The Effect of a Prefeeding Oral Stimulation Program on the Feeding Performance of Preterm Infants

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DEDICATION

I would like to dedicate this master's thesis in memory of my mother, Francesca Ida Fucile, who fought a courageous battle against cancer during the period of my graduate studies. Her strong will, positive outlook on life, and her belief in my success has inspired and given me the courage to achieve all my goals and most importantly to be happy. This master's degree is one of the first goals I have set to achieve and I did it! Grazie mama.

ABSTRACT

There is a lack of knowledge on the effect of an oral stimulation program, prior to the introduction of oral feeding, in preterm infants who are less than 30 weeks gestational age. The objective of this study was to assess whether a prefeeding oral stimulation program enhances the oral feeding performance of preterm infants born between 26-29 weeks gestational age.

A randomized trial was carried out. Thirty-two infants completed the study. The experimental group received the oral stimulation program. The control group received the sham stimulation program. The outcome measures were defined as: time to attain independent oral feeding, overall intake, rate of milk transfer (ml/min), maturation of sucking and length of stay at the hospital.

The experimental group attained independent oral feeding faster and demonstrated consistently greater overall intake and rate of milk transfer than the control group, as their oral feeding regimen was advanced. These findings are attributed in part to a more mature sucking pattern observed in the experimental group. There was no difference in length of stay at the hospital between the two groups.

This study demonstrates that an early oral stimulation program can enhance the development of sucking. This supports the concept that development of sucking is dependent on both physiological maturation and external experiences. Such a program may be included in neonatal developmental care plans because it is safe, simple and inexpensive.

ABRÉGÉ

Il y a un manque de connaissance de l'effet d'un programme de stimulation des structures orales offert avant l'introduction de la succion, pour les prématurés de moins de 30 semaines de gestation. L'objectif de cette étude était de déterminer si un tel programme pouvait améliorer la performance de la succion des prématurés nés entre 26 et 29 semaines de gestation.

Une étude randomisée comprenant trente-deux nouveau-nés de cet âge gestationnel fut réalisée. Le groupe expérimental reçut un programme spécifique de stimulations orales avant l'introduction de la tétée. Le groupe témoin reçut le faux programme. Les éléments suivants furent suivis: temps requis pour acquérir l'alimentation complète par voie orale, volume total ingéré et vitesse d'ingestion (ml/min) au cours des prises alimentaires, degré de maturation de la succion et durée d'hospitalisation.

Le groupe expérimental acquit plus rapidement l'alimentation complète par voie orale. De plus, le volume total ingéré et la vitesse d'ingestion furent plus élevés chez les sujets expérimentaux que témoins. Ces résultats peuvent être attribués à un profile de succion plus mûr observé au sein du groupe expérimental. La durée d'hospitalisation, cependant, fut la même parmi les deux groupes.

Cette étude démontre qu'un programme de stimulation orale offert avant l'introduction de l'alimentation par voie orale peut améliorer le développement de la succion. Ceci supporte l'hypothèse selon laquelle le développement de la succion dépend tout autant de la maturation physiologique ainsi que des expérience extérieures. Un tel

programme pourrait être inclu dans les initiatives de développement des soins en néonatalogie puisqu'il ne presente pas de risque, est simple et peu coûteux.

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STATEMENT OF AUTHORSHIP

I certify that I am the primary author of the manuscript contained in this thesis. I claim full responsibility for the content and style of the text included herein.

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1. GLOSSARY

Gestational Age (GA): Length of time in weeks from conception to day of delivery.

Independent Oral Feeding: Ability to take all the required volume of formula and/or breast milk in 8 oral feedings/day, within an allocated time, usually 20 minutes/feeding.

Oral Feeding: Feedings taken by mouth, through the process of sucking.

Oral Motor Kinetic Apparatus: A nipple/bottle instrument used to measure and analyze the components of sucking (e.g., suction, expression, sucking bursts, pauses, and suction amplitude).

Postmenstrual Age (PMA): Age in weeks from conception to current day.

Preterm Infants: Infants who are born less than 37 weeks gestational age.

Tube Feeding (a.k.a., gavage feeding): Feedings taken directly to the stomach, bypassing the mouth, via a tube through the nose (nasogastric), mouth (orogastric), or stomach (gastrostomy).

2. INTRODUCTION

Oral feeding difficulties are one of the most frequently encountered problems in preterm infants (Comrie & Helm, 1997; Hack et al, 1985). Almost half of all preterm infants (40-45%) may experience oral feeding difficulties within the first two years of their life (Pridham et al, 1992; Wingert et al, 1980). Most of these problems arise when preterm infants are introduced to oral feedings (Harris, 1986). Oral feeding difficulties may include a disorganized sucking pattern, incoordination of the suck-swallow-breathe sequence leading to episodes of apnea, bradycardia and oxygen desaturations, and aversion or hypersensitivity to touch around and/or in the mouth (Comrie & Helm, 1997; Harris, 1986; Krauss et al, 1978; Medoff-Cooper et al, 1993; VandenBerg, 1990; Wolf & Glass, 1992). There is an increased awareness and concern among health professionals with regards to oral feeding difficulties because they often affect infant's ability to reach independent oral feeding, prolong hospital stays, and may lead to long term feeding difficulties and developmental problems (Braun & Palmer, 1985; Bu'Lock et al, 1990; Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Hack et al, 1985; Harris, 1986; Schanler et al, 1999; Shiao et al, 1995; VandenBerg, 1990).

Feeding specialists have been challenged to treat these problems. They use various treatment strategies, such as oral sensory input, promoting appropriate feeding positions and controlling noise and light levels in the units (Comrie & Helm, 1997; Harris, 1986; VandenBerg, 1990; Wolf & Glass, 1992). These strategies can be effective (Anderson, 1986; Case-Smith, 1989, 1987; Comrie & Helm, 1997). However, the current practice is not efficient because feeding specialists are consulted after the oral feeding problems have become clinically significant and treatment using these strategies is a slow and arduous process (Vogel, 1986). Given that healthcare resources are limited, the focus of care is on prevention and earlier hospital discharge to control costs. Feeding specialists are beginning to recognize that they are consulted too late. To prevent and/or reduce the occurrence of feeding difficulties it is important to start intervening before oral feedings are initiated (Bazyk, 1990; Comrie & Helm, 1997; Harris, 1986; Morris & Klein, 1987). Thus, we propose that provision of an early oral stimulation program, prior to the introduction of oral feeding, will facilitate the development of existing rudimentary sucking skills. This, in turn, will accelerate the transition to independent oral feeding.

2.1. Objective

The main objective of this study is to assess whether a prefeeding oral stimulation program will improve the oral feeding performance of preterm infants.

3. LITERATURE REVIEW

Advances in perinatalogy, neonatology, and specific new therapies, such as antenatal steroids and exogenous surfactants have markedly increased the survival of preterm infants within the last twenty years (Berkowitz & Papiernick, 1993; Dezoete et al, 1997; Doyle et al, 1989; Emsley et al, 1997; Johnson et al, 1993; Kilpatrick et al, 1997; Lorenz et al, 1998). Although the number of preterm births has remained constant, the survival of preterm infants born less than 29 weeks of gestational age (GA) has greatly increased (Emsley et al, 1997; Kilpatrick et al, 1997; Piecuch et al, 1997). Emsley et al, (1997) reported that the survival rate of this age group has increased from 27% in 1984 to 42% in 1994.

Infants who are born prematurely need to adapt to the extrauterine environment (Als, 1986). Due to their immature organ systems, they are at risk for encountering various medical problems during this period, such as respiratory distress syndrome, bronchopulmonary dysplasia, necrotizing enterocolitis, and intraventricular hemorrhages (Dusick, 1997; Neal, 1995; Pearce, 1981; Rutter, 1995; Stjernqvist & Svenningsen, 1990; Volpe, 1997). In addition to these conditions, they often present with oral feeding difficulties (Braun & Palmer, 1985; Bu'Lock et al, 1990; Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Weaver & Anderson, 1988).

The treatment of preterm infants involves highly specialized medical care and prolonged hospital stays. This, in turn, involves high health care costs (Doyle et al, 1989; Kilpatrick et al, 1997; Newns et al, 1984; Piecuch et al, 1997; Rogowski, 1998; Stevenson et al, 1996). With the financial constraints on our healthcare system, there is a push towards earlier hospital discharge (American Academy of Pediatrics, 1998; Comrie

& Helm, 1997). Advances in medical technology have allowed infants to be sent home on apnea monitors and oxygen supplementation. As a result, oral feeding is often the remaining obstacle for discharge (Conway, 1994; Gardner & Hagedorn, 1991). To minimize the risk of any complications at home, the American Academy of Pediatrics (1998) and others (Trachtenbarg & Golemon, 1998) proposed that discharge of preterm infants be based on the following criteria: 1) ability to maintain stable cardio-respiratory function; 2) ability to maintain a normal body temperature while in a open crib, and 3) ability to feed safely by mouth to ensure a sustained pattern of daily weight gain.

3.1. Oral Feeding in Full Term and Preterm Infants

Oral feeding in infants consists of sucking, swallowing and breathing (Bu'Lock et al, 1990; Gryboski, 1969; Wolf & Glass, 1992; Wolff, 1968). To achieve safe and efficient oral feeding, infants must coordinate these 3 processes (Bu'Lock et al, 1990; Gryboski, 1969; Krauss et al, 1978; Lau & Hurst, 1999; Lau & Schanler, 1996; Medoff-Cooper et al, 1993; Timms et al, 1993). Sucking requires the integration of muscular activities of the lips, cheeks, jaws, tongue, and palate. There are two types of sucking: non-nutritive and nutritive. Non-nutritive sucking is described as sucking activity without the ingestion of nutrients. Nutritive sucking involves the ingestion of nutrients (Conway, 1994; Hack et al, 1985; McGowan et al, 1991; Medoff-Cooper et al, 1993; Meyer-Palmer, 1993; Sameroff, 1968; Wolff, 1968). Non-nutritive sucking normally has a higher sucking rate (2 sucks/second) than nutritive sucking (1 suck/second) (Wolff, 1968). During nutritive sucking, the bolus of fluid is obtained from either alternation of suction and expression or expression only (Lau et al, 1997). Suction is described as the negative intra-oral pressure created by lowering of the jaw and tongue to draw milk out.

Expression is believed to be the stripping/compression of the nipple between the tongue and the hard palate (Ardran et al, 1958; Colley & Creamer, 1958; Dubignon & Campbell, 1969; Eishima, 1991; Kron et al, 1963; Sameroff, 1968; Wolff, 1968). Swallowing is the mechanism by which the bolus of food is transported from the mouth into the pharynx and down to the esophagus. It is a complex process that requires the integration and precise timing of the muscles of the mouth, pharynx, larynx, and esophagus (Lau & Hurst, 1999; Lau & Schanler, 1996; Wolf & Glass, 1992). Respiration is interrupted during swallowing as a safeguard against aspiration (Lau & Hurst, 1999; Lau & Schanler, 1996; Logan & Bosma, 1967; Wolf & Glass, 1992).

Several studies have investigated the development of sucking in the fetus, full term and preterm infant. There is evidence to suggest that the oral motor and sensory systems develop in utero. The fetus first responds to touch in the peri-oral area at 7-½ weeks GA (Ross, 1984). By 11 weeks GA swallowing movements occur when the lips are touched. Swallowing and sucking are seen at 17-18 weeks GA (Dubignon et al, 1969; Ross, 1984). By 29 weeks GA a stimulus to the lips elicits sucking movements (Gryboski, 1965; Ross, 1984). The anatomical and neurological development of the components involved in sucking, swallowing, and breathing are almost fully mature at term. Thus, healthy full term infants are able to organize the coordination of suck-swallow-breathe within a few days after birth (Brake & Fleischman, 1988; Conway, 1994; Gryboski, 1969; Kramer, 1985; Krauss et al, 1978; Pollit et al, 1981; Ramsay & Gisel, 1996). The sequence of suck-swallow-breathe generally occurs in a synchronized manner in a 1:1:1 or 2:2:1 ratio (Bamford et al, 1992; Bu'Lock et al, 1990; Comrie & Helm, 1997; Koenig et al, 1990).

During oral feedings, full term infants demonstrate an initial period of continuous sucking, with prolonged sucking bursts, followed by a subsequent period of intermittent sucking with multiple swallows (Gryboski, 1969, 1965; Jain et al, 1987). Minute ventilation and oxygen saturations are markedly reduced during the initial continuous sucking phase. However, full recovery occurs during intermittent sucking (Oommen, 1991b; Oommen et al, 1985; Timms et al, 1993). The sucking pattern of full term infants consists of rhythmic alternation of the suction and expression components (Gryboski, 1969, 1965; Jain et al, 1987; Wolff, 1968).

Similar to full term infants, during oral feedings, preterm infants have a continuous period of sucking activity followed by intermitted sucking. In contrast to full term infants, the duration of sucking bursts is shorter, and only partial recovery of minute ventilation occurs during intermittent sucking (Gryboski, 1969, 1965; Jain et al, 1987; Koenig et al, 1990; Kron et al, 1968, 1967; Meyer-Palmer, 1993; Oommen, 1991a, 1988; Shivpuri et al, 1983; Timms at al, 1993; Wolff, 1968). Furthermore, the sucking pattern of preterm infants is not well organized (Lau et al, 1997). Lau et al, (2000) characterized the development of sucking pattern in infants born between 26-29 weeks GA into five stages. These stages are based on the presence/absence and the rhythmicity of the two components of sucking (suction and expression). Significant positive correlations were found between stages of sucking pattern and postmenstrual age. The sucking pattern of preterm infants, who are between 26-29 weeks GA, initially consists of the expression component only. With maturation, these infants demonstrate a more mature sucking pattern with rhythmic alternation of suction and expression, similar to that of full term infants (Lau et al, 2000; Lau et al, 1997). Several studies suggest that the sucking pattern of preterm infants begins to resemble the one of full terms at about 33-34 weeks postmenstrual age (PMA) (Brake & Fleischman, 1988; Hack et al, 1985; Medoff-Cooper et al, 1993; Wolff, 1968). As a result, preterm infants born less than 33-34 weeks GA obtain their nutritional requirement via non-oral feeding methods, such as tube feeding (Brake & Fleischman, 1988; Harris, 1986; Neal, 1995; Weaver & Anderson, 1988). Routinely, it is not until 33-34 weeks PMA that infants are introduced to oral feeding, when the sucking pattern resembles that of full term infants (Braun & Palmer, 1985; Harris, 1986; Lau & Schanler, 1996). Once oral feeding is initiated, the infants are gradually weaned from complete tube feedings to full oral feedings (Braun & Palmer, 1985; Harris, 1986; Neal, 1995; Weaver & Anderson, 1988).

3.2. Oral Feeding Difficulties in Preterm Infants

Some preterm infants make the transition from tube to oral feedings within a few days or weeks. However, those with feeding difficulties may take several months or years to become oral feeders (Bazyk, 1990; Braun & Palmer, 1985; Einarsson-Backes et al, 1993). Preterm infants have an underdeveloped oral musculature of the tongue, soft palate, lips, and cheeks. As a result, they may have less controlled movements of the tongue and jaw, leading to a wide jaw excursion, inefficient tongue compression, difficulty latching on the nipple, and a poor lip seal during sucking (Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Medoff-Cooper et al, 1993; VandenBerg, 1990; Wolf & Glass, 1992). This, in turn, may lead to a disorganized and inefficient sucking pattern thereby affecting their oral feeding performance (Braun & Palmer, 1985; Bu'Lock et al, 1990; Case-Smith et al, 1988; Hack et al, 1985; Jain et al, 1987; Lau et al, 1997; Medoff-

Cooper et al, 1993; VandenBerg, 1990; Wolf & Glass, 1992). Due to their immature cardio-respiratory and central nervous systems, preterm infants also have difficulty coordinating the suck-swallow-breathe sequence (Gardner & Hagedorn, 1991; Oommen, 1991a; Shivpuri et al, 1983; VandenBerg, 1990). This incoordination often leads to episodes of apnea, bradycardia and oxygen desaturations during oral feeding, which can be life threatening (Bragdon, 1983; Casaer et al, 1982; Comrie & Helm, 1997; Krauss et al, 1978; Oommen, 1991a; Shiao et al, 1995). Behavioral state has been found to influence oral feeding performance (Bragdon, 1983; McCain, 1997). Quiet and alert states are optimal for oral feeding (McCain, 1997). The feeding performance of preterm infants is often compromised because they are unable to sustain wakefulness during an entire feeding session (Bragdon, 1983; Case-Smith, 1987; Comrie & Helm, 1997; Kinner & Beachy, 1993; McCain, 1997). Certain medical conditions, such as gastroesophageal reflux, intraventricular hemorrhages, and tachypnea have been found to decrease preterm infants' tolerance to oral feeding (Bazyk, 1990; Bragdon, 1983; Comrie & Helm, 1997; Neal, 1995; VandenBerg, 1990). Several studies report that preterm infants may be aversive or hypersensitive to any stimulation around the oral area (Gardner & Hagedorn, 1991; Harris, 1986; Shiao et al, 1995; VandenBerg, 1990; Vogel, 1986). This may be due to frequent subjection to invasive medical procedures, such as suctioning of secretions and the use of tape on the face to hold the feeding tube and/or endotracheal tube in place (Anderson, 1986; Anderson & Auster-Liebhaber, 1984; Arens & Reichman, 1992; Gardner & Hagedorn, 1991; Harris, 1986; Shiao et al, 1995; Singer et al, 1996; VandenBerg, 1990). Several studies have suggested that the non-oral feeding methods, such as tube feedings (via the mouth or nose) may produce a constant aversive stimulus in the oral, pharyngeal and/or esophageal areas to which the infant may develop an excessive aversion or hypersensitivity (Bazyk, 1990; Gardner & Hagedorn, 1991; Harris, 1986; Pridham et al, 1992; Procter et al, 1998; Shiao et al, 1995). The oral feeding session may be stressful to a preterm infant (Gardner & Hagedorn, 1991). Customarily, oral feeding involves a positive interaction between the infant and the caregiver. Preterm infants in the neonatal intensive care unit are physically separated from their mothers, have multiple caregivers, and are exposed to bright lights and loud noises from medical equipment. These factors have been identified as potential contributors to the distress and irritability that infants manifest during oral feedings (Als, 1986; Anderson, 1986; Anderson & Auster-Liebhaber, 1984; Einarsson-Backes et al, 1993; Frank et al, 1991; VandenBerg, 1990).

The short-term effect of these oral feeding difficulties is that they interfere with the transition from tube to oral feeding, negatively affect the parent-infant bonding, and delay discharge from the hospital (American Academy of Pediatrics, 1998; Bazyk, 1990; Braun & Palmer, 1985; Holditch-Davies et al, 2000; Meyer et al, 1994; Singer et al, 1996; Trachtenbarg & Golemon, 1998). However, if they are not resolved they may have severe long-standing consequences, such as inability to breast/bottle feed, inability to make the transition to solid foods, refusal to accept any oral feeding (liquid or solid), growth retardation, and failure to thrive (Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Harris, 1986; Illingworth & Lister, 1963; Senez et al, 1996).

3.3. Current Therapeutic Management

The current practice in the management of oral feeding problems is to consult feeding specialists when the problems have become clinically significant (Bazyk, 1990; Harris, 1986; Vogel, 1986). Feeding specialists evaluate the infant to identify the underlying problem and then develop individual treatment plans (Harris, 1986; Wolf & Glass, 1992). Various intervention strategies have been developed to facilitate the transition from tube to oral feeding and to promote normal oral development. The most common treatment strategies include: 1) providing sensori-motor input, such as cheek/chin support, tactile/kinesthetic stimulation, and non-nutritive sucking; 2) providing appropriate positioning and handling; 3) assessing different nipple characteristics, such as rigidity and flow rate; 4) controlling the environment, such as noise and light level (Anderson, 1986; Case-Smith, 1989, 1987; Harris, 1986; Kinner & Beachy, 1993; Lau & Hurst, 1999; VandenBerg, 1990; Vogel, 1986; Wolf & Glass, 1992). There is some evidence that these methods are effective (Case-Smith, 1989; Comrie & Helm, 1997; Dieter & Emory, 1997; Einarrson-Backes et al, 1993). However, the current practice is not satisfactory. At the time when feeding specialists are consulted there is great pressure by the medical staff to discharge the infant as soon as possible. This requires the infant to be rapidly transitioned to independent oral feeding. However, by this time oral feeding problems are already established and treatment, using these techniques is a slow process, entailing frequent and prolonged interventions (Einarsson-Backes et al, 1993; Harris, 1986; Vogel, 1986; Wolf & Glass, 1992). Feeding specialists are recognizing the need to change the current practice, so that they start intervening earlier, prior to the start of oral feeding (Bazyk, 1990; Comrie & Helm, 1997; Harris, 1986; Vogel, 1986).

3.4. Early Intervention Strategies-Theoretical Framework

The rationale for providing early intervention, such as oral stimulation is to maintain and facilitate the development of existing rudimentary skills and to prevent or minimize the deleterious effects of the environment (Dieter & Emory, 1997; Harrison, 1985; Korner, 1990; Leib et al, 1980; McCarton et al, 1996; Mueller, 1996; Ross, 1984; Schaeffer, 1982). As previously described, the oral sensory and motor systems develop in utero (Gryboski, 1965; Ross, 1984). The normal maturation process of these skills is disrupted by preterm birth. Furthermore, early exposure to noxious stimuli and deprivation of consistent positive human contact has a negative impact on the development of oral-motor skills (Anderson, 1986; Anderson & Auster-Liebhaber, 1984; Catlett & Holditch-Davis, 1990; Cole & Frappier, 1985; Comrie & Helm, 1997; Kramer et al, 1975; Leib et al, 1980; Ottenbacher et al, 1987; Parmelee, 1985; Ross, 1984; Schaeffer, 1982).

The beneficial effects of early sensory stimulation in animal models (e.g., rat) are well established. Several studies have demonstrated that physical contact with the young in the immediate postnatal period is essential for normal growth and development in the rat pup (Evoniuk et al, 1979; Pauk et al, 1986; Schanberg & Field, 1987; Wang et al, 1996). Disruption of the mother-infant bonding causes marked behavioral and physiological changes (Dieter & Emory, 1997; Evoniuk et al, 1979; Schanberg & Field, 1987; Wang et al, 1996). These range from a reduction in ornithine decarboxylase (ODC), an index of cell growth and differentiation, to growth retardation and developmental delay. Several studies found that simulating the tongue-licking behavior of the mother, by stroking the pup with a foam paint brush, reversed the above adverse effects (Pauk et al, 1986; Schanberg & Field, 1987; Schanberg et al, 1984). These findings suggest that early sensory stimulation can elicit physiological responses which are essential for proper growth and development of the rat pup. A parallel may be drawn with the human model as preterm infants in the neonatal intensive care unit are physically separated from their mother for a prolonged period of time. As a result, they are deprived of the continuous positive and nurturing contact that healthy infants are regularly exposed to (Field et al, 1986; Korner, 1990; Ross, 1984; Scarr-Salapatek & Williams, 1973; Schaeffer, 1982). Although studies on human infants are less definitive, growth failure, failure to thrive, and developmental delay are common problems in the preterm population. Inadequate and inappropriate stimulation have been implicated as contributors to these problems (Anderson, 1986; Anderson & Auster-Liebhaber, 1984; Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Korner, 1990; Schanberg & Field, 1987; VandenBerg, 1990). The notion that early sensory stimulation has beneficial effects for preterm infants is supported by several studies. These studies have shown that stimulation of any type (e.g., tactile, kinesthetic, oral, and vestibular stimulation) leads to improved outcomes, such as increased weight gain, increased alertness and better performance on developmental assessments (Field, 1995, 1988, 1986, 1980; Field et al, 1987; Kramer et al, 1975; Kuhn et al, 1991; Leib et al, 1980; Rausch, 1981; Rose et al, 1980; Scafidi et al, 1993; Scarr-Salapatek & Williams, 1973; Schaeffer, 1982; White-Traut et al, 1997). These studies lend support to the premise that oral stimulation has beneficial effects on oral feeding performance (Dipietro et al, 1994; Einarsson-Backes et al, 1993; Field & Goldson, 1984; Field et al, 1982; Gaebler & Hanzlik, 1996; Leonard et al, 1980; Measal & Anderson, 1979).

3.5. Review of Oral Stimulation Studies

Oral stimulation is defined as acts which activate the muscles of the oral structures (Ross, 1984). Non-nutritive sucking on a pacifier and stimulation of oral structures via stroking with fingers are the two most commonly used oral stimulation strategies (Bernbaum et al, 1983; Gaebler & Hanzlik, 1996; Measel & Anderson, 1979).

Substantial evidence supports the notion that non-nutritive sucking is an effective strategy to help improve oral feeding performance in preterm infants. Several studies have shown that non-nutritive sucking during tube feeding promotes earlier readiness for bottle feeding, accelerates the transition from tube to independent oral feeding, and enhances the maturation of the sucking reflex (Bernbaum et al, 1983; Field et al, 1982; Measel & Anderson, 1979; Sehgal et al, 1990). Bernbaum et al, (1983) reported that infants who received non-nutritive sucking demonstrated more organized sucking bursts and a higher sucking rate than those who did not. Non-nutritive sucking is an intervention that may also assist preterm infants in achieving physiological homeostasis during oral feeding (Gill et al, 1988; McCain, 1995; Paludetto et al, 1986, 1984; Pickler et al, 1991; Shiao et al, 1997; Woodson & Hamilton, 1986). Investigators report that non-nutritive sucking stabilizes the heart rate and increases oxygen saturation during oral feedings (Burroughs et al, 1978; Paludetto et al, 1986, 1984; Pickler et al, 1991; Shiao et al, 1997; Woodson & Hamilton, 1986). This is supported by the observation that non-nutritive sucking reduces the occurrence of bradycardia and oxygen desaturations (Burroughs et al, 1978; Pickler et al, 1991; Shiao et al, 1997). Non-nutritive sucking is also an effective method for improving behavioral state organization (Gill et al, 1988; McCain, 1995; Pickler et al, 1991). Infants provided with non-nutritive sucking demonstrated more optimal behavioral states, such as increased quiet awake states, increased alertness, decreased restlessness and decreased fussiness during oral feeding, than those who did not receive the interventions (Gill et al, 1988; McCain, 1995; Pickler et al, 1991). In addition, there is some evidence that non-nutritive sucking may lead to earlier hospital discharge and decrease the occurrence of medical complications such as patent ductus arteriosus and necrotizing enterocolitis (Bernbaum et al, 1983; Field et al, 1982; Measel & Anderson, 1979; Pickler & Terrel, 1994; Sehgal et al, 1990). There is no consensus on the effect of weight gain, gastrointestinal transit time, and release of gastrin, insulin and somatostatin hormones (Bernbaum et al, 1983; Curtis et al, 1986; Dipietro, 1994; Ernst et al, 1989; Field et al, 1982; Kanarek et al, 1991; Marchini et al, 1987; Measel & Anderson, 1979; Sehgal et al, 1990; Widstrom et al, 1988).

The effect of oral stimulation via stroking the oral structures on the oral feeding performance of preterm infants has been investigated in several studies. Although different oral stimulation strategies were used, beneficial effects on the oral feeding performance were found. Leonard and colleagues (1980) examined the effect of providing touch-pressure stimulation to the oral musculature via stroking the cheeks during an oral feeding session and reported an enhanced sucking rate. Einarsson-Backes et al, (1993) demonstrated an increase in volume intake when oral support via cheek and chin support was provided during an oral feeding. Furthermore, oral support provides stability to the jaw during sucking and does not interfere with cardiopulmonary functions, such as respiratory rate, heart rate, and oxygen saturation (Hill et al, 2000). Gaebler & Hanzlik, (1996) investigated the effects of a specific oral stimulation program, which consisted of stroking the cheeks, lips and gums for 2 minutes, 3 times per day until oral feeding was initiated. Preterm infants who received the oral stimulation program required fewer tube feedings, scored better on the neonatal oral motor assessment scale; which assesses sucking ability (Braun & Palmer, 1985), had greater weight gain, and had fewer days of hospitalization (Gaebler & Hanzlik, 1996). Appendix A provides a table describing each of these studies in more details.

Across all studies there is considerable evidence that oral stimulation via non-nutritive sucking or sensori-motor input to the oral structures has beneficial effects on the oral feeding performance of preterm infants. However, several limitations in these studies have been identified. The majority of the investigations lack a theoretical rationale for selecting the specific type and quantity of stimulation. Most studies do not provide an explanation of the mechanisms behind the beneficial effects that were observed. Studies that carried out a randomized trial did not provide a sham intervention to the control group. Without a sham intervention program results can be biased because the extra human contact that the experimental group received from the intervention may be a factor that influenced the results. The sample size in most studies was small, thus generalization of results is limited. The range of gestational age and birth weight within the samples are large in most studies. These samples were generally treated as homogeneous groups and the large differences in level of maturity were not considered when statistical analyses were conducted. Studies that investigated the effect of oral stimulation via sensori-motor input to oral structures were carried out on infants who were older than 30 weeks of GA. Furthermore, in all these studies, except for that of Gaebler and Hanzlik (1996), the intervention was provided when subjects were already feeding orally. Thus oral feeding problems may have been established already. These studies demonstrate that oral stimulation is an effective treatment strategy to enhance oral feeding performance. However, knowledge is lacking on the effect of oral stimulation as an early intervention strategy, prior to onset of oral feedings, in preterm infants who are less than 30 weeks GA.

3.6. Summary and Significance of the Literature Review

1) With the increasing survival rate of preterm infants born less than 29 weeks GA, oral feeding difficulties have become a growing concern to health professionals because of their impact on infants' ability to reach independent oral feeding and the resulting delay in hospital discharge.

2) The current practice for treating oral feeding difficulties is not efficient. Rudimentary sucking skills are present in preterm infants. Feeding specialists are recognizing the importance of starting interventions before oral feeding is initiated in order to further develop existing skills.

3) Animal and human studies have shown that early sensory stimulation has beneficial effects on growth and development. More specifically, early oral sensory stimulation has been shown to enhance oral feeding performance of preterm infants older than 30 weeks GA.

4) There is no knowledge on the effect of early oral stimulation on the oral feeding performance in preterm infants who are less than 30 weeks GA.

4. RATIONALE

With the increasing survival rate of preterm infants less than 29 weeks GA, oral feeding difficulties will continue to be prominent in this population (Emsley et al, 1997; Kilpatrick et al, 1997). Oral feeding difficulties are not solely due to the infant's neurological and structural immaturity. It has been proposed that frequent aversive stimuli around the mouth (e.g., suctioning of secretions), negative environmental stimuli in the neonatal intensive care units (e.g., bright lights and loud noises) and the early physical separation from the mother may also contribute to these problems (Als, 1986; Gardner & Hagedorn, 1991; VandenBerg, 1990). Infants born less than 29 weeks GA are more immature, have longer periods of separation from their mothers and have greater exposure to factors contributing to oral feeding difficulties than infants who are older than 29 weeks GA. Thus, it is conceivable that infants less than 29 weeks GA are more likely to encounter oral feeding difficulties. The impact that early oral feeding difficulties may have on breast/bottle feeding ability, length of hospital stays, and parental attachment makes it increasingly critical to prevent such problems and to facilitate more normal development (Bazyk, 1990; Comrie & Helm, 1997; Harris, 1986). Several studies have demonstrated that oral stimulation has beneficial effects on oral feeding performance (Einarsson-Backes et al, 1993; Gaebler & Hanzlik, 1996; Hill et al, 2000; Leonard et al, 1980). However, the majority of these studies were carried out on medically stable preterm infants greater than 30 weeks GA. Furthermore, oral feeding problems may already be established because the intervention was provided concomitant with oral feedings. With the increased focus on prevention, studies that examine the effect of early oral stimulation on preterm infants less than 30 weeks GA are needed.

Taking all of the above factors into consideration, we propose that the introduction of an oral stimulation program, before oral feedings are initiated, will facilitate the development of sucking skills in preterm infants, between 26-29 weeks GA, resulting in a faster transition from tube to oral feedings.

5. HYPOTHESES

The following hypotheses are advanced:

Preterm infants, between 26-29 weeks GA, who receive a specific prefeeding oral stimulation program, will demonstrate better oral feeding performance than those who do not receive the intervention. More specifically,

1) They will attain independent oral feeding sooner, and as a result will be discharged earlier from the hospital than the control group.
2) They will demonstrate an enhanced rate of milk transfer and greater overall intake than the control group.
3) They will develop a mature sucking pattern more rapidly than the control group.

6. RESEARCH DESIGN

A randomized clinical trial was carried out to assess the efficacy of a prefeeding oral stimulation program on the oral feeding performance of preterm infants.

7. MATERIALS and METHODS

7.1. Sample

A total of 32 "healthy" preterm infants (13 males, 19 females) participated in the study. Infants were enrolled if: 1) they were born between 26 to 29 weeks GA as determined by obstetrical ultrasound and clinical exam; 2) they were of appropriate size for their gestational age (AGA); 3) they were receiving tube feedings, and 4) they did not have any chronic medical complications, such as bronchopulmonary dysplasia (BPD), intraventricular hemorrhage grades III & IV (IVH), necrotizing enterocolitis (NEC), and congenital anomalies (e.g., oral, heart, etc.).

Sampling Frame: All subjects were recruited from the neonatal intensive care unit at Texas Children's Hospital (TCH). TCH is a tertiary care hospital in Houston, TX, USA. It is one of the largest pediatric centres in the United States. The neonatal intensive care unit (i.e., level 3 care) consists of 68 beds, and the infant care unit (i.e., level 2 care) consists of 76 beds. A large variety of infant conditions are treated in this centre, ranging from "healthy" to extremely ill preterm and full term infants. The Institutional Review Board for Human Subject Research of Baylor College of Medicine and Affiliated Hospitals approved the research protocol (Appendix B). Written consent to participate was obtained from parents prior to entry into the study (Appendix C).

7.2. Standard Care Management of Preterm Infants at TCH

At TCH, all infants born less than 30 weeks GA receive mechanical ventilation via an endotracheal tube (ET), placement of umbilical venous and arterial catheters, sedation with phenobarbital and morphine, placement of an orogastric tube, and if indicated clinically, artificial surfactant. The infants are not subjected to adverse stimuli such as routine tracheal suctioning or weighing during the time of "minimal stimulation" (i.e., the first 3 to 7 days of life). The procedures are designed to prevent fluctuating vascular pressure and apnea which may increase the risk of intraventricular hemorrhage.

As respiratory status improves, the infants are weaned from the mechanical ventilator and switched to continuous nasal positive airway pressure (NCPAP). If this is tolerated, the infants are gradually weaned from NCPAP to a nasal cannula and then to breathing on their own.

With regards to the management of feeding, the attending neonatologist is responsible for the management of both tube and oral feedings (i.e., initiation and advancement of feedings). Nurses are responsible for feeding the infant if the parents are not available. Routinely, infants are on tube feedings until they reach 33 to 34 weeks PMA, at which point oral feedings are usually initiated. The neonatologist prescribes one oral feeding per day, the other feedings are taken via the tube. There are 3 criteria for a safe and successful oral feeding: 1) the infant has to take the prescribed amount of formula and/or breast milk within an allocated time, usually 20 minutes; 2) the infant has no episodes of apnea, bradycardia, and oxygen desaturations during the oral feeding, and 3) the infant shows adequate daily weight gain, approximately 15-20 grams/kg/day. If the infant meets all these criteria, oral feedings are advanced according to the attending neonatologist's discretion. The process of weaning from tube to oral feedings will continue until the infant is able to take all of the required volume of formula and/or breast milk in eight oral feedings per day, at three-hour intervals.

Preterm infants are discharged from the hospital when all of the following criteria are met: 1) the infant is medically stable; 2) the infant is able to maintain his/her body temperature while in an open crib; 3) the infant has attained independent oral feeding, and 4) the infant has an adequate weight gain of 15-20 grams/kg/day.

7.3. Study Variables

The intervention consisted of either a prefeeding oral stimulation program or a sham stimulation program. The primary outcome variable was time to attainment of independent oral feeding. The secondary outcome variables were overall intake, rate of milk transfer, maturation of sucking, and length of stay at the hospital. Covariates were gestational age, birth weight, behavioral states, co-interventions, and breastfeeding.

7.4. Intervention:

7.4.1. Prefeeding Oral Stimulation Program: The prefeeding oral stimulation program consisted of peri-oral and intra-oral stimulation of oral structures. It was a 15 minutes stimulation program, whereby the first 12 minutes involved stroking the cheeks, lips, gums and tongue; and the final 3 minutes consisted of sucking on a pacifier (Appendix D). This program was based on Beckman's principles (Workbook of training program, 1998). The prefeeding oral stimulation program was initiated 48 hours after the NCPAP was discontinued. It was administered once per day for 10 consecutive days, 15-30 minutes prior to a tube feeding. The choice of this regimen was based on studies using tactile, kinesthetic, or vestibular stimulation which demonstrated that a total of 15 minutes per day for 10 days of stimulation leads to a positive effect on weight gain, alertness, and increased food intake (Harrison et al, 1996; Raush, 1981; White-Traut & Goldman, 1988). The stimulation was provided in the afternoon (after 12:00 pm) because the medical rounds in the units routinely occurred in the mornings. Thus, the units were quieter and more conducive to our research protocol. A screen was placed around the infant's isolette so as to blind the nurses and family members to group assignment. A note indicating the time when the intervention would occur was placed on the front of the chart and on the isolette to ensure that the nurses did not start tube feeding before the program was given.

The program was administered by the researcher, who is an occupational therapist trained in providing this technique. To minimize the possibility of infection, the researcher washed her hands with a synthetic brush and wore gloves for each stimulation session. Prior to commencing the program, the researcher positioned the infant in supine in the isolette and ensured that the infant was in an optimal state to receive the program. Studies have shown that the optimal state to provide any stimulation was either quiet alert or active alert (Als, 1986). If the infant was sleeping or crying, the researcher provided arousal or containment techniques, respectively, in an attempt to induce the optimal state. The infant's state at the start of the session was recorded using the Assessment of Preterm Infant's Behavior State Scale (Appendix E) as adopted from the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) (Als, 1995; Als et al, 1982). The scale has been validated (Als, 1995; Als et al, 1982). The researcher also recorded the time at which the intervention was provided and any interruptions of a session (Form is appended, appendix F). To ensure that the program was not stressing the infant, it was delayed and/or terminated if: 1) the infant was stimulated or disturbed 30 minutes prior to the program (e.g., heel stick procedure, ophthalmologic examination); 2) the infant was medically unstable (e.g., respiratory distress, fever); 3) the therapist was unable to induce the optimal state at the start of the session after trying for 5 minute, and/or 4) the infant had any episode of apnea, bradycardia, or oxygen desaturation during the intervention. Any session that was delayed and/or terminated, was made up at a later time after a minimum of a 3-hour interval, or was cancelled for that day and taken up the next day.

7.4.2. Sham Stimulation Program: The sham stimulation program was identical to the prefeeding oral stimulation program with the exception that infants did not receive the 15 minutes of oral stimulation. A screen was placed around the bedside to ensure blinding of parents and caretakers with respect to the type of intervention the infants received. The infants were placed in supine position, and the researcher placed her hands in the isolette, but did not touch the infant. The researcher observed the infant for 15 minutes. The frequency, duration, and criteria for delaying or terminating the session were similar to the prefeeding oral stimulation program.

7.5. Primary Outcome Variable:

7.5.1. Time to attainment of independent oral feeding: This was defined as the number of days necessary to transition from complete tube feeding to independent oral feeding. This included the first day oral feeding was initiated up until eight oral feedings were achieved for two consecutive days. This was selected as the primary outcome because it is one of the criteria for hospital discharge. For the purpose of this study, two milestones prior to reaching this outcome were also monitored. These were defined as the number of days to reach one and four successful oral feedings per day.

7.6. Secondary Outcome Variables:

7.6.1. Overall Intake: This was defined as the percent volume transferred during an entire feeding session over the prescribed volume to be taken. The volume taken was measured by taking the difference in the weight of the bottle at the start and end of the oral feeding session. This is based on the density of breast milk and formula being about 1.011 grams, approximating that of water (1 gram = 1 cc).

7.6.2. Rate of Milk Transfer: This was defined as the volume transferred per unit time (ml/min) during an oral feeding session.

7.6.3. Maturation of Sucking: A study by Lau et al, (2000) characterized the development of sucking in infants born between 26-29 weeks GA. They identified five stages of sucking based on the presence and/or absence of suction, expression, duration of sucking bursts and the amplitude of the suction component (Appendix G). Briefly, stage 1 consists primarily of arrhythmic expression with no suction (stage 1a) and/or infrequent appearances of arrhythmic suction (stage 1b). Stage 2 includes emergence of rhythmic expression alone (stage 2a) and/or the appearance of arrhythmic alternation of suction/expression suction. Stage 3 consists of sustained rhythmic expression alone (stage 3a) and/or some rhythmic alternation of suction and expression with longer sucking bursts and stronger suction amplitude. Stage 4 and 5 includes rhythmic alternation of suction and expression, with stage 5 demonstrating greater suction amplitude and longer duration of sucking than stage 4. Significant positive correlations were observed between the five stages of sucking and postmenstrual age, overall intake, rate of milk transfer, and the number of daily oral feedings (Lau et al, 2000). At present, this is the only scale available to measure the maturation of sucking pattern. Thus, this scale was used to assess the maturation of sucking. The entire oral feeding session was scored. A score of 1 through 5 was given for each sucking burst frame based on the above characteristics. Sucking pauses greater than 1.5 seconds delineated the beginning and end of a sucking burst. The primary stage of sucking demonstrated by infants during the first 5 minutes, the remaining 5-20 minutes and the entire (20 minutes) oral feeding session was calculated as the weighted average of stages 1-5. As shown in the formula below:

$$\text{Weighted Average} = \frac{(\%\text{ stage } 5 \times 5) + (\%\text{ stage } 4 \times 4) + (\%\text{ stage } 3 \times 3) + (\%\text{ stage } 2 \times 2) + (\%\text{ stage } 1 \times 1)}{100}$$

% Stage: Percent time of each sucking stage occurring over the entire feeding time.
5,4,3,2,1: Weight assigned to the respective stages of sucking.

The first five minutes were scored because fatigue was assumed to be minimal. The remaining 5-20 minutes and entire (20 minutes) oral feeding session were scored because it is a reflection of infants' sucking skill with the fatigue component included.

The oral motor kinetic (OMK) apparatus, developed by Lau & Schanler, (1996) was used to measure sucking pattern (Appendix H). This system uses nipples that are available in the nurseries. The suction component was monitored from a Mikro-tip sensor transducer (Millar Instruments, Houston, TX) inserted through a catheter (PE200) flush to the tip of the nipple without protruding into the infant's mouth. The expression component was monitored via another Mikro-tip sensor inserted through a silastic catheter to 0.5 cm. from the tip of the nipple. For proper recording of the expression component, care was taken so that the silastic portion of the catheter and transducer was always positioned downward on the midline of the tongue. The transducers were connected to a Biopac MP 100 WSP system (Biopac Systems, Inc., Santa Barbara, CA) which was linked to a laptop computer. Suction and expression were monitored directly on the computer screen providing a direct feedback to the researcher during the course of the study. Data were stored for later analyses using the Acqknowledge software program included with the Biopac system.

7.6.4. Length of Stay: This was defined as the time from day of birth to discharge from the hospital. Delay in hospital discharge was also recorded. It was defined as infants who remained in the hospital for greater than seven days from the time they achieved independent oral feeding. Seven days was selected because it was considered a sufficient amount of time to plan discharge.

7.7. Covariates:

7.7.1. Gestational Age: This was defined as the length of time in weeks from conception to day of delivery. This was determined by obstetrical ultrasound and clinical exam. If a difference of greater than two weeks were noted between the two methods, gestational age was determined using the clinical exam.

7.7.2. Birth Weight: This was defined as the weight at birth in grams. As part of standard procedures, all infants are weighed in the nude. These data were obtained from the medical chart.

7.7.3. Behavioral State: The infants' state was measured at the start, 5 minutes and at the end (20 minutes) of the oral feeding sessions. The researcher used the APIB state scale as adopted from NIDCAP to assess the infants' state (Als, 1995; Als et al, 1982).

7.7.4. Co-interventions: This was defined as the number and duration (in minutes) of occupational and physical therapy sessions that infants received in addition to the stimulation program. The researcher reviewed the medical charts daily to gather this information.

7.7.5. Breastfeeding: The number of breastfeeding sessions that infants received was noted. The researcher obtained this information from the medical charts. As part of standard procedures, nurses record the type (breast or bottle) of oral feedings infants receive for each session.

7.8. Procedures

The researcher identified potential participants from a computer list that contained the name, date of birth, and bed number of all new admissions to the neonatal intensive care unit. This list is produced on a daily basis as part of standard procedures at the hospital. The researcher reviewed the charts of all potential candidates. When the infants who met the inclusion criteria were medically stable, as determined by the attending physician, the principal investigator (Chantal Lau, Ph.D.) and the researcher approached the parents of all potential subjects to obtain written consent. The reasons for non-participation were noted from those who refused to participate.

After written consent was obtained, each infant was randomized into the control or experimental group using a stratified blocked randomization method with a block size of four. Stratification on gestational age (26-27 weeks GA vs. 28-29 weeks GA) was used to ensure that the two groups had similar gestational age distribution. Baseline data were gathered (Form is appended, appendix I), such as gestational age, birth weight, Apgar scores, gender, ethnicity, number of days on oxygen, number of days on tube feedings prior to the start of oral feedings, and occurrence of gastroesophageal reflux on all candidates. These were collected to ensure that both groups were similar with regards to baseline characteristics and health status.

After randomization, preterm infants were discontinued from the study if they: 1) developed chronic medical problems, such as BPD, NEC, IVH grades III & IV; 2) developed medical instability, such as sepsis and respiratory distress for greater than 7 consecutive days, and/or 3) had their oral/tube feedings discontinued due to medical instability for greater than 7 consecutive days.

In addition to standard care management, infants in the control group received the sham stimulation program and those in the experimental group received the prefeeding oral stimulation program. Both interventions were started 48 hours following discontinuation of NCPAP.

Both groups were monitored from the time of entry into the study until hospital discharge. The outcome variables were measured at specific time points throughout the study. Time to attainment of independent oral feeding was considered attained the first time an infant reached 8 oral feedings per day for two consecutive days. Overall intake, rate of milk transfer and maturation of sucking were monitored for three oral feeding intervals, once when the infant was taking 1-2, 3-5, and 6-8 oral feedings per day. In addition, specific information on the postmenstrual age, weight, gastric residuals (remaining undigested nutrient in the stomach), oxygen requirement during oral feedings, volume taken, duration of the feeding session (in minutes), behavioral state of the infant, and any episodes of apnea/bradycardia or oxygen desaturations were gathered at these 3 oral feeding sessions because of the potential impact on the outcomes (Form is appended, appendix J). The initiation and advancement of oral feedings was left to the discretion of attending physician who was blind to group assignment.

7.9. Statistical Analyses

A sample size of 32 was calculated based on a type I error of 0.05 and a power of 0.80. Sample size estimation was based on the primary outcome, time to attainment of independent oral feeding. Sample size estimation were derived from a review of 62 "healthy" preterm infants born less than 29 weeks GA, from March 1998 to March 1999, at TCH. From the review the mean transition time from tube feedings to independent oral feedings was 14 days with a standard deviation of 8 days. A decrease of 8 days (i.e., 1 SD) in the attainment of independent oral feeding was considered a clinically significant effect of the stimulation program as it may reduce hospital stay.

Descriptive statistics were used to determine whether infants in both groups were similar with regards to baseline characteristics. To assess whether both groups had similar distribution of covariates an independent groups t-test was used.

To examine the effect of the prefeeding oral stimulation program versus the sham stimulation program on mean time to achieve the defined oral feeding milestones (i.e., 1, 4 and 8 successful oral feedings/day) and on the mean length of stay, an independent groups t-test was used.

To determine the effect of the intervention on overall intake, rate of milk transfer, and maturation of sucking stages over time an unbalanced repeated measures analysis of variance was used. Analyses were carried out using the BMDP5V statistical program. A fully parameterized covariance structure was used for errors. Upon detection of a statistically significant interaction between time and group effect, separate univariate post-hoc analyses with independent groups t-test was used to assess differences between groups at specific times.

To compare the number of infants who completed their oral feedings at the three time periods (1-2, 3-5, 6-8 oral feedings/day), as well as the postmenstrual ages when they achieved independent oral feeding a Fischer Exact test was used.

All hypothesis testing was carried out at a 0.05 level of significance.

8. RESULTS

8.1. Subject Characteristics

A total of 38 parents were approached to obtain consent. Four parents refused to participate because they did not want any supplemental intervention for their infants. After randomization, two infants were excluded because of medical instability (sepsis). The infants were in different study groups (1 experimental, 1 control). Hence, elimination of their outcomes from the statistical analysis would not bias results. A total of 32 infants completed the study. The characteristics of the 32 infants (16 experimental, 16 control) are shown in Table 1. Both groups were comparable for gestational age, birth weight, Apgar scores, gestational age distribution and gender distribution. Ethnicity was not equally distributed between the two groups. There was a substantially greater number of Hispanic infants in the experimental group and a greater number of Caucasian infants in the control group. To the author's knowledge there is no evidence that race may affect oral feeding performance. Thus, this imbalance is not likely to bias results. Specific variables related to infants' health status were compared between the two groups. There was no difference in number of days of oxygen requirement ($p = 0.296$), number of tube feedings received prior to the start of oral feeding ($p = 0.547$) and occurrence of gastroesophageal reflux ($p = 0.518$) between the two groups.

Table 1. Subject Characteristics

	Experimental Group (n = 16)	Control Group (n = 16)
Gestational Age Distribution		
26/27 wks GA	6 (38%)	6 (38%)
28/29 wks GA	10 (62%)	10 (62%)
Gestational Age (wks)	28.2 ± 1.3[a] (26.4 - 29.9)[b]	28.1 ± 1.1 (26.0 - 29.7)
Birth Weight (g)	1044 ± 260 (740 - 1500)	959 ± 244 (560 - 1300)
Gender Distribution		
Male	7 (44%)	6 (37%)
Female	9 (56%)	10 (63%)
Ethnic Distribution		
African American	2 (12%)	4 (25%)
Caucasian	5 (32%)	10 (63%)
Hispanic	9 (56%)	2 (12%)
Apgar (5 min)	2 (12%)[c]	2 (12%)

[a] Means $\pm$ SD.
[b] Range.
[c] Number infants scoring < 7.

Results of potential covariates are shown in Table 2. There were no significant differences ($p \geq 0.132$ on all tests) between the experimental and control groups with regards to behavioral state at the start, during and end of the oral feeding session, occurrence of co-interventions, number of breastfeeding sessions, presence of gastric residuals, oxygen requirement and episodes of apnea, bradycardia and/or oxygen desaturations during the oral feedings.

Table 2. Covariates

Covariates	Experimental Group	Control Group	* P Value
Behavioral state score (1 min)	4 ± 1[a]	4 ± 1	0.164
Behavioral state score (5 min)	3 ± 1	3 ± 1	1.000
Behavioral state score (end)	3 ± 1	3 ± 1	0.438
No. of co-interventions	0 ± 0	0.1 ± 0.3	0.375
No. of breastfeeding sessions	0.2 ± 0.6	0.2 ± 0.4	0.966
Infants who had gastric residuals	0 ± 0	0 ± 0	1.000
Infants who required oxygen during the oral feeding	0.2 ± 0.4	0.3 ± 0.5	0.146
Episodes of apnea, bradycardia, &/or O_2 desaturations	0.3 ± 0.5	0.5 ± 0.5	0.132

* Independent groups t-test.
[a] Means ± SD.

8.2. Attainment of Independent Oral Feeding-Oral Feeding Milestones

As a first step, analyses for attainment of independent oral feeding were stratified by gestational age: 26-27 and 28 – 29 weeks GA. No difference in time to attainment of independent oral feeding was noted between groups (p=0.839). Thus, all data from 26-29 weeks GA were pooled. The results of the oral feeding milestones are presented in Table 3. The two groups were introduced to oral feedings at similar postmenstrual ages, days of life, and weight. Infants in the experimental group achieved one successful (p = 0.010), four successful (p = 0.019), and independent (p = 0.005) oral feedings faster than infants in the control group. There was no statistically significant difference between the two groups with regards to postmenstrual age, days of life, and weight at each of these three milestones. Figure 1 shows the percent of infants who attained independent oral feedings at each postmenstrual age. There was no significant difference in the distribution of postmenstrual ages between the two groups (p = 0.558).

Table 3. Oral Feeding Milestones

	Experimental Group	Control Group	* P Value
Introduction to Oral Feeding			
PMA (wks)	34.6 ± 1.7[a]	34.5 ± 1.5	0.880
DOL (days)	46 ± 17	46 ± 16	0.950
Weight (grams)	1666 ± 270	1598 ± 289	0.500
1 Oral Feeding/day			
No. Days	2 ± 2	6 ± 5	**0.010**
PMA (wks)	34.8 ± 1.8	35.4 ± 1.6	0.390
DOL (days)	47 ± 18	51 ± 16	0.541
Weight (grams)	1700 ± 294	1735 ± 353	0.767
4 Oral Feedings/day			
No. Days	8 ± 4	13 ± 6	**0.019**
PMA (wks)	35.7 ± 1.8	36.3 ± 1.6	0.261
DOL (days)	53 ± 18	58 ± 17	0.473
Weight (grams)	1859 ± 328	1936 ± 427	0.572
8 (Independent) Oral Feedings			
No. Days	11 ± 4	18 ± 7	**0.005**
PMA (wks)	36.1 ± 1.8	36.9 ± 1.8	0.193
DOL (days)	57 ± 18	62 ± 17	0.364
Weight (grams)	1928 ± 343	2043 ± 461	0.431

* Independent groups t-test.
[a] Means ± SD.
No. Days: Number of days from introduction to 1, 4, & 8 oral feedings/day.
PMA: Postmenstrual age.
DOL: Days of life.

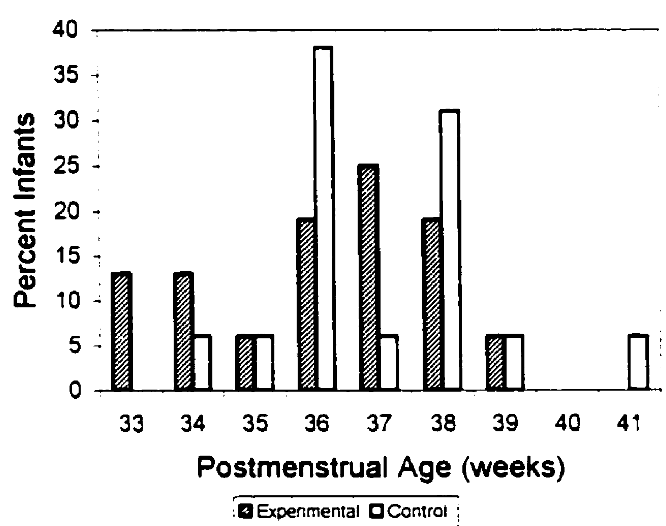

Figure 1. Postmenstrual Ages When Infants Reached Independent Oral Feeding.
Fischer Exact test: p = 0.558.

8.3. Overall Intake

As a first step, analyses of overall intake and rate of milk transfer (described below) were stratified by gestational age: 26-27 and 28-29 weeks GA. No systematic difference in the estimated effect of the interaction between gestational age and group was observed ($p > 0.105$ for all tests). Therefore, all data from 26-29 weeks GA were pooled.

Figure 2 shows the results for overall intake expressed as a percent of volume prescribed. There was no interaction between time and group effect ($p = 0.798$). Significant differences in overall transfer over time ($p = 0.014$) and between groups ($p = 0.0002$) were found with the experimental group demonstrating better overall intake than the control group.

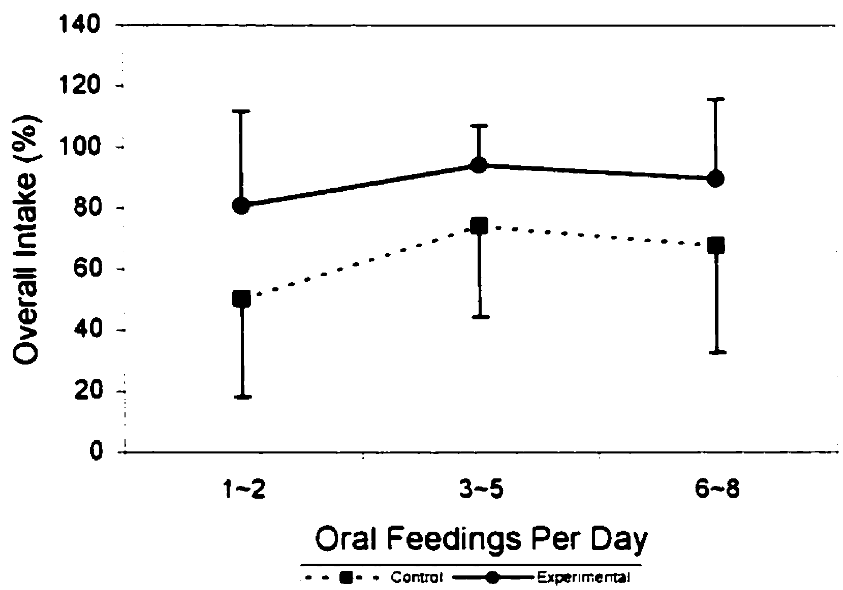

Figure 2. Overall Intake.
Repeated measures ANOVA: Group X Time Interaction $p = 0.798$; Group $p = 0.0002$; Time $p = 0.014$.
Data represent means ± SD.

Table 4 demonstrates the percent of infants who achieved 100% overall intake. A significantly greater number of infants in the experimental group achieved 100% overall intake at the first time point than their control counterparts (p = 0.003). Although the experimental group had a greater percent of infants completing their oral feeding at the second time point, the difference was close to significance (p= 0.066). There was no difference between the two groups at the third time point (p = 1.000). As shown in Table 5, there were no significant differences in the mean duration (in minutes) of oral feeding sessions between the two groups at any of the three time points (p = 0.235, 0.699, 0.775 at 1~2, 3~5, 6~8 oral feedings/day, respectively).

Table 4. Number of Infants Achieving 100% Overall Intake at the Three Time Points Monitored.

Oral feedings per day	Experimental Group (n = 16)	Control Group (n =16)	* P Value
1~2	11 (69%)	2 (13%)	0.003
3~5	13 (81%)	7 (44%)	0.066
6~8	12 (75%)	11 (69%)	1.000

* Fischer Exact test.

Table 5. Duration (minutes) of Oral Feedings

	Experimental Group	Control Group	* P Value
1~2 PO/day	19.43 ± 2.61[a]	17.74 ± 4.73	0.235
3~5 PO/day	18.68 ± 5.21	17.84 ± 5.77	0.669
6~8 PO/day	18.50 ± 3.25	18.92 ± 3.25	0.775

* Independent groups t-test.
[a] Means ± SD.
PO/day: oral feedings per day.

8.4. Rate of Milk Transfer

The results of a repeated measures ANOVA for rate of milk transfer are illustrated in Figure 3. The time by group interaction was not significant ($p = 0.805$). However, time ($p = 0.0001$) and group ($p = 0.046$) effects were statistically significant with the experimental group showing higher rates of milk transfer than the control group.

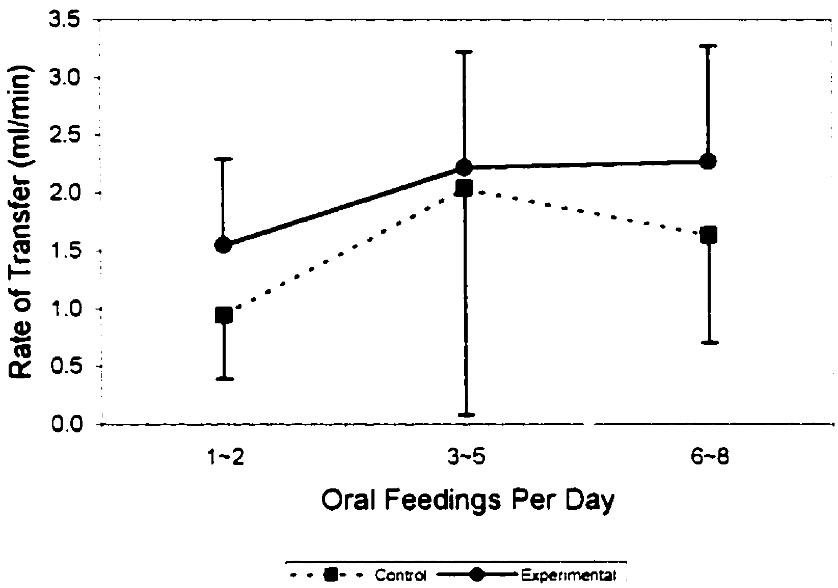

Figure 3. Rate of Milk Transfer.
Repeated measures ANOVA: Group X Time Interaction $p = 0.805$; Group $p = 0.046$; Time $p = 0.0001$.
Data represent means $\pm$ SD.

8.5. Maturation of Sucking

Table 6 illustrates the changes in the stages of maturation of infant's sucking at 5 minutes, 5-20 minutes and 20 minutes at each of the three oral feeding time points. At 5 minutes, the time by group interaction was not significant ($p = 0.165$). The time effect was significant ($p = 0.008$). Although infants in the experimental group had more mature sucking stages than the controls, the group effect was close to significance ($p = 0.068$). At 5-20 minutes, both the time by group interaction ($p = 0.508$) and time effect were not significant (p = 0.436). There was a group effect (p = 0.009) with the experimental group demonstrating overall more mature stages of sucking than the control group. At 20 minutes, the time by group interaction was not significant (p = 0.905) and the time effect was marginally not significant (p = 0.100). There was a group effect (p = 0.026) with the experimental group showing overall a more mature stage of sucking than their control counterparts.

Table 6. Maturation of Sucking Stages at 5, 5-20 and 20 Minutes at Each Oral Feeding Session.[d]

	Experimental Group	Control Group
5 Minutes		
1~2 PO/day	2.5 ± 0.9[a] (1 - 5)[b]	1.9 ± 0.7 (1 - 4)
3~5 PO/day	2.5 ± 0.7 (2 - 5)	2.4 ± 0.5 (1 - 5)
6~8 PO/day	2.9 ± 0.7 (2 - 5)	2.1 ± 0.8 (2 - 5)
5-20 Minutes		
1~2 PO/day	2.0 ± 0.5 (1 - 5)	1.6 ± 0.7 (1 - 4)
3~5 PO/day	2.3 ± 0.7 (2 - 5)	1.6 ± 0.5 (1 - 5)
6~8 PO/day	2.0 ± 0.6 (2 - 5)	1.8 ± 0.6 (1 - 5)
20 Minutes		
1~2 PO/day	2.1 ± 0.6 (1 - 5)	1.6 ± 0.6 (1 - 4)
3~5 PO/day	2.3 ± 0.6 (2 - 5)	1.8 ± 0.7 (1 - 5)
6~8 PO/day	2.2 ± 0.7 (2 - 5)	1.8 ± 0.7 (1 - 5)

Repeated measures ANOVA:
5 Minutes: Group X Time Interaction p = 0.165; Group p = 0.068; Time p = 0.008.
5-20 Minutes: Group X Time Interaction p = 0.508; Group p = 0.009; Time p = 0.436.
20 Minutes: Group X Time Interaction p = 0.905; Group p = 0.026; Time p = 0.100.
[a] Means ± SD.
[b] Ranges.
[d] Sucking stages as defined by Lau et al. 2000.
PO/day: oral feedings per day.

8.6. Length of Stay

The average length of stay at the hospital for the experimental group was 65 days $\pm$ 16 SD and 70 days $\pm$ 22 SD for the control group. Although the experimental group was discharged an average of 5 days sooner, the difference was not statistically significant (p = 0.459). Table 7 lists the reasons for the delay in hospital discharge. There was no statistical difference in the number of infants whose discharge was delayed between the two groups (p = 0.154).

Table 7. Causes for Delay in Hospital Discharge

Causes for Delay	Experimental Group (n = 16)	Control Group (n = 16)
Infection	3[ε]	1
Caretaker not available	2	0
Weight < 2000 grams at discharge	2	1
Twins	1	0
Unstable respiratory status	1	2
Gastroesophageal reflux	0	1
Total *	9 (56%)	5 (31%)

[ε] Number of infants.
* χ^2 p = 0.154

8.7. Prefeeding Oral Stimulation Program

From the 160 stimulation programs that were administered 7 were delayed or terminated and taken up the following day. Four sessions were delayed because infants were disturbed 30 minutes prior to the program; 2 sessions were delayed because infants were medically unstable (tachypnea); and 1 session was terminated because the infant had an episode of bradycardia which resolved spontaneously.

9. DISCUSSION

Preterm infants frequently encounter difficulty with feeding when they are first introduced to oral feeding. Oral stimulation is one intervention strategy that is used to treat oral feeding difficulties. Although oral stimulation has been shown to have beneficial effects on the oral feeding performance of preterm infants, the effects of such a program prior to the commencement of oral feeding on preterm infants who are less than 30 weeks GA are unknown. The objective of this study was to assess whether a prefeeding oral stimulation program enhances the oral feeding performance of preterm infants who are born between 26 and 29 weeks GA.

Results from this study support the hypothesis that a prefeeding oral stimulation program has beneficial effects on the oral feeding performance of preterm infants who are between 26-29 weeks GA. Infants in both groups were introduced to oral feeding at similar postmenstrual ages, days of life and weight. However, the experimental group attained oral feeding milestones, such as one successful, four successful and independent (eight) oral feedings faster than the control group. Studies that assessed non-nutritive sucking and stroking of oral structures similarly reported a more rapid transition to oral feedings for infants who received the intervention (Bernbaum et al, 1983; Field et al, 1982; Gaebler & Hanzlik, 1996; Measal & Anderson, 1979; Sehgal et al, 1990).

There was no significant difference in postmenstrual age, days of life, and weight between both groups when independent oral feeding was achieved. The lack of difference in weight may be due to the standard care procedure at TCH, which involves strict control of infants' weight gain. A neonatal nutritionist reviews daily all medical charts and prescribes the necessary caloric intake to ensure a daily weight gain of 15-20 grams/kg/day. In addition, if the infant does not complete the prescribed volume during the allotted time (20 minutes) to orally feed, the remaining milk/formula is inserted into the feeding tube. The experimental group had greater overall intake than the control group. Hence, if the research protocol included that the remaining milk/formula would not be inserted in the feeding tube a difference in weight might have been noted. The lack of differences in postmenstrual age, days of life, and weight may also be attributed to the large variances. In this study, the management of oral feedings was left to the discretion of the attending neonatologists. Although there are general guidelines for the management of oral feedings, there is no specific protocol for initiating and advancing oral feedings. Thus, the observed variances in these variables may be due to the subjectivity of each attending neonatologist. For instance, some clinicians would not advance oral feedings because they felt the infant was either too young or too small. Therefore, differences in these variables (postmenstrual age, days of life and weight) may become significant if a larger sample size and/or a structured feeding protocol for initiation and advancement of oral feedings were used.

Both groups had similar baseline characteristics and no confounding variables were detected. This negates the possibility that the experimental group achieved oral feeding milestones faster because they were "healthier" and/or more mature than their counterparts. The more rapid transition to independent oral feeding in the experimental group was associated with better oral feeding performance. More specifically, the experimental group demonstrated greater overall intake and rate of milk transfer than the control group. The study of Seghal et al (1990) supports this finding. They noted an increase in sucking efficiency (ml/min) in infants who received 3 minutes of non-nutritive sucking during all tube feedings. The authors speculated that non-nutritive sucking accelerated maturation of sucking. However, no objective measure of sucking was monitored to support this notion.

Overall intake and rate of milk transfer reflect infants' sucking skills (e.g., sucking pattern maturation, sucking rate and suction/expression amplitudes), suck-swallow-breathe coordination, endurance, and behavioral state. From the present investigation, the improved performance in overall transfer and rate of milk transfer noted in the experimental group may be attributed in part to maturation of sucking pattern. Indeed, infants who received the stimulation program demonstrated more mature sucking stages than infants who did not. This would suggest that the stimulation program accelerated the maturation of sucking.

A gradual increase in the number of infants who completed their oral feedings at each time point in the control group was observed. At 1~2, 3~5, 6~8 oral feedings per day the percent increased from 13%, 44%, to 67%, respectively. It is speculated that the gradual increase in the control group may be a reflection of the natural maturation process. This pattern was not observed in the experimental group. From the first time point, the experimental group demonstrated a high percent (69%) of infants who completed their oral feedings. These findings are another indication that the prefeeding oral stimulation program accelerated the maturation of sucking.

Given that the overall intake and rate of milk transfer improved over time in all infants, it was expected that the maturation of sucking also would improve over the same time course. This was observed during the first five minutes when fatigue was assumed to be minimal. However, during the last three quarters of the oral feeding (5-20 minutes) there was no time effect but there was a group effect. It is speculated that the lack of improvement over time during the last three quarters of the oral feeding may be due to the infants' increasing fatigue and/or changes in behavioral state incurred by the infants as they were feeding. Initially, infants were awake and demonstrated a more mature sucking stage. As the feeding session continued, infants became drowsy or fell asleep and the sucking stage regressed. The use of weighted averages to calculate the primary stage of sucking utilized by infants over an entire feeding session takes into account these important elements. As a result, the sucking stage scores during an entire (20 minutes) oral feeding session are somewhat lower than those observed during the first five minutes. This indicates that infants in both groups experienced fatigue. In spite of this, infants in the experimental group were able to sustain a more mature sucking pattern throughout the entire oral feeding session than the controls.

As previously described, overall intake and rate of milk transfer may be influenced by infants' behavioral state (McCain, 1997). No difference was noted in behavioral state between the experimental and control groups at the beginning, during and end of the oral feeding sessions. These results are limited because behavioral state was monitored only at three time points during the oral feeding session. The frequency of the recordings was not sufficient because a well-known characteristic of preterm infants is the frequent fluctuation and disorganization of their states (Als, 1989, 1986; Rose et al, 1980; Tronik et al, 1990). Thus, more frequent recordings, such as every 30 seconds, is recommended and might have given more accurate information on the effect of behavioral states on oral feeding performance.

The enhanced oral feeding performance observed in the experimental group may also be due to greater endurance in this group. There was no difference in the duration of oral feedings between the two groups. However, a greater number of experimental infants completed their oral feedings as compared to controls. Although a more mature sucking pattern in the experimental group accounts in part for this improved performance, it is speculated that these findings may have resulted also from greater endurance. However, verification with more objective measures of endurance, such as comparison of sucking rate, average duration of sucking burst and amplitude of suction between the start and end of the oral feeding session are necessary.

Contrary to other studies, there was no significant difference in length of stay at the hospital between the two groups (Bernbaum et al, 1983; Field et al, 1982; Gaebler & Hanzlik, 1996; Measal & Anderson, 1979; Sehgal et al, 1990). This was an unexpected finding. It was anticipated that experimental infants would be discharged earlier because they achieved independent oral feeding 7 days earlier than the controls. A total of 14 infants had a delay in hospital discharge. Eight infants (n = 4 experimental, n = 4 control) whose discharge was delayed resulted from medical instabilities such as sepsis, unstable respiratory status and gastroesophageal reflux. The remaining 6 (n = 5 experimental, n = 1 control) was due to insufficient body weight (i.e., infants weighed less than 2000 grams) and social factors, such as caretakers not being available and twins not being ready to be discharged at the same time. Although there are specific criteria to discharge infants from the hospital, there is no set time to initiate discharge planning. This may explain the lack of difference observed in length of stay between the two groups. If a set time for initiating discharge planning were part of the research protocol a difference in length of stay at the hospital may have been observed.

The model of family-centred developmental care is emerging in most neonatal intensive care units across North America. This model encourages parents to become more involved in the clinical care and discharge planning of their infants. This prefeeding oral stimulation program may be implemented in neonatal developmental care plans because it is safe, simple, and inexpensive. It is a safe program because the methodologies are non-invasive. In this study, only one out of 16 infants had an episode of bradycardia during the intervention that resolved spontaneously without any medical intervention. It is a simple program to administer, both nurses and parents can be taught to provide the program. It is inexpensive: the only expense incurred is a pacifier that is already provided by the neonatal intensive care unit. However, before such a program can be implemented, its effectiveness and safety when administered by the parents needs to be ascertained.

This study showed that a prefeeding oral stimulation program, as implemented herein, could advance the maturation of sucking. This was reflected by enhanced overall intake, rate of milk transfer, and a faster transition from tube to oral feedings. These findings support the concept that the development of sucking is not only an inborn conditioned reflex dependent upon neurophysiological maturation, but also that it can be strengthened with learning experiences (Bernbaum et al, 1983; Eishima, 1991; Harris, 1986; Lipsitt et al, 1985; Sameroff, 1968). Repetitive exercise often improves one's ability to perform specific tasks. This study demonstrates that the stimulation program provided infants with repetitive oral exercise, which improved their oral feeding performance.

10. FUTURE DIRECTIONS

This study has shown that a prefeeding oral stimulation program, such as the one devised in this study, can benefit "healthy" preterm infants born between 26 to 29 weeks GA. Infants born less than 26 weeks GA and those with chronic medical complications such as bronchopulmonary dysplasia, necrotizing enterocolitis and intraventricular hemorrhages III & IV frequently encounter oral feeding difficulties (Comrie & Helm, 1997; Harris, 1986; VandenBerg, 1990). Their medical status and greater exposure to the noxious stimuli put them at higher risk of encountering oral feeding difficulties. Thus, it is of great importance to determine the benefits of a prefeeding oral stimulation in these infants because such a program may safeguard the infants' innate sucking skills as well as potentially reduce and/or prevent the occurrence of oral feeding difficulties in this population.

Oral feeding difficulties that arise early on may lead to long-term feeding difficulties and problems in growth and development (Comrie & Helm, 1997; Gardner & Hagedorn, 1991; Harris, 1986; Senez et al, 1996). Only the short-term effects of a prefeeding oral stimulation program were investigated in this study. The long-term effects of such a program on oral feeding skills, e.g., ability to transition to solid foods and on developmental skills, e.g., assessing neurodevelopmental outcomes at discharge and at one year of age, would be of significance.

11. SUMMARY

Preterm infants who are less than 30 weeks GA are more susceptible to oral feeding difficulties. Oral feeding problems in this population are gaining increased attention among health professionals because they may affect the ability to reach independent oral feeding, delay hospital discharge and lead to long term feeding difficulties and developmental problems.

Feeding specialists are usually consulted when oral feeding problems are already established. They are consulted too late. Early intervention, prior to the initiation of oral feedings is encouraged. The rationale for early oral stimulation is that it may facilitate the appropriate development of sucking skills and reduce/prevent the occurrence of oral feeding problems.

Several studies report that oral stimulation has beneficial effects on oral feeding skills. The majority of these studies were carried out on infants greater than 30 weeks GA. The interventions were provided when oral feedings were already initiated. No study has investigated the effect of an oral stimulation, prior to the initiation of oral feedings, on preterm infants who are less than 30 weeks GA. Thus, the purpose of this study was to determine whether a prefeeding oral stimulation enhances the oral feeding performance of preterm infants who are between 26-29 weeks GA. The results demonstrate that such an intervention does improve the oral feeding performance of this population of preterm infants. More specifically the program: 1) accelerated the transition from full tube feeding to independent oral feeding; 2) improved overall transfer and rate of milk transfer; and 3) enhanced the development of a more mature sucking pattern. There was no difference in length of stay at the hospital between the two groups.

This study has demonstrated that an oral stimulation program accelerates maturation of sucking. However, the effect of such a program on other factors that may influence oral feeding performance, such as suck-swallow-breathe coordination and endurance have not been assessed. Investigations on these components would provide a more in-depth understanding of the effects of oral stimulation on the oral feeding performance of preterm infants.

12. CONCLUSION

A prefeeding oral stimulation program accelerated the transition to independent oral feeding. In addition, infants who received the program demonstrated greater overall intake and rate of milk transfer than those who did not. This improved oral feeding performance is attributed in part to a more mature sucking pattern demonstrated by these infants. These data support the concept that development of sucking is dependent on both maturation and external experiences (Bernbaum et al, 1983; Harris, 1986; Lipsitt et al, 1985). Incorporating a prefeeding oral stimulation program in neonatal developmental care plans is feasible because it is safe, simple and inexpensive. The program would be beneficial to both preterm infants and their caretakers/parents. It would enhance the oral feeding performance of preterm infants while giving caretakers/parents the opportunity to interact with their infant in a positive meaningful manner.

In conclusion, preterm infants have innate sucking skills. They are at risk of encountering oral feeding problems. This study demonstrates that a prefeeding oral stimulation program enhances the development of existing rudimentary sucking skills in preterm infants born between 26-29 weeks GA.

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14. APPENDICES

Appendix A: Summary of Oral Stimulation Studies

Investigator	Subjects	Intervention	Results
Hill et al, 2000	N=20 G-32.1 $\pm$ 2.3 wks GA	Chin and cheek support during an oral feeding.	Number and duration of pauses decreased during the intervention. No difference in number of sucks, rate of sucks, number of sucking bursts, and duration of sucking bursts. No difference in heart rate, respiratory rate, and oxygen saturations.
Gaebler & Hanzlik, 1996	N=18 (9 E, 9 C) E-32.3 wks GA C-32.4 wks GA	E received 5 min body stroking and 2 min oral motor stimulation. C received 5 min body stroking.	E received fewer tube feedings. E scored higher on the neonatal oral motor assessment scale. E was discharged from hospital earlier. E had greater average daily weight gain. No difference in volume ingested in the first 5 min.
McCain, 1995	N=20 G-31.6 $\pm$ 1.7 wks GA	10 min NNS before 2 oral feedings.	Infants were more often in alert, inactive, and quiet awake states. Fewer changes in behavioral state noted during the oral feeding.
Pickler & Terrel, 1994	N=20 G-range 26-34 wks GA	5 min NNS pre- and post- oral feeding.	Decreased occurrence of necrotizing enterocolitis in E, but not statistically significant.
Einarsson-Backes et al, 1993	N=13 G-33 $\pm$ 3 wks GA	Chin and cheek support for 2 min during an oral feeding.	Increased volume intake during the intervention.
Pickler et al, 1991	N=20 G-range 26-34 wks GA	5 min NNS pre- and post- oral feeding.	E more likely to be in quiescent behavioral state after the feeding session.

Investigator	Subjects	Intervention	Results
Sehgal et al, 1990	N=40 (20 E, 20 C) E-32.9 $\pm$ 1.1 wks GA C-32.9 $\pm$ 1.1 wks GA	NNS during tube feedings for 3 min.	No difference in weight gain. E transitioned to full oral feedings faster. E had greater sucking efficiency (ml/min). E had shorter lengths of stay at the hospital. E had shorter gastrointestinal transit time.
Ernst et al, 1989	N=18 (9 E, 9 C) E-29 $\pm$ 0.3 wks GA C-29 $\pm$ 0.4 wks GA	NNS during tube feedings for 14 days.	No difference in weight gain, occipital frontal circumference, arm circumference, and triceps skin fold. No difference in gastrointestinal transit time, stool frequency, gastric residual, and regurgitation.
Gill et al, 1988	N=24 (12 E, 12 C) E-30.5 wks GA C-31.5 wks GA	5 min NNS prior to first oral feeding.	E was more in an awake state during the feeding and less restless.
Widstrom et al, 1988	N=8 G-32.3 $\pm$ 1.1 wks GA	15 min NNS before and during a tube feeding.	Decreased gastric retention when NNS was provided. Somatostatin levels were significantly reduced when NNS was provided. Gastrin levels were increased but not statistically significant.
Woodson & Hamilton, 1986	N=24 G-31.4 $\pm$ 3.2 wks GA	NNS for 30 min 1 hour after a feeding.	NNS significantly reduced heart rate.
Marchini et al, 1987	N=13 (6 E, 7 C) E-33 $\pm$ 1.0 wks GA C-35 $\pm$ 3.1 wks GA	5 min NNS during tube feedings.	No difference in release of gastrin, insulin, and somatostatin hormones.
Curtis et al, 1986	N=10 G-28 $\pm$ 2.3 wks GA	NNS during 3 tube feedings.	No difference in gastrointestinal transit time.

Investigator	Subjects	Intervention	Results
Paludetto et al, 1986	N=12 G-range 32-37 wks GA	3 NNS periods provided: less than 3 sec, between 3 and 6 sec, and greater than 6 sec.	There was an interaction between respiratory rhythmicity and NNS. Increased respiratory rate at 32-33 and 36-37 wks PMA when NNS was less than 3 sec. Increased respiratory rate at 32-37 wks when NNS was between 3-6 sec.
Paludetto et al, 1984	N=14 G-range 25-33 wks GA	5 min NNS.	Increase in transcutanous PO_2 in preterm infants between 32 to 35 wks PMA.
Bernbaum et al, 1983	N=30 (15 E, 15 C) E-31.5 $\pm$ 1.6 wks GA C-31.5 $\pm$ 1.3 wks GA	NNS during all tube feedings.	E developed a more organized sucking pattern. E had greater average daily weight gain. E transitioned to total oral feedings sooner. E had decreased gastrointestinal transit time. E reached discharge weight sooner. E was discharged sooner from the hospital.
Field et al, 1982	N=57 (30 E, 27 C) E-32 $\pm$ 2.2 wks GA C-32 $\pm$ 1.8 wks GA	NNS during all tube feedings until full oral feedings.	E was ready for bottle feeding earlier. E required fewer tube feedings. E had greater average daily weight gain. E was discharged from the hospital sooner. E had inferior score on Brazelton Assessment (developmental assessment).

Investigator	Subjects	Intervention	Results
Leonard et al, 1980	N=5 G-range 27-40 wks GA	Stroking the cheek muscles for 1 sec during the oral feeding when the infant stops sucking for 2 sec.	Greater number of sucks per minute during the stimulation.
Measal & Anderson, 1979	N=59 (29 E, 30 C) E-32.1 ± 0.2 wks GA C-32.5 ± 0.2 wks GA	NNS during all tube feedings until full oral feeding.	E started oral feedings earlier. E received fewer tube feedings. E had greater average daily weight gain. E had shorter lengths of stay at the hospital. E had less medical complications.
Burroughs et al, 1978	N=11 G-range 26-36 wks GA	8 min NNS.	Increase transcutaneous PO_2 in preterm infants on room air and assisted ventilation during and after NNS.

GA is expressed in means ± SD unless otherwise stated.
E=experimental group; C=control group; G=group; GA=gestational age; PMA=postmenstrual age; NNS=non-nutritive sucking.

Appendix C: Consent Form

BAYLOR COLLEGE OF MEDICINE AND AFFILIATES CONSENT TO PARTICIPATE IN A RESEARCH PROJECT (HPC) (99.6-08)

1. TITLE OF PROTOCOL
Oral Feeding in Premature Infants

2. BACKGROUND
The duration of hospitalization of premature infants is highly correlated with the attainment of oral feeding. Oral feeding is related to neural development. Recent studies suggest that simple therapies such as touch, sound or oral stimulation may help babies' growth, allowing them to be discharged earlier from the hospital.

3. PURPOSE OF THE STUDY
The purpose of this study is to test whether oral feeding of premature infants can be facilitated when they receive touch, sound and/or oral stimulation.

4. PROCEDURES
There will be approximately 80 subjects in this study.
My baby will be randomized (like by a toss of a coin) to receiving the current care provided in the nursery or in addition to that care, a touch, sound, a combination of touch and sound or oral intervention. These interventions will consist of 15-minute sessions, provided once to 3 times a day, 5 days a week for 4 weeks beginning when the doctors say that my baby is stable. The touch intervention consists of gentle massage of the back, arms and legs. For the sound intervention, I will record my voice (reading, singing, or talking) for 5 minutes, in the language of my own choice. This will be recorded 3 times to make a 15-minute. If my baby is randomized to the combination of touch and sound, he/she will receive both interventions at a convenient schedule. The oral intervention will consist of routine stimulations used by occupational therapists to prepare babies to oral feedings.

To follow how well my baby is growing, the investigators will monitor the development of his/her sucking on a pacifier (non-nutritive) and a bottle (nutritive). To do this, 2 small soft tubes will be placed on a pacifier or a bottle nipple. To measure swallowing, a small drum (1/4 inch diameter) held by an elastic to a stockinette cap will be placed under my baby's chin. To measure breathing, a belt with a sensor will be placed snugly around his/her chest. The two tubes from the pacifier/nipple, the swallowing drum and the sensor will be connected to a machine which will measure the pressures and rhythms of my baby's sucking, swallowing, and breathing. Each measurement will take 20 to 30 minutes. The investigators will monitor the heart rate and respiration of my baby before and during each of these measurements to insure that the intervention is not stressful to him/her. If it is, the intervention will be stopped. There will be up to 5 measures while my baby progresses in his/her oral feedings.

5. RISKS/DISCOMFORTS
There is no known risk to my baby.

6. BENEFITS

I have been told that if the results obtained show that the number of oral feedings my baby is taking can be increased, the investigators will notify the doctor in charge. If doctors identify a problem with the way my baby feeds, the types of measurements taken from this study may be helpful in deciding how to best feed him/her. However, my baby may receive no benefit from participating in this study, but my participation may help the investigators better understand the development oral feeding in premature infants.

7. ALTERNATIVES

The only alternative to this study is non-participation.

8. FINANCIAL COSTS TO SUBJECTS

There is no cost to the subjects.

9. PATIENT RIGHTS

I have been informed that there may be unknown risks/discomforts involved, and that I will receive any new information discovered during the course of the study, concerning significant treatment findings that may affect my willingness to continue to participate. Every effort will be made to maintain the confidentiality of my study records. The data from the study may be published; however I will not be identified by name. The confidentiality of the data will be maintained within legal limits.

In the event of injury resulting from this research, Baylor College of Medicine and Texas Children's Hospital are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to research subjects, just as they are to the community generally. My signature below acknowledges my voluntary participation in this research project. Such participation does not release the investigators, institutions sponsor(s) or granting agency(ies) from their professional and ethical responsibility to me.

My participation is voluntary and I may refuse to participate or may discontinue my participation AT ANY TIME, without penalty, loss of benefits, or change in my present or future care. The investigator has the right to withdraw me from the study at any time. My withdrawal from the study may be for reasons related solely to me (e.g. not following study-related directions from the Investigator; a serious adverse event reaction) or because the entire study has been terminated. The Sponsor has the right to terminate the study or the Investigators participation in the study at any time.

The investigator or her designee has answered all of my questions. If I have additional questions during the course of this study about the research or my rights as a research subject, I may address them to the Baylor Affiliates Review Board for Human Subject Research at (713) 798-6970. In the event of a research-related injury or if any other problems arise, I may contact Dr. Lau at (713) 798-6710 or Dr. Schanler at (713)798-7178.

CHILDREN CONSENT ONLY - My signature on this consent form attests to the fact that my child ____________________________ has, within the limits imposed by age, maturity, and psychological state, given his/her assent (affirmative agreement) to participate in this research project.

I HAVE READ THE INFORMATION PROVIDED ABOVE (OR HAVE HAD IT READ TO ME) AND HAD MY QUESTIONS ANSWERED TO MY SATISFACTION. I VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY. I WILL RECEIVE COPY OF THIS CONSENT FORM.

Signature of Research Subject (Including children - when applicable) — Date

Signature of Legal Representative or next of kin (If applicable) (Relationship - i.e. Father, Mother, etc.) — Date

Signature of Investigator or Designee Obtaining Consent — Date

NOT VALID WITHOUT THE INSTITUTIONAL REVIEW BOARD STAMP OF CERTIFICATION

The Institutional Review Board for Human Subject Research Baylor College of Medicine & Affiliated Hospitals

FEB 09 1999

VALID FOR 1 YEAR FROM ABOVE DATE

LAST DATE AMENDED: AUG 11 1999

Appendix D: Prefeeding Oral Stimulation Program

Adopted from Beckman, D. Oral motor assessment and intervention manual, 1998.

Structure	Stimulation Steps	Purpose	Frequency	Duration
Cheek	1)Place index finger at the base of the nose. 2)Compress the tissue, move finger toward the ear, then down and towards the corner of the lip (i.e., C pattern). 3)Repeat for other side.	Improve range of motion and strength of cheeks, and improve lip seal.	4X each cheek	2 min.
Upper lip	1)Place index finger at the corner of the upper lip. 2)Compress the tissue. 3)Move the finger away, in a circular motion, from the corner towards the center and to the other corner. 4)Reverse direction.	Improve lip range of motion and seal.	4X	1 min.
Lower lip	1)Place index finger at the corner of lower lip. 2)Compress the tissue. 3)Move the finger away, in a circular motion, from the corner towards the center and to the other corner. 4)Reverse direction.	Improve lip range of motion and seal.	4X	1 min.
Upper & lower lip curl	1)Place index finger at center of lip. 2)Apply sustained pressure, stretch downward towards the midline. 3)Repeat for lower lip-apply sustained pressure, and stretch upward toward the midline.	Improve lip strength, range of motion and seal.	2X each lip	1 min.
Upper gum	1)Place finger at the center of the gum, with firm sustained pressure slowly move towards the back of the mouth. 2)Return to the center of the mouth. 3)Repeat for opposite side.	Improve range of motion of tongue, stimulate swallow, and improve suck.	2X	1 min.
Lower gum	1)Place finger at the center of the gum, with firm sustained pressure slowly move towards the back of the mouth. 2)Return to the center of the mouth. 3)Repeat for opposite side.	Improve range of motion of tongue, stimulate swallow, and improve suck.	2X	1 min.

Structure	Stimulation Steps	Purpose	Frequency	Duration
Internal cheek	1)Place finger at inner corner of lips. 2)Compress the tissue, move back towards the molars and return to corner of lip. 3) Repeat for other side.	Improve cheek range of motion and lip seal.	2X each cheek	2 min.
Lateral borders of the tongue	1)Place finger at the level of the molar between the side blade of the tongue and the lower gum. 2)Move the finger toward midline, pushing the tongue towards the opposite direction. 3)Immediately move the finger all the way into the cheek, stretching it.	Improve tongue range of motion and strength.	2X each side	1 min.
Midblade of the tongue	1)Place index at the center of the mouth. 2)Give sustained pressure into the hard palate for 3 seconds. 3)Move the finger down to contact the center blade of the tongue. 4)Displace the tongue downward with a firm pressure. 5)Immediately move the finger to contact the center of the mouth at the hard palate.	Improve tongue range of motion and strength, stimulate swallow, and improve suck.	4X	1 min.
Elicit a suck	1)Place finger at the midline, center of the palate, gently the stroke palate to elicit a suck.	Improve suck, and soft palate activation.	N/A	1 min.
Pacifier	1)Place pacifier in mouth.	Improve suck, and soft palate activation.	N/A	3 min.

Appendix E: APIB State Scale as adopted from NIDCAP

Als, H. Manual for naturalistic observation (preterm and full term infants), 1995.

1. Sleep States

- State 1 — Deep sleep

  State 1A: Diffuse deep sleep with obligatory regular breathing or breathing in synchrony with only the respirator, eyes closed, no eye movements under closed lids; quiet facial expression; no spontaneous activity; typically poor color.

  State 1B: Robust deep sleep with predominantly modulated regular breathing; eyes closed, no eye movements under closed lids, relaxed facial expression; no spontaneous activity except isolated startles.

- State 2 — Light sleep

  State 2A: Diffuse light sleep with eyes closed, rapid eye movements may be observed under closed lids; low amplitude activity level with diffuse and disorganized movements; respirations are irregular and there are many sucking and mouthing movements, whimpers; facial, body, and extremity twitchings, much grimacing; the impression of a diffuse state is given. Color is typically poor.

  State 2B: Robust light sleep with eyes closed; rapid eye movements may be observed under closed lids; low activity level with movements and dampened startles; movements are likely to be of lower amplitude and more monitored than in State 1; the infant responds to various internal stimuli with dampened startle. Respirations are more regular, mild sucking and mouthing movements may occur off and on; one or two whimpers may be observed, as well as infrequent sighs or smiles.

2. Transitional States

   - State 3 Drowsy

State 3A: Diffusely drowsy, semi-awake or semi-asleep; eyes may be open or closed, eyelids fluttering or blinking very exaggeratedly; if eyes are open, they may have a glassy veiled look; activity level is variable, with or without interspersed, startles from time to time; diffuse movement; fussing and/or much discharge of vocalization, whimpers, facial grimacing, etc.

State 3B: Robustly drowsy, as above yet with little discharge of vocalization, whimpers, facial grimacing, etc.

3. Awake States

   - State 4 Quietly awake and/or alert

State 4A: Diffusely awake. Two types of diffuse alertness are distinguished, 4AL and 4AH. L or H is marked instead of a check mark

4AL: Low keyed, lidded, diffuse awakeness; quiet, minimal motor activity, eyes half open or open with glazed, dull, or pained look, giving the impression of little energy; or focused yet strained alertness, appearing to look through, rather than at, an object or the caregiver.

4AH: Hyperalert; eyes wide open, giving the impression of panic, fear, or overwhelmedness; appearing to be hooked by the stimulus; the infant seems to have difficulty in modulating or breaking the intensity of the fixation to an object or the caregiver, and appears not in a position to turn the gaze away.

State 4B: Robustly alert with bright shiny eyes, animated facial expression; the infant appears to focus attention on a source of stimulation or a person and appears to process information actively and with modulation; motor activity is at a minimum.

- State 5 — Actively awake and aroused

State 5A: Diffusely actively aroused; eyes may or may not be open; the infant is clearly awake and aroused, as indicated by motor arousal, tonus, and distressed facial expression, grimacing, or other signs of discomfort. Vocal fussing, if present, may be diffuse or strained.

State 5B: Robustly actively aroused; eyes may or may not be open; infant is clearly awake and aroused, with considerable, yet well defined, motor activity. The infant may also be clearly fussing without crying robustly.

- State 6 — Highly aroused, agitated, upset, and/or crying

State 6A: Diffusely highly aroused with intense upset, as indicated by intense grimace and cry face, yet cry sound may be very strained, weak, or absent; intensity of upset is very high.

State 6B: Robustly highly aroused with rhythmic, intense, lusty crying which is robust and vigorous in sound.

- AA State — Removal from the state continuum

AA: Should the infant move into a prolonged respiratory pause, e.g., beyond 8 seconds, AA should be marked, indicating that the infant has removed him or herself from the state

Appendix F: Stimulation Program Record

Subject Name:_________________ Case #:_____________

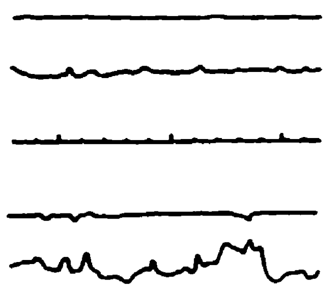
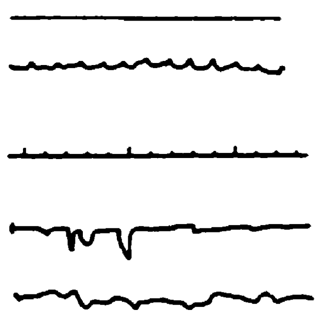
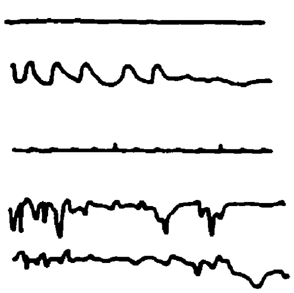
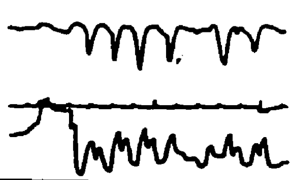
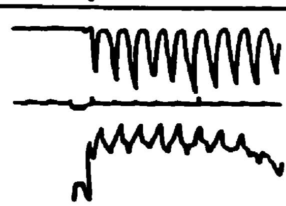
Date of Admission:_____/_____/_____

Date	Received Stimulation Program		Time		Physiological Response		State
	Yes	No Why	Start	End	Yes (a/b/$O_{2\ desat}$)	No	Start

a=apnea; b=bradycardia; O_2 desat.=oxygen desaturations.

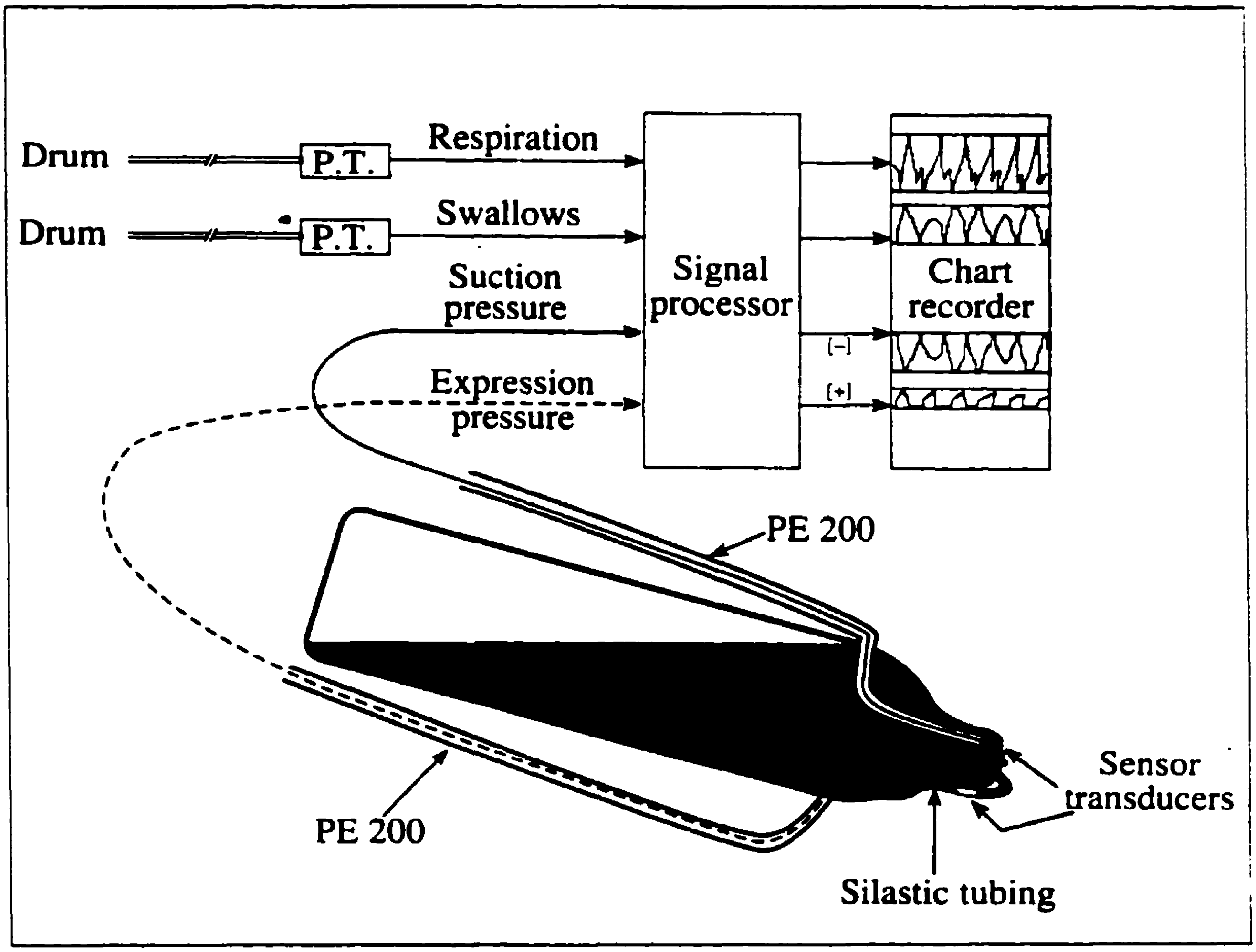
Appendix G: Maturation of Sucking Stages

Lau C., et al. Acta Pediatrica, 89, 846-852, 2000.

Stage	Sample Tracings	Suction/Expression Amplitude Range of Tracings (mm Hg)	Description
1A	Suction Expression 	Absent + 0.5 to + 1.0 mm Hg	No Suction *Arrhythmic Expression
and	Time (sec)		and
1B	Suction Expression	- 2.5 to - 12.5 mm Hg + 0.5 to + 1.0 mm Hg	Arrhythmic alternation Suction /Expression
2A	Suction Expression 	Absent + 0.2 to + 0.4 mm Hg	No Suction Rhythmic Expression
and	Time (sec)		and
2B	Suction Expression	- 7.5 to - 15.0 mm Hg – + 0.2 mm Hg	Arrhythmic alternation of Suction/Expression Presence of Sucking bursts
3A	Suction Expression 	Absent + 0.8 to + 1.0	No Suction Rhythmic Expression
and	Time (sec)		and
3B	Suction Expression	- 15 to - 75 + 0.5 to + 0.7	Rhythmic suction/Expression: - Suction amplitude increases - Wide amplitude range - Prolonged sucking bursts
4	Suction Time (sec) Expression 	- 50 to - 75 + 0.4 to + 1.0	Rhythmic suction/expression: - Suction well defined - Decreased amplitude range
5	Suction Time (sec) Expression 	- 110 to - 160 + 0.6 to + 0.75	Rhythmic /well defined suction/expression: - Suction amplitude increases - Sucking pattern similar to that of fullterm infant

Appendix H: Oral Motor Kinetic Apparatus

Modified from: Lau, C., & Schanler, R. Clinics in Perinatology, 23, 161 –178, 1996.



PT=Pressure transducer, PE= Polyethylene tubing

Appendix I: Baseline Data

Date:_____/_____/_____ Data Collector:_____________________

Infant Baseline:

Subject Name:_____________________ Med #:_____________________
Date of Admission:_____/_____/_____ Case #:__________

Date of Birth:_____/_____/_____
Birth Weight: ________ grams
Gestational Age:________weeks
Sex: M F
Apgar 1 min.: ________
Apgar 5 min.: ________

Health Status:

Oxygen Requirement: start___/___/___ end___/___/___ #days_____
Tube Feedings: start___/___/___ end___/___/___ #days_____

Gastroesophageal Reflux: Yes No Date___/___/___

Parents Baseline:

Mother's name:_________________ Father's Name: __________________
Date of Birth:_______________
Age:_______________
Ethnicity:_______________
Education:_______________

Tel #: _______________________ Name:__________________________
ER Tel #:_____________________ Name:__________________________

Appendix J: Oral Feeding Observations

Subject Name:___________________ Case #:____________

Date:_____/_____/______ Date of Adm:_____/_____/_____

PMA age:________________weeks

Weight:_______________grams

Feeder:_______________________ Observer:________________________

Recording Session: 1-2 PO, 3-4-5 PO, 6-7-8 PO

OG Tube: In Out

NG Tube: In Out

Oxygen Requirement: No Yes Amount_________

Start time________ End time________ Duration________

Bottle + formula and/or breast milk initial weight: _________g

Bottle + formula and/or breast milk 5 min. weight: _________g

Bottle + formula and/or breast milk end weight: _________g

Volume Prescribed: __________cc

Volume 5 minutes: __________cc

Total volume taken: __________cc

First Bib: Wet weight_______g Dry weight_______g Net weight______g

2nd Bib: Wet weight_______g Dry weight_______g Net weight______g

Net Intake (total vol. taken - total vol. loss)________cc

Behavioral State: Start_____ 5 min_____ End_____

Respiratory Rate: Start_____ End_____

Heart Rate: Start_____ End_____

O_2 saturation: Start_____ End_____

Apnea: No Yes____________

Bradycardia: No Yes____________

O_2 desaturations: No Yes____________

Interruptions: Time_________ Reason (burp, spit-up, a/b) __________________

____

____