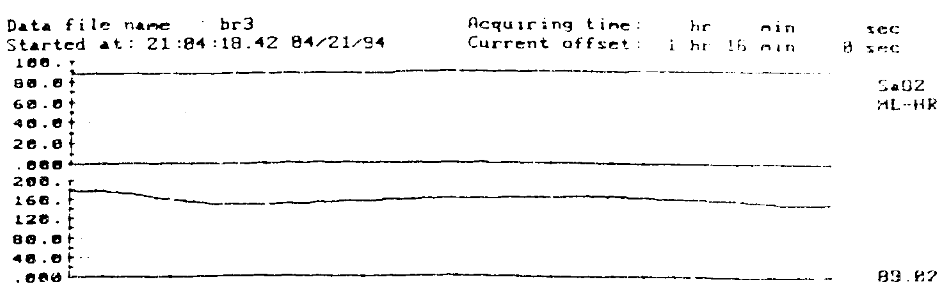
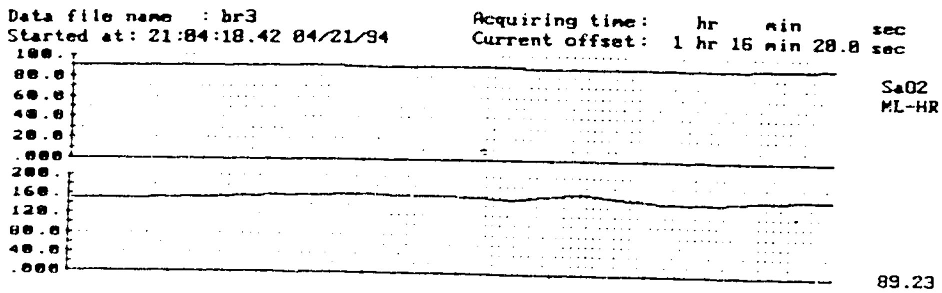
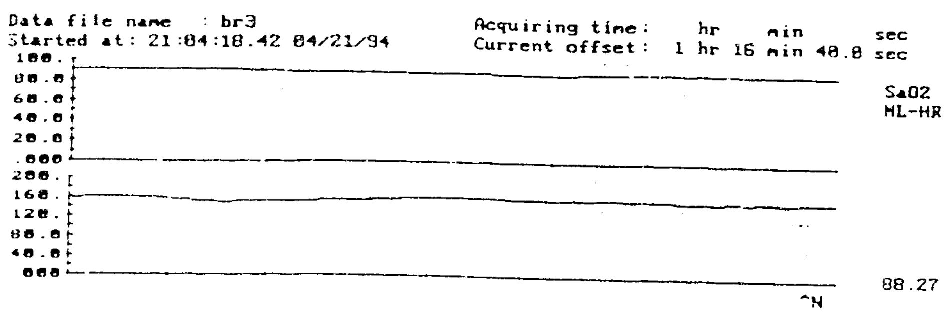


Figure 8. Desaturation periods P and Q for Br3

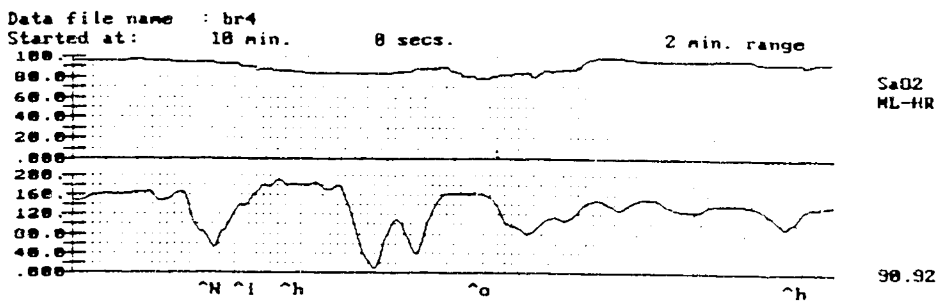
P

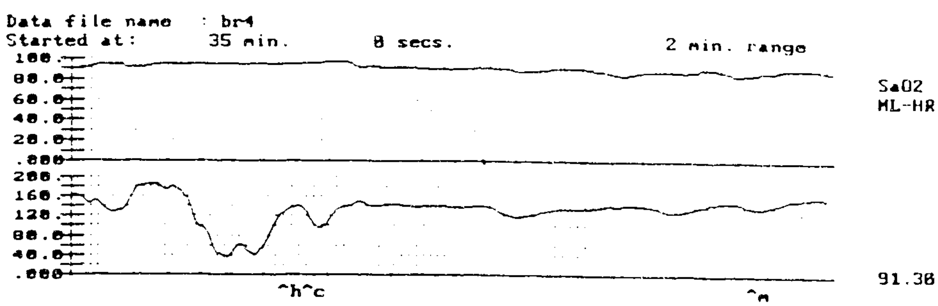


Q



<u>Figure 9.</u> Desaturation periods for Br4





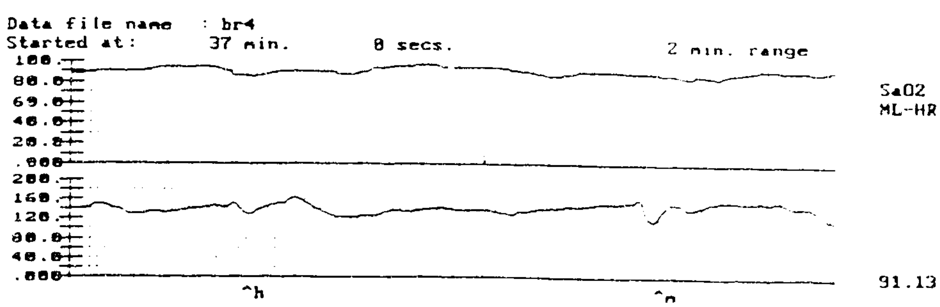
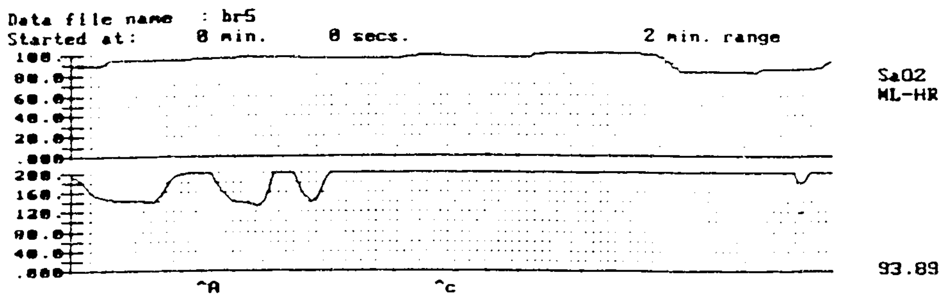
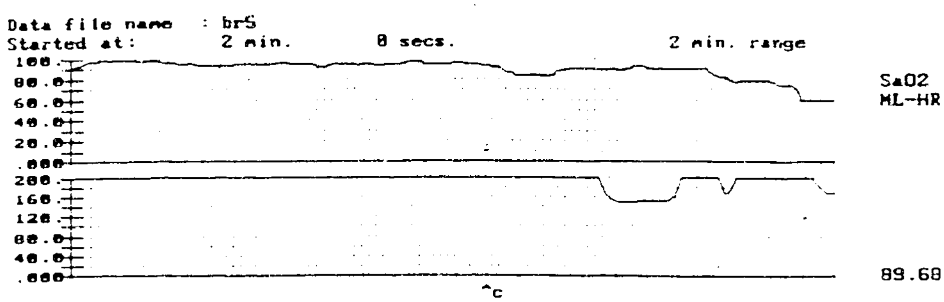


Figure 10. Desaturation periods A, B and C for Br5

A



B



C

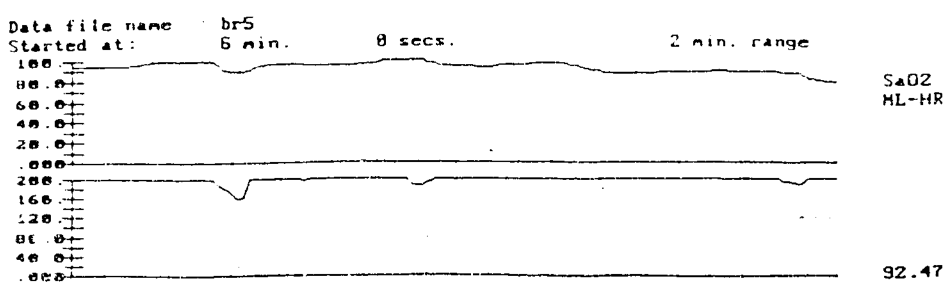
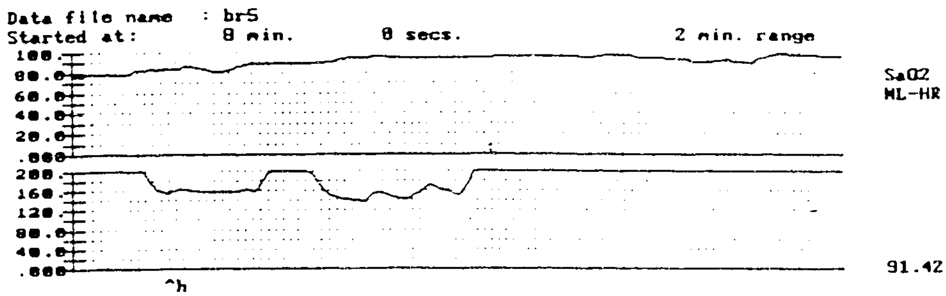


Figure 11. Desaturation periods D and E for Br5

D



E

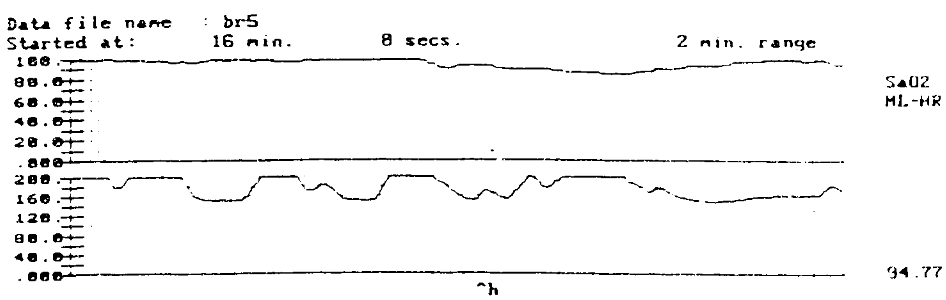
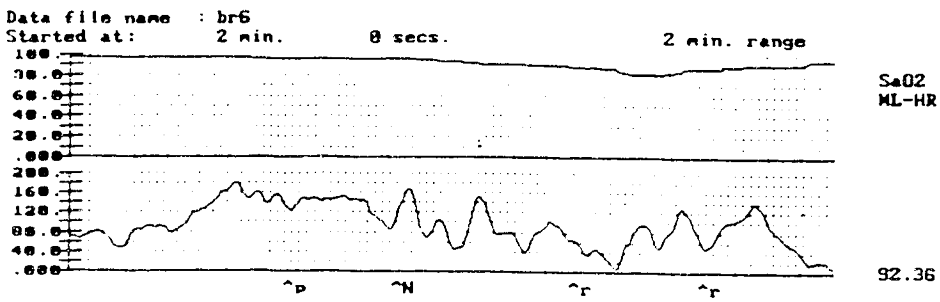


Figure 12. Desaturation periods for Br6



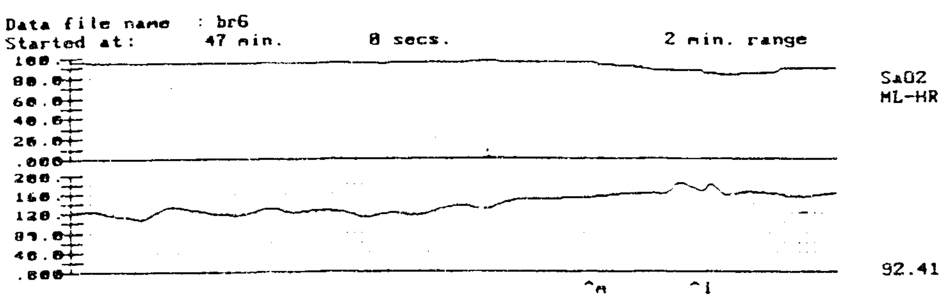


Figure 13. Desaturation periods for Br7

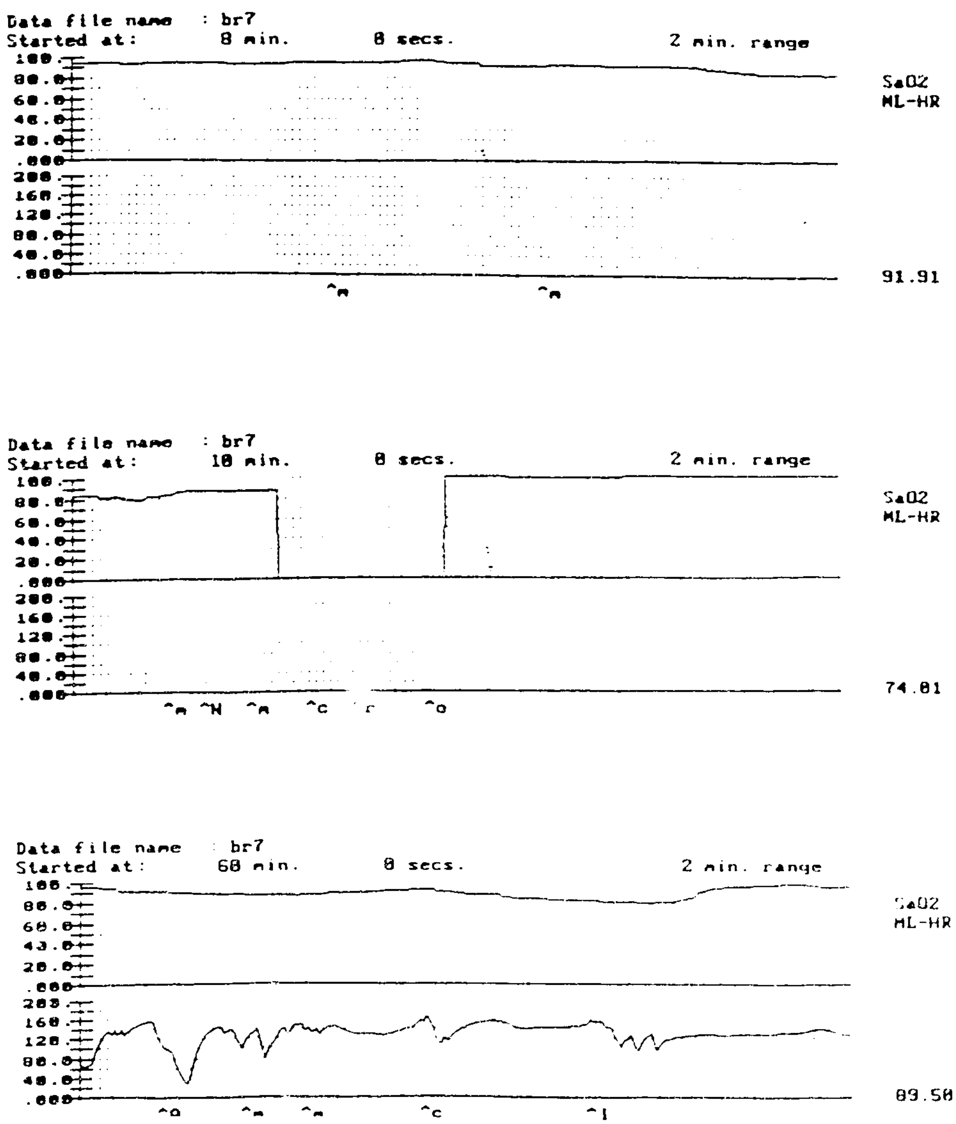


Figure 14. Desaturation periods for Br8

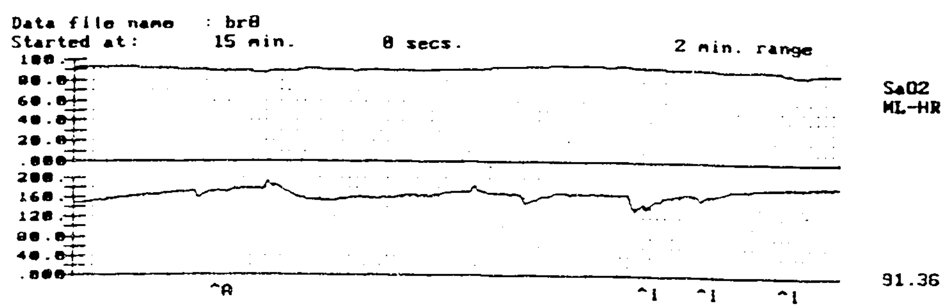
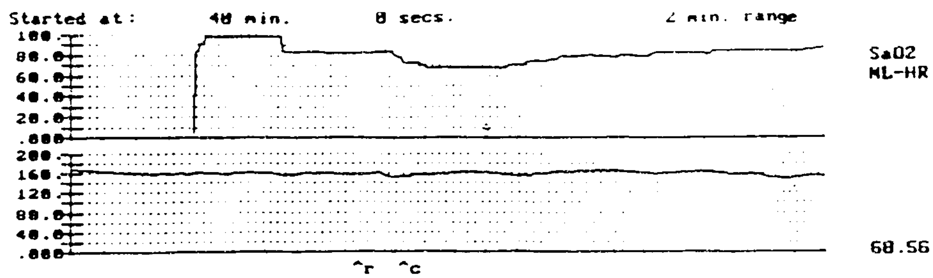
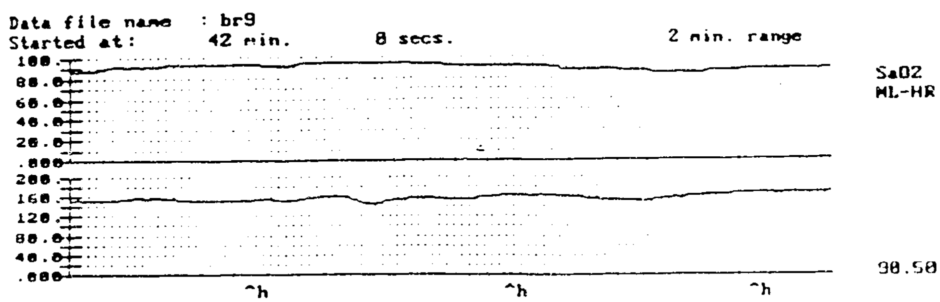


Figure 15. Desaturation periods for Br9





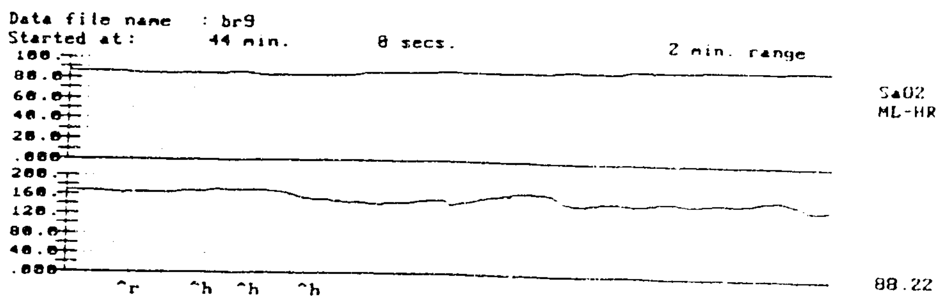
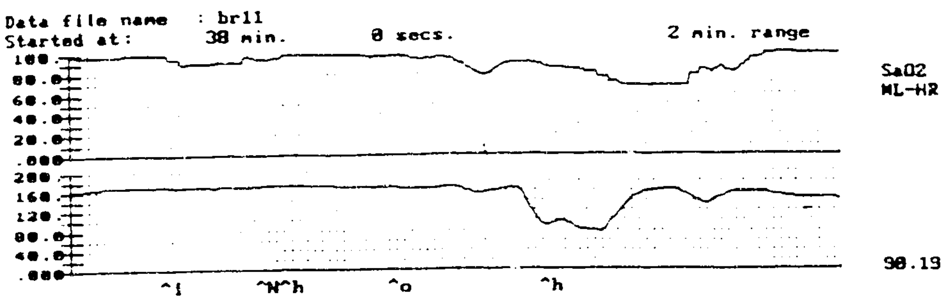


Figure 16. Desaturation periods for Br11



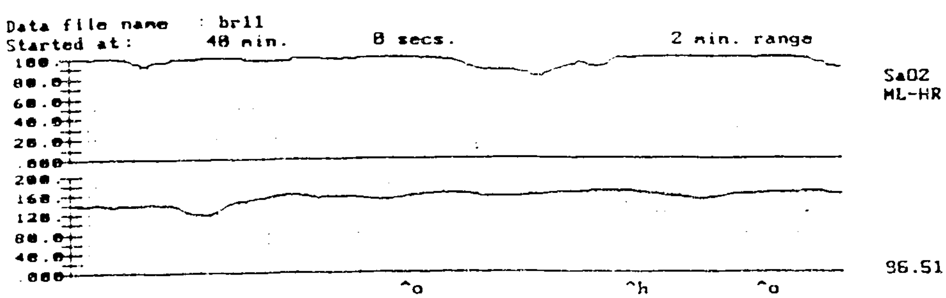
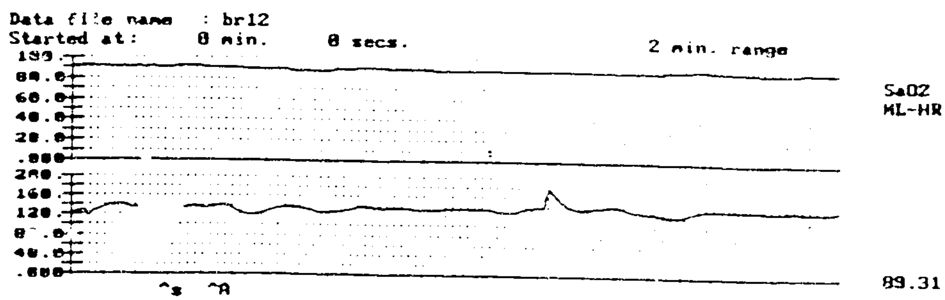
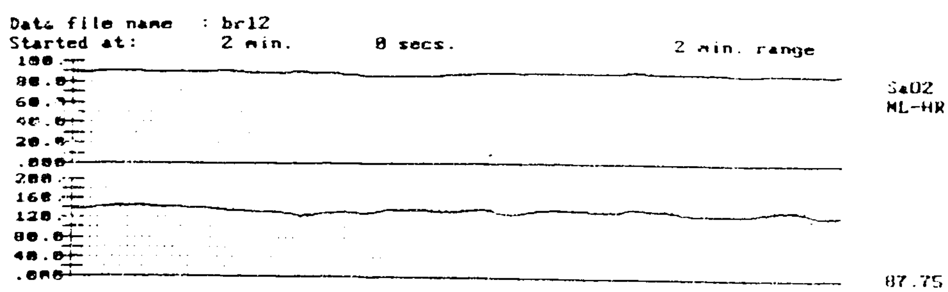


Figure 17. Desaturation periods A, B and C for Br12

A



B



C

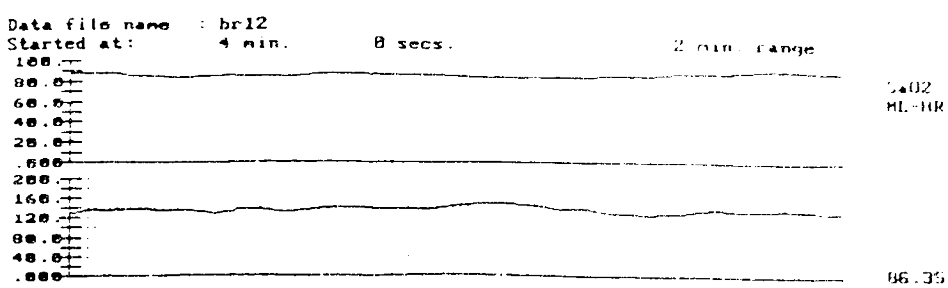
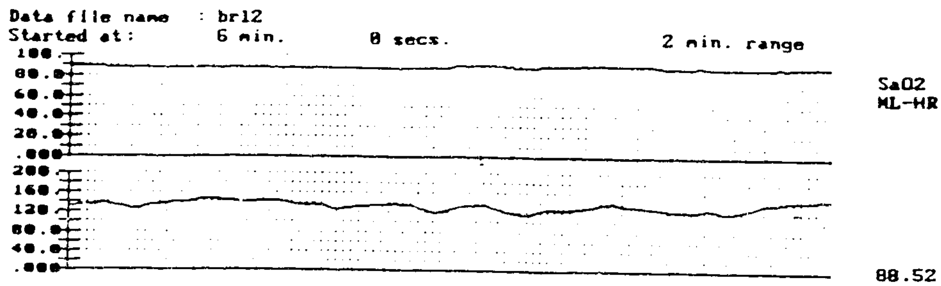
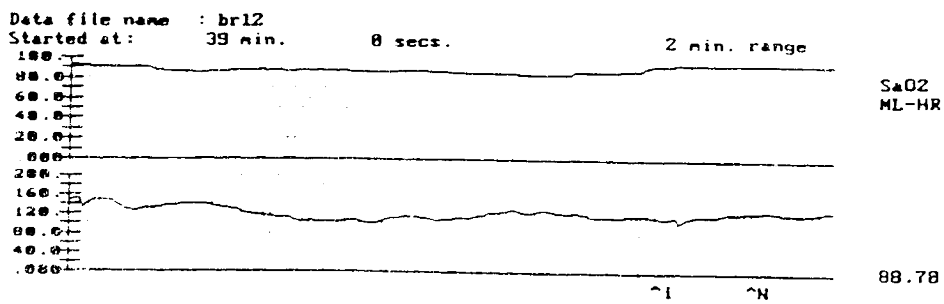


Figure 18. Desaturation periods D, E and F for Br12

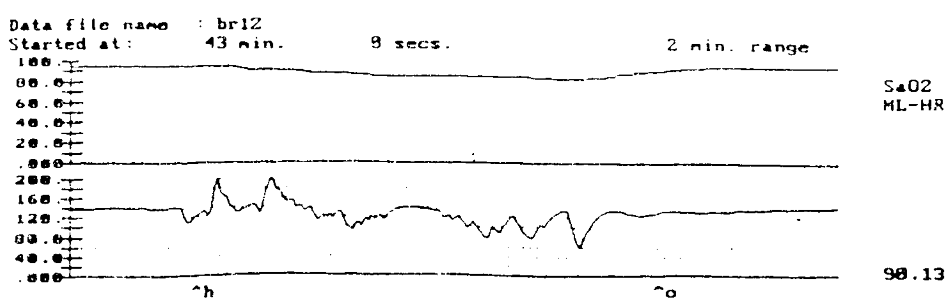
D



E



F



First Time Bottlefeeders

Two of the infants, BR7 and BR11 had not fed from an artificial nipple prior to the study date. Subject Br7 remained normoxemic, and exhibited minimal variation in oxygen saturation levels throughout the first five minutes of the bottle feeding session, except for a brief period from 14 minutes 10 seconds to 14 minutes 40 seconds when the oxygen saturation levels fell below 90%. ...ever, this fall corresponded with burping and with a pulse oximetry device alarm. Upon resumption of bottlefeeding, the oxygen saturation returned to normoxemic levels within 10 seconds (see Figure 19).

In sharp contrast, BR11 did not remain stable upon initiation of bottlefeeding. Within 10 seconds of oral feeding via the bottle, the baby dramatically desaturated to levels below 80%. The feeding was immediately interrupted, the bottle was removed from the baby's mouth and the infant was seated upright and assessed by the researcher. This resulted in a brief recovery to normoxemic levels, followed by a second desaturation lasting approximately 35 seconds. The baby was provided manual stimulation and recovered. The researcher allowed the infant to stabilize for one minute. The second attempt at bottlefeeding again resulted in desaturation within 10 seconds. Bottlefeeding was discontinued, and manual stimulation was provided. The infant required 40 seconds to restabilize to normoxemia (see Figures 20-21). The bedside nurse and charge nurse were notified of the infant's physiological response to bottlefeeding. The mother was present during the bottlefeeding session. A review of the charting revealed that this infant had breastfed without exhibiting cardiorespiratory instability.

Normoxemia and Breastfeeding

In one of the infants, Br3, the initiation of breastfeeding resulted in an increase in oxygen saturation, rather than an interruption in ventilation or no difference in ventilation as the literature suggests. Br3 demonstrated desaturation related to handling just prior to latching at the breast. However when the baby latched, and began actively sucking with audible swallowing as signified by the intervention code (r); the oxygen saturation level increased over a 30 second period, and then stabilized (see Figures 22).

<u>Figure 19.</u> Response of subject Br7 to bottlefeeding

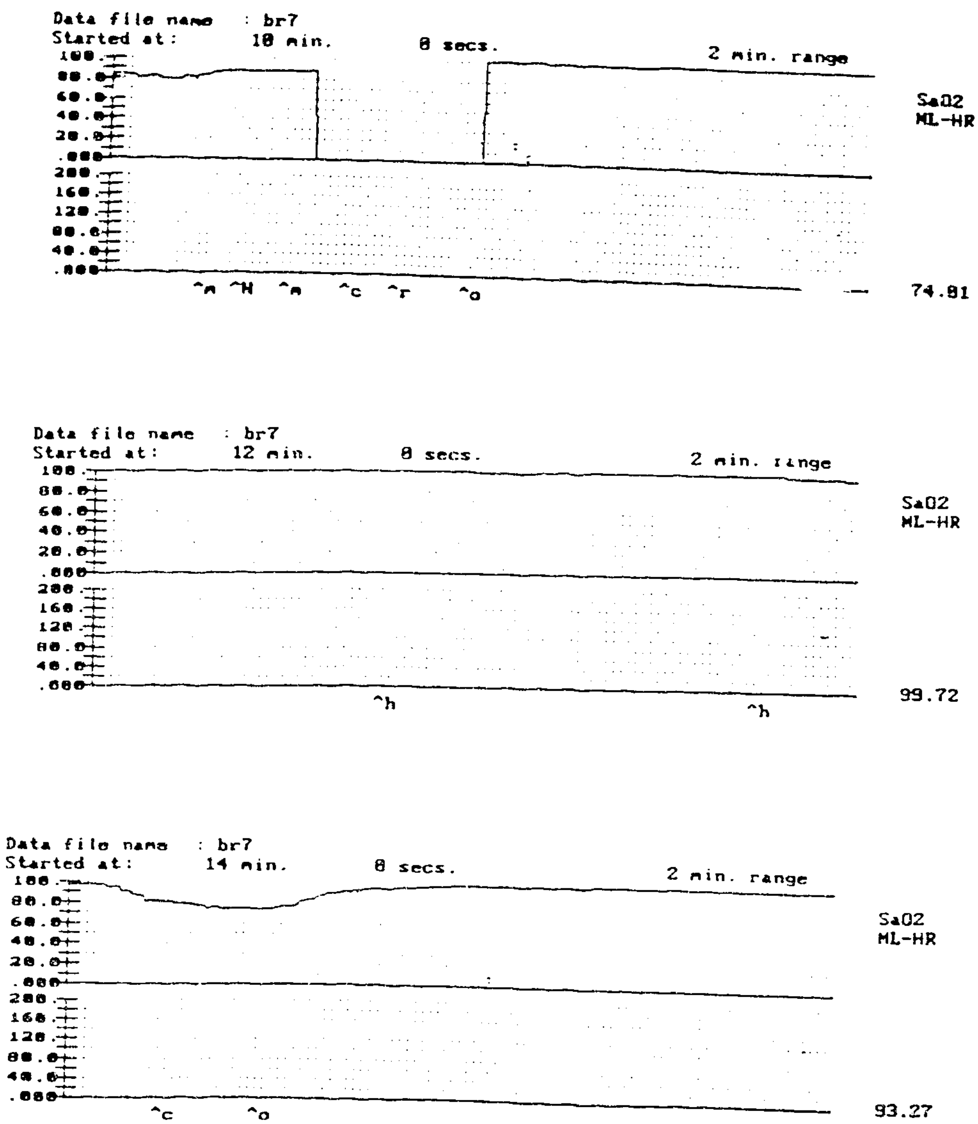
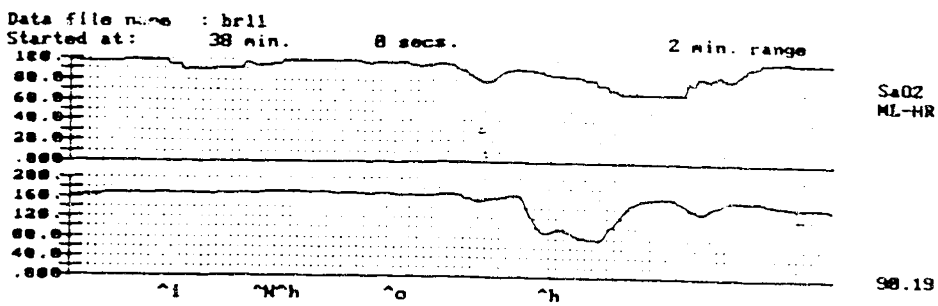


Figure 20. First response of subject Br11 to bottlefeeding



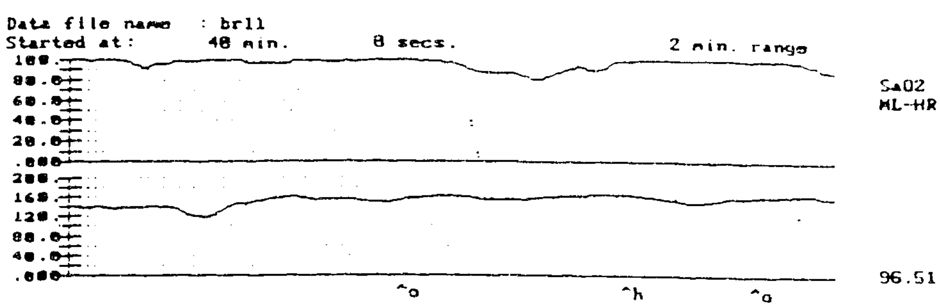
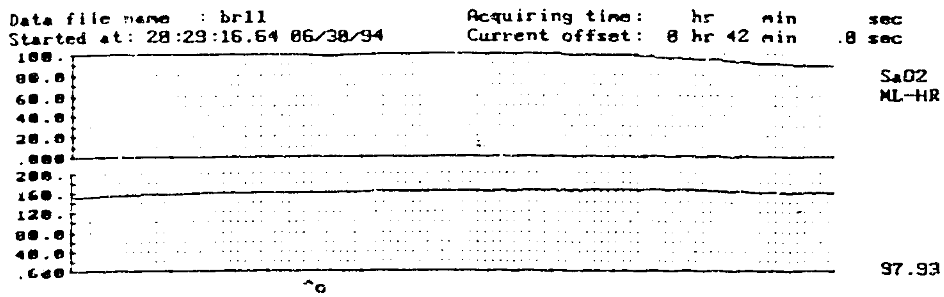
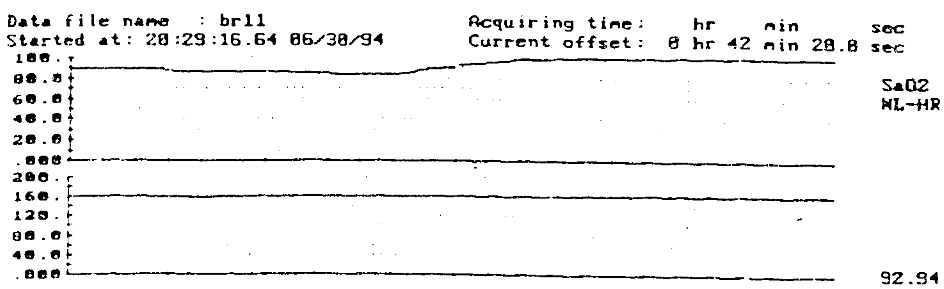


Figure 21. Second response of subject Br11 to bottlefeeding





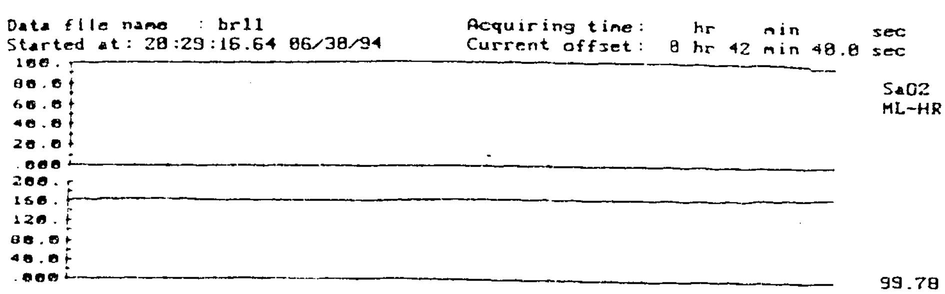
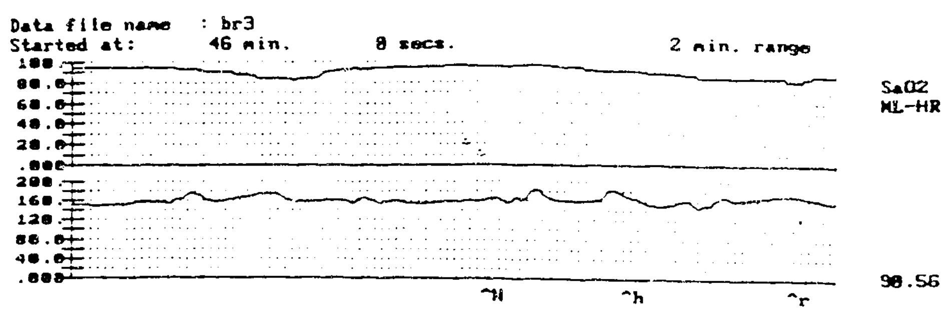
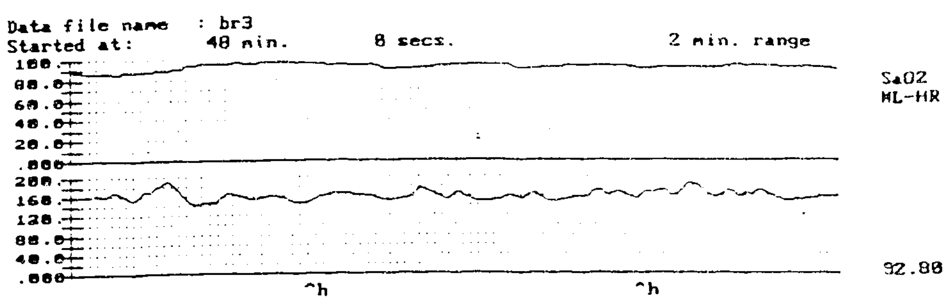


Figure 22. Response of subject Br3 to breastfeeding





Comparison of the Effects of Feeding Method on the Oxygen Saturation of the Premature Infant

The average oxygen saturation was calculated per phase for the breastfeeding session and the bottlefeeding session (see Table 9). The average oxygen saturation per phase for each infant is presented in Appendix C. A visual representation of the 95% Confidence Intervals for oxygen saturation per feeding is provided in Figure 23. Repeated measures ANOVA was calculated using oxygen saturation means for Phases I-IV, with two within subjects measures of importance, time and feeding method. Recognizing that it is imperative to have equal numbers of observations in each group for repeated measures ANOVA, the case of Br8 had to be excluded as the percentage of data loss for Phase II was 100%.

Mauchly's test of sphericity was used to test the assumptions underlying the univariate approach. The data met the assumption of compound symmetry. There were no significant differences in mean oxygen saturation levels by feeding method [$F(1,8)=1.65$, $p>0.05$]. There were no significant differences in mean oxygen saturation levels by time [$F(3,24)=0.41$, $p>0.05$]. Also, the time by feeding method interaction was not significant [$F(3,24)=1.59$, p>0.05]. Tables 10-12 present the results of the repeated measures ANOVA including post hoc power testing results.

Table 9

Mean Oxygen Saturations per Phase

	Bottlefeeding		Breastfeeding	
Phase	Mean	SD	Mean	SD
I	93.8	2.65	94.5	3.17
II	95.7	3.09	94.3	3.99
III	93.4	2.18	95.4	3.36
IV	93.6	2.66	94.9	2.46

Table 10

Results of Repeated Measures ANOVA

Tests involving Treatment Within-Subject Effect

SOURCE OF VARIATION	**SS**	**DF**	**MS**	**F**	**Significance of F**
Within + Residual	36.79	8	4.60		
Treatment	7.61	1	7.61	1.65	0.234

Observed Power at the 0.05 Level

SOURCE OF VARIATION	**NONCENTRALITY**	**POWER**
Treatment	1.655	0.205

Table 11

Results of Repeated Measures ANOVA

Tests involving Time Within-Subject Effect

SOURCE OF VARIATION	SS	DF	MS	F	Significance of F
Within + Residual	152.77	24	6.37		
Time	7.82	3	2.61	0.41	0.748

Observed Power at the 0.05 Level

SOURCE OF VARIATION	NONCENTRALITY	POWER
Time	1.229	0.120

Table 12

Results of Repeated Measures ANOVA

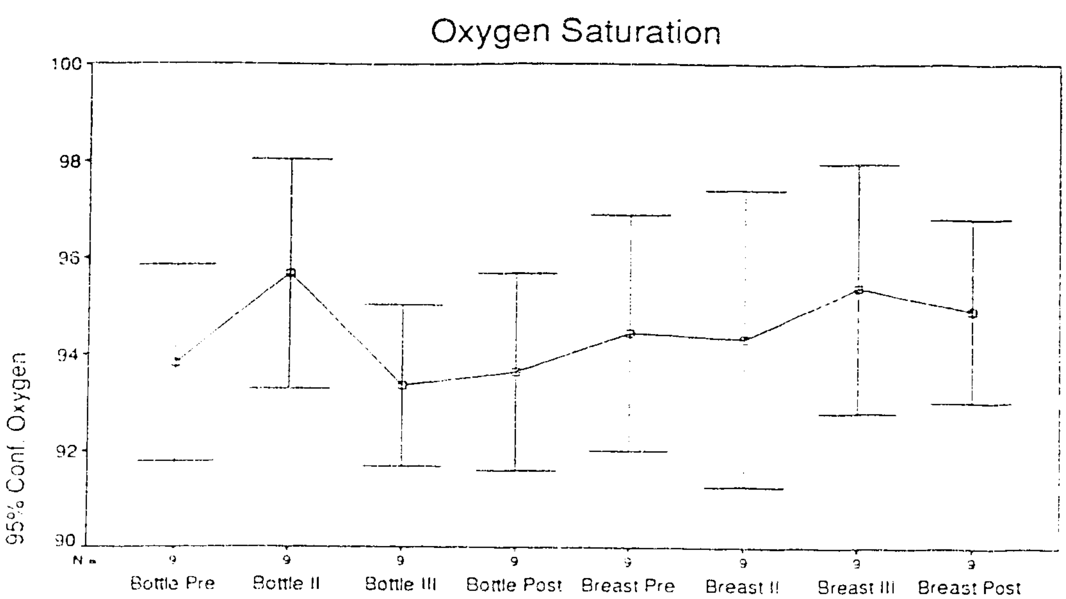
Tests involving Treatment by Time Within-Subject Effect

SOURCE OF VARIATION	SS	DF	MS	F	Significance of F
Within + Residual	141.24	24	5.88		
Treatment	28.00	3	9.33	1.59	0.219

Observed Power at the 0.05 Level

SOURCE OF VARIATION	NONCENTRALITY	POWER
Treatment by Time	4.758	0.363

Figure 23. Oxygen saturation levels per phase of bottlefeeding and breastfeeding: means and 95% confidence intervals



CHAPTER 5

DISCUSSION

The results of this study support other studies which demonstrate that breastfeeding does not place more demand than bottlefeeding on the ventilatory stability of the premature infant. The results of the study are consistent with Snell (1991) who hypothesized that oxygen saturation levels would not be significantly different during the early initiation of breastfeeding versus bottlefeeding in 10 premature infants of 27-32 weeks gestational age.

Blaymore, Ferguson, Anderson, Solomon, Voltas, Oh, and Vohr (1993), also compared the clinical effects of breastfeeding and bottlefeeding on 20 infants weighing <1500 grams (24-32 weeks gestational age) at birth. All infants admitted to their study were introduced to the breast and the bottle at the same postconceptual age. The results of their study showed no significant difference in oxygen saturation during breastfeeding as compared to bottlefeeding ($p = 0.056$), although there was a trend with a lower overall incidence of oxygen desaturation during breastfeeding (21%), as compared to bottlefeeding (38%).

In the current study the researcher also found a trend toward more frequent periods of desaturation during bottlefeeding than during breastfeeding. During Phase II three episodes of desaturation were recorded during bottlefeeding, as compared to two episodes of desaturation during breastfeeding. During Phase III, three episodes of desaturation were recorded during bottlefeeding as compared to zero episodes during breastfeeding. As periods of desaturation which corresponded with activities such as handling, movement, or crying, were excluded from the data analysis the remaining periods of desaturation are more likely due to the method of feeding than to other extraneous variables.

There is some support from the study data to suggest that premature infants may be capable of breastfeeding earlier than they are able to bottlefeed. Subject BR11 was stable during breastfeeding but was not able to safely bottlefeed. Subject Br11 exhibited many of the clinical symptoms of a disorganized feeder described by D'Apolito (1991) during bottlefeeding: apnea, bradycardia, pallor mottling, hicupping, choking, and gagging. Yet during breastfeeding this infant demonstrated ventilatory stability and a rhythmic suck-swallow-breathe pattern.

Subject Br11 was the smallest baby admitted to the study at 1785 grams, as well as the most premature infant admitted to the study at 32 weeks gestation (see Appendix D). This finding supports the research done by Meier, Engstrom, Estrada, and Mikulajcik (1991) who reported that the ten clinically stable premature infants admitted to their study were unable to safely bottlefeed as early as they were able to safely breastfeed.

The lack of statistically significant differences in oxygen saturation levels between feeding methods is notable, in light of the longer mean duration of breastfeeding sessions. The average duration of a bottlefeeding session of 11.534 minutes is comparable to findings put forth by Mathew, Belan, and Thoppil (1992), who recorded a total feeding time of less than 10 minutes during bottlefeeding. The average duration of a breastfeeding session of 20.925 minutes, is longer than the average duration of breastfeeding reported by Lucas, Lucas, and Baum (1979) of 8-14 minutes.

In the current study, the mean duration of breastfeeding was significantly longer than the duration of bottlefeeding. Meier et al (1987), also found that the mean duration of breastfeedings was statistically greater than the mean duration of bottlefeedings ($p < .001$). Meier et al (1987) speculate that "...the greater duration of breast-feedings may have important psychological and physiological advantages for premature infants and their mothers" (p.104).

Possible explanations for this finding may be related to differences in the mode of feeding: breastfeeding is infant-directed, and bottlefeeding is feeder-directed. Breastfeeding is unrestricted in the sense that the close of the feed is determined by the cessation of active sucking by the infant. Conversely, the end of a bottlefeeding session is regulated by the feeder and it corresponds with the time required to consume the prescribed volume.

Perhaps the proximity of the mother to the infant during breastfeeding versus the clinical method used by the researcher to bottlefeed the infants, contributed to the difference in average duration of the two feeding methods. The manner in which the mothers held their infants, the baby's capacity to hear, see, and smell their mother, the taste and smell of the breastmilk, the warmth of their mother's skin, and the opportunity for entrainment have all been noted during breastfeeding (Klause and Kennel, 1982). This interaction provided the infant with a different experience from the bottlefeeding session.

Two of the mothers held their babies in skin to skin contact during the breastfeeding session (Br4 and Br 6). This skin to skin contact, otherwise known as kangaroo care originated in Bogata Columbia (Ludington-Hoe, Thompson, Swinth, Hadeed, & Anderson, 1994), and may or may not include nutritive sucking at the breast. Numerous researchers have pointed to the benefits of this intervention such as increased breastmilk production (Narayanan, Mehta, Choudhury, & Jainm 1991), and increased maternal satisfaction (Bosque, Brady, Affonso, & Wahlberg, 1988).

Skin to skin contact may serve to promote temperature stability during feeding (Whitelaw, Heisterkamp, Sleath, Acolet & Richards, 1988). It has been shown that temperature instability can lead to ventilatory instability by increasing metabolic demands (Sinclair, 1970). Yet physiological stability of the infant, including temperature stability, has been reported during kangaroo care (Ludington-Hoe, Hadeed, &

Anderson, 1991). When infants were permitted to breastfeed at liberty during skin to skin contact, these infants demonstrated less incidence of bradycardia during breastfeeding than during bottle or gavage feeding (Bosque, Brady, Affonso, and Wahlberg, 1988). In contrast with the findings of Bosque and others (1988), both subjects Br4 and Br6 exhibited periods of desaturation during Phase II of the breastfeeding sessions despite skin to skin contact.

In the majority of the infants the greater overall duration of the breastfeeding sessions as compared to the bottlefeeding sessions, did not seem to contribute to a tiring phenomenon leading to ventilatory compromise. There was one exception however, Br3 was the only subject to exhibit periods of desaturation in the postprandial phase of either of the two feeding methods. The two periods of desaturation occurred during the post-treatment phase following breastfeeding. Although subject Br3 was the second oldest infant in the sample, and had the highest birthweight, this infant demonstrated the greatest variability in oxygen saturation levels.

Limitations

Limitations to the study include: sampling, the instrument, variation in the use of touch, environmental factors, and variations in the method of feeding.

Sample Size

One possible explanation for the lack of a statistically significant difference ($p > .05$) between baseline, feeding and postfeed periods was the small sample size, which may have contributed to intersubject variability as well as decreased power of the study (see Table 10 for post hoc power testing results). The small convenience sample also limits generalizability to other premature infant populations. Hence, a larger sample size is warranted to increase the power of the study and to enhance the generalizability of the findings.

A second explanation may be that only one feeding session per method of feeding was measured. Measuring oxygen saturation continuously over numerous feeding sessions may have provided a more accurate assessment of the infant's true ventilatory status during oral feeding, and increased the possibility of detecting significant changes in SaO2 levels.

Limitations of the Instrument

Pulse oximetry provided a non-invasive, relatively instantaneous, and safe means of measuring the oxygenation status of the premature infant during oral feeding. However, the major drawback in using this monitoring device was the degree of data loss related to movement artifact despite employing the C-LOCK ECG synchronization feature. Selection of the Mode 2 operation mode may have also contributed to the amount of motion artifact accumulated during data acquisition. The use of a 2-3 second averaging time in Mode 2, versus the 5-7 second averaging time of Mode 1, did provide the fastest response time, but this mode was also more sensitive to motion.

Although the pulse oximeter device provides a readout of heart rate, this study was limited to an exclusive examination of oxygen saturation levels. The continuous monitoring of heart rate via a Hewlett Packard monitor was used to assist the researcher to assess the clinical stability of the infant during feeding. Heart rate was not statistically analyzed. Yet an analysis of the reliability of the pulse oximeter heart rate output within 10 beats/minute of the cardiac monitor heart rate tracing would have assisted the researcher to more accurately detect periods of unreliable oxygen saturation data (Barrington et al, 1988). Furthermore, research assistants were not instructed to record specific error messages displayed by the Nellcor 200 pulse oximetry monitor. This information would have further facilitated an analysis of the reliability of the oxygen saturation tracings.

Finally, factors such as percentage of fetal hemoglobin, altitude, total hemoglobin content, oxygen-hemoglobin affinity, and external noise have all been cited as interfering with the accuracy and reliability of the pulsatile wave of the pulse oximeter (Zubrow, 1990; Hay et al, 1989; Anderson, 1987; Pologue et al, 1987). These confounding variables were beyond the control of the researcher.

Variations in the Use of Touch

The researcher held the babies during bottlefeeding in a consistent manner. Moreover, all of the mothers breastfed their infants in the cradle-hold position. The researcher did not touch the babies beyond what was required to feed and burp the babies during bottlefeeding sessions, or hold the babies during the baseline and post-treatment phase. However, the mothers and some of the fathers talked to their infants and stroked their infants. The difference in positioning and touch of the babies during the two feeding methods was not controlled. The importance of this parent-infant interaction is demonstrated by Harrison, Leeper, and Yoon (1990), who noted that infants of 27-33 weeks gestational age experienced significantly higher oxygen saturation levels during parent touch periods on 19% of parental visits.

Environmental Factors

Events other than the feeding session such as noise (Avery & Glass, 1989), behavioral state of the infant (Hanson & Okken, 1980), handling (Danford et al., 1983), or lighting (Shogun, & Schumann, 1993), may have affected the oxygenation status of the neonate. Although an attempt was made to record and visually analyze the direct effects of such factors on the immediate oxygenation status of the neonate, the cummulative effect of these factors could not be accounted for. Also, research assistants were instructed to enter an intervention code whenever an environmental stimuli occurred. However, no intervention code was entered when the environmental stimuli was no longer present. Thus, only general correlations can be made related to the occurrence of an environmental stimuli and the subsequent effects of the stimuli on the oxygenation status of the premature infant. Moreover, the difficulty involved in accurately recording numerous complex physiological, behavioral, and environmental data during a feeding session may have contributed to an undetermined amount of loss of data.

Variations in the Method of Feeding

An unexpected variation in feeding method occurred when two of the ten infants were bottlefed for the first time during data acquisition. It was beyond the scope of this study to determine the extent to which each infant may have adapted, or not adapted, from one feeding method to another regardless of the introduction of the experimental condition. The effects of carry-over from one feeding type to the other were not determined.

One of the mothers used a nipple shield during breastfeeding (Br10). No periods of desaturation were detected during breastfeeding, yet difficulty arises when interpretting the difference in oxygen saturation during breastfeeding and bottlefeeding when a nipple shield is used. Woolridge, Baum, and Drewett (1980) noted a 22% decrease in milk supply when a thin silicone nipple shield is used similar to the product used by the mother in question. The authors also note decreased tactile stimulation of the nipple and consequently decreased extraction of breastmilk from the breast during breastfeeding. The change in milk flow with and without the use of the nipple shield was not measured or noted with an intervention code.

Implications for Future Research

Sterling and McNally (1992) advocate greater use of replicated single subject research designs by clinical nurse specialists. They argue that " ... nursing has pursued, independently, two courses that could converge: use of the nursing process ... and attempts to build a base of clinically relevant documented knowledge. Replicated single-subject designs seem well suited to link ... nursing practice and research" (Sterling and McNally, 1992, p.22). As such, the researcher recommends replication of the study with consideration given to two previously mentioned points: 1) increasing sample size and 2) measuring oxygen saturation levels during numerous feeding sessions.

Two additional recommendations are made in relation to enhancing the interpretation of the results through: 1) increasing control over the loss of the oxygen saturation tracing and 2) documenting research assistant interrater reliability. Utilization of simultaneous pulse oximetry heart rate and oxygen saturation readout would be a valuable adjunct to the proposed data acquisition system. The addition of the heart rate tracing from the pulse oximeter would allow the researcher to: 1) more definitively trace the source of loss of oxygen saturation tracing, 2) more accurately determine the cardiorespiratory response of the premature neonate to oral feeding, and 3) discern with greater confidence the infant's physiological response to the independent variable, environmental stimuli, or other extraneous variables.

Instructing research assistants to record pulse oximeter alarms and error messages, as well as entering intervention codes not only at the beginning but at the end of an environmental stimuli, would be advantageous to the interpretation of the data. Measurement of interrater reliability of observer recording of intervention coding during a training period, prior to formalized data collection, would be a warranted addition to future research endeavors. Use of video recordings that were representative of breastfeeding and bottlefeeding sessions of premature infants within the NICU would be a reasonable approach for interrater reliability training.

Ideally, factors associated with oxygenation such as: percent of hemoglobin, respiratory rate, heart rate, and temperature; combined with pertinent aspects of the suck-swallow-breathe cycle such as: sucking pressure, sucking frequency, effectiveness of sucking action, and ratios of sucks per swallow (Palmer, Crawley, and Blanco, 1993), should be measured in one comprehensive assessment of both methods of feeding. A study designed in this manner would likely result in a more complete composite of the ventilatory status of the premature infant during oral feeding.

Implications for Nursing Practice

The results of the study may be employed by nurses in an evaluation of present nursery feeding routines. The findings of this study and others (Blaymore et al, 1993; Meier et al 1991; Snell, 1991), call into question the present nursery routine of providing both feeding methods to healthy breastfeeding premature infants, based on the assumption that breastfeeding is more physiologically stressful for the premature infant. Furthermore, it is possible that premature infants may demonstrate ventilatory stability with breastfeeding at an earlier age than bottlefeeding (Meier, 1991; Snell, 1991). The clinical practice of limiting access to the breast until ventilatory stability during bottlefeeding is established was not supported by the results of this study.

Conclusions

The commonly held assumption that bottlefeeding is less stressful for the premature infant in terms of ventilatory stability as compared to breastfeeding is not supported by the results of this study. The findings of this study support other studies (Blaymore et al, 1993; Snell, 1991; Meier et al, 1991) which found that premature infants do not experience more ventilatory instability during breastfeeding as compared to bottlefeeding. Healthy premature infants of 32-36 weeks gestational age at birth experienced fewer incidences of oxygen desaturation during breastfeeding than during bottlefeeding.

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Appendix A

Consent Form

Consent Form

PROJECT TITLE: The Effect of Feeding Method on Oxygenation in Premature Infants

PRINCIPAL INVESTIGATOR:
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PURPOSE: The purpose of the study is to look at how much oxygen premature babies get during feeding. The study will test if bottlefeeding or breastfeeding make a difference on how well oxygenated the baby is.

PROCEDURE: A small disk will be taped to your baby's foot before your baby is fed. This disk will measure how much oxygen your baby is getting. The disk will not harm your baby. Your baby will be bottlefed and breastfed at separate times. The order of feeding type will be random. I will bundle and hold your baby for ten minutes before your baby is fed. I will bottlefeed your baby your breastmilk. I am an experienced nurse specializing in the care of babies. I am also a breastfeeding specialist. You will breastfeed your baby. Your baby will be burped after the feed. Your baby will then be held for ten minutes.

PARTICIPATION: There will be no harm to you if you participate in the study. There is a small risk of a fall in heart rate and the amount of oxygen your baby is getting during any feeding. Your baby's heart rate will be monitored throughout the study. The amount of oxygen your baby is getting will be monitored throughout the study. The researcher is an experienced NICU nurse. The researcher will take the appropriate measures if your baby's heart rate, or the level of oxygen your baby is getting fall.

There will be no direct benefit to you or your baby for participating in this study. Results from this study may help nurses understand the oxygenation of premature infants during feeding. This may help to improve the care that nurses give to mothers and babies.

You and your baby do not have to be in this study if you do not wish to be. If you decide to be in the study, you may drop out at any time by telling the researcher. Taking part in the study or dropping out will not affect the care of your baby in the hospital.

Your name will not appear in the study. The name of your baby will not appear in the study. Only a code number will appear on any forms or data. All data will be kept in a locked cabinet. Consent forms will be saved for five years. The data will be stored a minimum of seven years. The data will be stored separate from the consent forms. If the data is used for another study in the future, the researcher will obtain approval from the appropriate ethical review committee.

The findings of this study may be published or presented at conferences. Your name, the name of your baby, or any information that may identify you both will not be used. If you have any questions or concerns about this study at any time, you can call the researcher at the number above.

CONSENT: I acknowledge that the above research procedures have been described. Any questions have been answered to my satisfaction. I know I may contact the person named below, if I have further questions either now or in the future. I have been informed of the alternatives to participating in this study. I understand the possible benefits of joining the study. I understand the possible risks of the study. I have been assured that records related to this study will be kept confidential.

I understand that I am free to withdraw from the study at any time. I understand that if I do not participate in the study or withdraw at any time, the nursing care for my baby will not be affected. I understand that if any knowledge from the study becomes available that could influence my decision to continue in the study, I will be promptly informed. I have been given a copy of this form to keep. I hereby give consent for my baby's participation in the study.

________________________ (Signature of Mother) ____________ (Date)

________________________ (Signature of Researcher) ____________ (Date)

________________________ (Signature of Witness) ____________ (Date)

If you wish to receive a summary of the study when it is finished, please complete the next section:

Name: ____________________________________

Address: ____________________________________

Appendix B

Demographic Form

Demographic Form

Number:

Sex:

Birthweight:

Current Weight:

Gestational Age at Birth:

Postconceptual Age:

Type of Feeding prior to Measurement period:

Volume of milk per bottlefeed:

Nipple Unit:

Environmental factors
noted during measurement period:

Appendix C

Demographic Characteristics of Subjects Br3-Br12

Demographic Data

SUBJECT NUMBER	BW	CW	GEST	POST	GENDER
Br3	2505	2435	34	36.57	male
Br4	1990	1910	33+	34.43	male
Br5	2500	2430	35	36	male
Br6	1840	2035	32+	35.29	female
Br7	2015	2135	33	35.43	male
Br8	1815	1970	32+	35.29	female
Br9	1800	1995	32+	35.29	female
Br10	2350	2265	35	36	female
Br11	1785	1930	32	34.43	female
BR12	2410	2450	35	36.7	female

Legend
BW = Birthweight
CW = Current Weight on the day of data acquisition
GEST = Gestational Age at birth
POST = Postconceptual age at the day of data acquisition

Appendix D

Mean Oxygen Saturation per Phase for Subjects Br3-Br12

Br3 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.22 - 10.68	Minimum: 83.15 Maximum: 98.44 Mean: 90.14
Phase II Treatment o - o(30)	10.92 - 11.42	Minimum: 87.94 Maximum: 98.44 Mean: 94.75
Phase III Treatment o(30) - o(5)	11.42 - 16.42	Minimum: 87.16 Maximum: 98.44 Mean: 93.80
Phase IV Post-Treatment A-N (post)	25.97 - 36.07	Minimum: 75.05 Maximum: 99.12 Mean: 91.98

Br3 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	36.94 - 47.03	Minimum: * Maximum: 99.12 Mean: 91.13
Phase II Treatment r - r(30)	47.87 - 48.37	Minimum: 85.30 Maximum: 99.95 Mean: 91.68
Phase III Treatment r(30) - r(5)	48.37 - 53.37	Minimum: 84.03 Maximum: 99.12 Mean: 93.25
Phase IV Post-Treatment A-N (post)	66.60 - 76.60	Minimum: 83.25 Maximum: 99.17 Mean: 92.54

Note. * = loss of data

Br4 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.29 - 10.32	Minimum: 85.25 Maximum: 99.95 Mean: 96.04
Phase II Treatment o - o(30)	11.04 - 11.54	Minimum: 89.11 Maximum: 99.12 Mean: 93.52
Phase III Treatment o(30) - o(5)	11.54 - 16.52	Minimum: 79.98 Maximum: 99.95 Mean: 91.72
Phase IV Post-Treatment A-N (post)	21.0 - 30.93	Minimum: 78.96 Maximum: 99.95 Mean: 93.99

Br4 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	31.63 - 42.15	Minimum: 74.90 Maximum: 99.95 Mean: 92.59
Phase II Treatment r - r(30)	44.24 - 44.74	Minimum: 93.12 Maximum: 98.44 Mean: 97.17
Phase III Treatment r(30) - r(5)	44.74 - 49.74	Minimum: 89.16 Maximum: 99.22 Mean: 97.08
Phase IV Post-Treatment A-N (post)	63.40 - 73.45	Minimum: 92.24 Maximum: 99.95 Mean: 97.50

Br5 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.31 - 10.40	Minimum: 58.64 Maximum: 99.95 Mean: 91.89
Phase II Treatment o - o(30)	13.11 - 13.61	Minimum: 95.95 Maximum: 97.07 Mean: 96.68
Phase III Treatment o(30) - o(5)	13.61 - 18.61	Minimum: 85.01 Maximum: 99.95 Mean: 95.02
Phase IV Post-Treatment A-N (post)	23.56 - 26.83	Minimum: 78.86 Maximum: 99.95 Mean: 92.04

<u>Br5 Breastfeed</u>

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	27.64 - 37.78	Minimum: 78.17 Maximum: 99.95 Mean: 93.81
Phase II Treatment r - r(30)	38.53 - 39.03	Minimum: 92.48 Maximum: 96.24 Mean: 94.23
Phase III Treatment r(30) - r(5)	39.03 - 44.03	Minimum: 87.06 Maximum: 97.07 Mean: 93.89
Phase IV Post-Treatment A-N (post)	83.78 - 89.75	Minimum: 78.17 Maximum: 99.22 Mean: 93.96

Br6 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.60 - 2.86	Minimum: 90.92 Maximum: 98.29 Mean: 96.32
Phase II Treatment r - r(30)	3.32 - 3.82	Minimum: 80.76 Maximum: 98.29 Mean: 86.71
Phase III Treatment r(30) - r(5)	3.82 - 8.82	Minimum: 94.09 Maximum: 98.34 Mean: 97.43
Phase IV Post-Treatment A-N (post)	31.03 - 41.07	Minimum: * Maximum:* Mean: 93.89

Note. * = loss of data

<u>Br6 Bottlefeed</u>

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	42.26 - 52.32	Minimum: * Maximum: * Mean: 94.5
Phase II Treatment o - o(30)	52.71 - 53.21	Minimum: 96.83 Maximum: 98.29 Mean: 97.85
Phase III Treatment o(30) - o(5)	53.21 - 58.21	Minimum: 85.99 Maximum: 98.29 Mean: 94.79
Phase IV Post-Treatment A-N (post)	63.32 - 73.32	Minimum: 88.04 Maximum: 98.54 Mean: 94.18

<u>Note.</u> * = loss of data

Br7 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.22 - 10.32	Minimum: * Maximum: * Mean: 92.84
Phase II Treatment o - o(30)	10.90 - 11.40	Minimum: 96.97 Maximum: 99.95 Mean: 98.85
Phase III Treatment o(30) - o(5)	11.40 -16.40	Minimum: 74.12 Maximum: 99.95 Mean: 97.21
Phase IV Post-Treatment A-N (post)	25.58 - 35.64	Minimum: 69.82 Maximum: 99.22 Mean: 90.26

Note. * = loss of data

Br7 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	36.17 - 46.47	Minimum: 89.26 Maximum: 99.27 Mean: 96.22
Phase II Treatment r - r(30)	48.26 - 48.76	Minimum: 97.02 Maximum: 99.95 Mean: 99.02
Phase III Treatment r(30) - r(5)	48.76 - 53.76	Minimum: 92.38 Maximum: 99.95 Mean: 98.18
Phase IV Post-Treatment A-N (post)	60.19 - 70.22	Minimum: 78.91 Maximum: 99.95 Mean: 96.79

Br8 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.14 - 4.49	Minimum: 81.93 Maximum: 99.07 Mean: 92.50
Phase II Treatment r - r(30)	6.29 - 6.79	Minimum: * Maximum: * Mean: *
Phase III Treatment r(30) - r(5)	6.79 - 11.79	Minimum: 94.87 Maximum: 99.12 Mean: 97.65
Phase IV Post-Treatment A-N (post)	15.44 - 17.42	Minimum: 84.03 Maximum: 95.17 Mean: 90.73

Note * = loss of data

Br8 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	17.82 - 24.56	Minimum: 82.08 Maximum: 99.32 Mean: 95.35
Phase II Treatment o - o(30)	24.82 - 25.32	Minimum: 95.02 Maximum: 98.34 Mean: 97.79
Phase III Treatment o(30) - o(5)	25.32 - 30.32	Minimum: 85.21 Maximum: 99.95 Mean: 96.03
Phase IV Post-Treatment A-N (post)	40.40 - 45.44	Minimum: 89.16 Maximum: 95.17 Mean: 93.17

Br9 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.15 - 2.21	Minimum: 87.16 Maximum: 93.26 Mean: 90.98
Phase II Treatment o - o(30)	2.38 - 2.58	Minimum: 89.94 Maximum: 91.26 Mean: 90.70
Phase III Treatment o(30) - o(5)	2.58 - 7.58	Minimum: * Maximum: * Mean: 90.98
Phase IV Post-Treatment A-N (post)	18.22 - 28.29	Minimum: 76.17 Maximum: 97.22 Mean: 93.65

Note. * = loss of data

Br9 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	29.18 - 39.22	Minimum: 89.11 Maximum: 98.49 Mean: 93.81
Phase II reatment r - r(30)	40.74 - 41.24	Minimum: 89.06 Maximum: 91.26 Mean: 90.54
Phase III Treatmen r(30) - r(5)	41.24 - 46.24	Minimum: 76.95 Maximum: 95.31 Mean: 88.76
Phase IV Post-Treatment A-N (post)	82.81 - 84.94	Minimum: 89.84 Maximum: 99.27 Mean: 96.37

Br10 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.42 - 2.65	Minimum: * Maximum: * Mean: 97.94
Phase II Treatment o - o(30)	3.04 - 3.54	Minimum: 98.10 Maximum: 99.95 Mean: 99.52
Phase III Treatment o(30) - o(5)	3.54 - 8.54	Minimum: 81.88 Maximum: 99.95 Mean: 92.83
Phase IV Post-Treatment A-N (post)	22.18 - 31.56	Minimum: 96.09 Maximum: 99.95 Mean: 98.91

Note. * = loss of data

Br10 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	32.90 - 35.57	Minimum: * Maximum: * Mean: 100.50
Phase II Treatment r - r(30)	36.88 - 37.38	Minimum: 92.92 Maximum: 99.95 Mean: 97.24
Phase III Treatment r(30) - r(5)	37.38 - 42.38	Minimum: 93.19 Maximum: 99.95 Mean: 98.38
Phase IV Post-Treatment A-N (post)	50.85 - 60.85	Minimum: 92.29 Maximum: 99.95 Mean: 98.36

Note. * = loss of data

Br11 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.18 - 3.49	Minimum: 81.83 Maximum: 99.95 Mean: 95.75
Phase II Treatment r - r(30)	4.29 - 4.79	Minimum: 94.04 Maximum: 99.07 Mean: 97.25
Phase III Treatment r(30) - r(5)	4.79 - 9.79	Minimum: 92.14 Maximum: 99.95 Mean: 98.49
Phase IV Post-Treatment A-N (post)	24.40 - 34.81	Minimum: 77.00 Maximum: 99.95 Mean: 93.83

<u>Brll Bottlefeed</u>

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	35.18 - 38.49	Minimum: 83.06 Maximum: 99.95 Mean: 96.51
Phase II Treatment o - o(30)	38.82 - 39.32	Minimum: 81.93 Maximum: 99.95 Mean: 92.01
Phase III Treatment o(30) - o(5)	39.32 - 42.65	Minimum: 67.04 Maximum: 99.95 Mean: 93.53
Phase IV Post-Treatment A-N (post)	42.69 - 46.22	Minimum: 87.84 Maximum: 99.95 Mean: 96.29

Br12 Breastfeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	0.36 - 10.51	Minimum: 83.15 Maximum: 98.44 Mean: 89.94
Phase II Treatment r - r(30)	11.51 - 12.01	Minimum: 87.99 Maximum: 98.44 Mean: 95.12
Phase III Treatment r(30) - r(5)	12.01 - 17.01	Minimum: 87.16 Maximum: 96.48 Mean: 92.95
Phase IV Post-Treatment A-N (post)	25.38 - 35.40	Minimum: 75.05 Maximum: 98.49 Mean: 90.99

Br12 Bottlefeed

PHASE	MINUTES	OXYGEN SATURATION
Phase I Baseline A-N (pre)	35.92 - 40.76	Minimum: 83.11 Maximum: 99.12 Mean: 93.51
Phase II Treatment o - o(30)	41.31 - 41.81	Minimum: 87.99 Maximum: 95.21 Mean: 97.09
Phase III Treatment o(30) - o(5)	41.81 - 46.81	Minimum: 78.17 Maximum: 97.17 Mean: 90.29
Phase IV Post-Treatment A-N (post)	56.33 - 66.33	Minimum: 85.21 Maximum: 98.39 Mean: 91.47