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***A NEW BOTTLE DESIGN TO
CORRECT MECHANICAL DEFECT
DURING FEEDING IN CLEFT LIP
AND PALATE BABIES***

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CHAPTER 1: OVERVIEW OF CLEFT LIP AND PALATE

1.1 ABSTRACT:

Babies with cleft lip and palate which is a common craniofacial deformity suffer from feeding problem which interfere with their growth and development and render the subsequent corrective surgery and also endure their daily suffering during the feeding time. This thesis reports the design of a new bottle feed to overcome this problem. Also a clinical study was performed to study the patterns of baby feed in cleft lip and palate babies to support the use of the bottle feeding for this group of babies.

1.2 INTRODUCTION:

Behind this project is a big story, which motivated me to design such a bottle for babies with cleft lip and palate. One morning in my early days of practising paediatrics when I was doing my routine round, and was called over by the nurse as I entered the ward because she was facing problem in feeding one

baby and she kept him in the treatment room waiting for the first doctor who



could help her, the mother and the poor baby. The first doctor was me. I thought it was a simple problem. I asked the nurse kindly to bring the file and to help me in examining the small hungry crying baby cradled in the arms of a very young worried and crying mother. When I took the baby from her to

examine him, I recognized the problem that I faced; because the baby had cleft lip and palate, his mother and the nurse have found it difficult time to feeding him. He was crying continuously and knew one thing, only, that; he was hungry and wanted milk, like any other new born baby. I had newly graduated had little experience in such cases and the mother was looking at me for a solution which I did not have at the time, I never forget that look from the crying mother whose major problem was simply to feed her crying baby.

I tried to quieten him and started feeding him myself very slowly but he started to choke and became cyanosed I tried again by changing the nipple but it made no great difference because there is a defect in the roof of his mouth. Because the milk was going from the mouth to the nose and the baby choke. At this point I stopped trying to feed him and started an i.v fluid feed (intravenous) and gave him an artificial teat to satisfy him until I could consult senior doctor.

From this incident I recognized how difficult it is to deal with this group of babies, not only as regard managing them but also in supplying them their daily needs in term of feeding.

The caregivers of this group of babies with cleft lip and palate babies are facing a difficult task when it comes to feeding ;starting from taking a longer time ,happen more frequently feed and often results in chock which in small babies can lead to chest infection ,also a higher incidence of ear infections. Usually such babies need to undergo corrective surgery to correct their defect, but this surgery can often be delayed because the baby has not reach the recommended weight for it to be perform due to failure to be absorb the requisite recommended amount of calories they need .

From this time I tried hard to understand the pathophysiology of feeding in normal babies compared to babies with c.l.p (cleft lip and palate) I did not sleep that night until I had come up with the design for the bottle based on my understanding of the problem .It was urgent how to find a solution to help this suffering group of babies.

The patent of the bottle had a serial number of ((11/370,045)) and won the grand prize and the gold medal in Seoul International Fair held Korea in Seoul 1 December.2006 where it compete entries from 360countries worldwide and 1000 items in the exhibition .The invention was also honoured by his Highness the Amir of Kuwait, Sheikh Sabah Al Ahmad Al Sabah.

To realize how big the problem a mother is facing in feeding a baby with cleft lip palate, this chapter will discuss initially the definition of cleft lip and palate, how common is the condition ,what cause it , how to diagnose it what complication they can face and finally the treatment and outcomes.

1.3DEFINITION OF CLEFT LIP AND PALATE:

The palate is another name for the roof of the mouth .In fact, the palate comprises both the roof of the mouth and the floor of the nose:

- The palate has two parts:

1-The front, or hard palate.

2- The back, or soft palate.

Basic information about cleft lip and palate:

-The hard palate is made of bone and the soft palate is made of muscle.

-Cleft of the lip and palate are birth defects which occur early in gestation.

-A cleft is simply a gap, a separation, or a hole that resulting from an abnormal fetal development.

It occurs as a birth defect which resulted when the tissues of the palate failed to fuse during early fetal development.

- This failure can occur during the 8th and 12th week of gestation.

-The condition varies from a defect in the muscles of the soft palate only (asubmucous cleft palate) only to a complete separation of the skin and bone of the hard and soft palate.

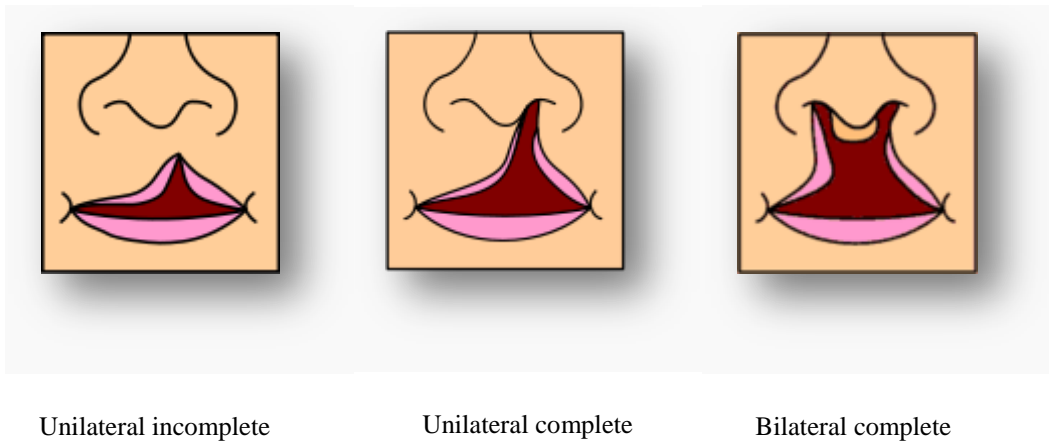
-It is also possible to have a cleft of the soft palate without a cleft of the hard palate, but it is not possible to have a cleft of the hard palate without a cleft of the soft palate.

- If the cleft does not affect the palate structure of the mouth it is referred to as a cleft lip.

-A cleft lip is formed on the top of the lip either as a small gap or as an indentation in the lip (partial or incomplete cleft) or it continues into the nose (complete cleft).

-Lip cleft can occur as a one sided (unilateral) or two sided (bilateral). It is due to the failure of fusion of the maxillary and medial nasal processes.

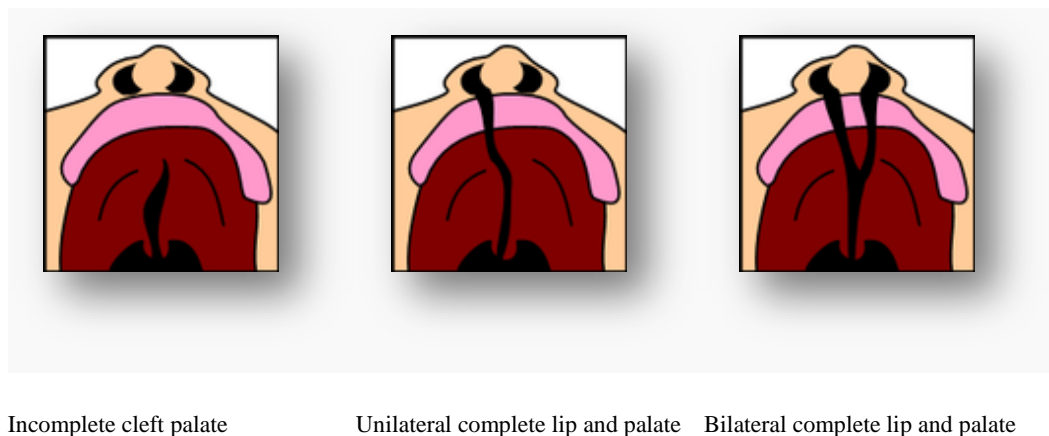
Fig 1.1 cleft frontal view



-A mild form of a cleft lip is a microform cleft which could appear as small as a little dent in the red part of the lip or looks like a scar from the lip up to the nostril.

Note: the following images show the roof of the mouth. The top shows the nose, the lips are colored pink. For clarity; the images depict a toothless infant.

Fig 1.2 cleft from roof side view



1.4 HOW COMMON

-Prevalence rates reported for live births for cleft lip with or without cleft Palate (CL +/- P) and Cleft Palate alone (CPO) vary within different ethnic groups.

-The highest prevalence rate for (CL +/- P) is reported for Native Americans and Asians. Africans have the lowest prevalence rates.

- Native Americans: 3.74/1000
- Japanese: 0.82/1000 to 3.36/1000
- Chinese: 1.45/1000 to 4.04/1000
- Caucasians: 1.43/1000 to 1.86/1000
- Latin Americans: 1.04/1000
- Africans: 0.18/1000 to 1.67/1000

-The rate of occurrence of CPO is similar for Caucasians, Africans, North American natives, Japanese and Chinese.

-The incidence rate is that one (1) out of every 700 -900 children are born with a cleft palate.

-About 70% of these children will also have a cleft lip.

-Most cleft palate involves both the hard and soft palate.

-They are more common among Asians and certain groups of American Indian than among Caucasians.

1.5 HOW A CLEFT DEVELOPS



-Late in the first month of pregnancy, the baby's mouth develops in two halves, which then growing closer together.

-Somewhere around the sixth to eighth week of pregnancy, the two halves of the baby's hard palate fuse (join) together to form the roof of the mouth.

-Next, the fusing seam travels forward and backward to seal the lips and the uvula (the teardrop-shaped tissue which hangs at the back of the throat).

-By the tenth week of pregnancy, the mouth is fully formed and the nose has separated itself into its familiar structure and location.

In the case of a child with a cleft defect, the two halves of the palate and/or the lip fail to fuse properly. Other areas that may fail to properly join up include the soft palate, located at the back of the roof of the mouth, and the nostril.

A child may be affected by one or both of these conditions:

- Cleft lip only – around 25 per cent of all children in the group.
- Cleft palate only – around 25 per cent of them.
- Both cleft lip and palate – around 50 per cent of them.

1.6 WHAT CAUSES CLEFT LIP AND PALATE

In most cases, the cause of cleft lip and cleft palate is unknown. These conditions cannot be prevented. Most scientists believe that clefts are due to a combination of genetic and environmental factors. There appears to be a greater chance of clefting in a newborn if a sibling, parent, or relative has had the problem.

Another potential cause may be related to a medication the mother may have taken during her pregnancy. Some drugs may cause cleft lip and cleft palate. Among them: anti-seizure/anticonvulsant medications, acne medications containing accutane, and methotrexate, a drug commonly used for treating cancer, arthritis, and psoriasis.

Cleft lip and cleft palate may also occur as a result of exposure to viruses or chemicals while the fetus is developing in the womb.

1.7 HOW ARE CLEFT LIP AND CLEFT PALATE DIAGNOSED

Because clefting causes very obvious physical changes, a cleft lip or cleft palate is easy to diagnose. Prenatal ultrasound can sometimes determine if unborn child has a cleft. If the clefting has not been detected by ultrasound before the baby's birth, a physical examination of the mouth, nose, and palate confirms the presence of cleft lip or cleft palate afterwards. Sometimes diagnostic testing may be conducted to determine or rule out the presence of other abnormalities.

1.8 WHAT ARE THE COMPLICATIONS ASSOCIATED WITH CLEFT LIP AND PALATE

1.8.1 COSMETIC ABNORMALITIES:

Bonding with the infant, socializing with the family and community may be interrupted by the unexpected appearance, unusual speech and surgical intervention necessary. Support for the parents as well as for the child can be pivotal.

1.8.2 FEEDING DIFFICULTIES (ALSO WILL BE DISCUSSED WITH MORE DETAILED BELOW):

A child may be unable to suck properly because the roof of the mouth is not completely formed. Due to lack of suction, an infant with a cleft may have trouble feeding. An infant with a cleft palate will have greater success feeding in more upright position.

Gravity will help prevent milk from coming through the baby's nose if he or she has cleft palate. Gravity feeding can be accomplished by using specialized equipment, such as the Heberman Feeder, or by using a combination of nipples and bottle is commonly used with this group of infants.

A larger hole, crosscut, or slit in the nipple, a protruding nipple and rhythmically squeezing the bottle can result in controllable flow to the infant without the stigma caused by specialized equipment.

Although the above described bottle and nipples can work to some extent with this group of babies they are not imitating the normal pathophysiology of feeding in babies because feeding an infant is a dynamic process with a lot of parameters to be considered during the process of feeding which will be discussed later in more detail.

1.8.3 EAR INFECTIONS AND HEARING LOSS:

Children with cleft palate are at increased risk of ear infections since they are more prone to fluid build-up in the middle ear because their Eustachian tubes don't drain fluid properly from the middle ear into the throat.

Fluid accumulates, pressure builds in the ears, and infection may set in. If left untreated, ear infections can cause hearing loss. To prevent this from happening, children with cleft palate usually need special tubes placed in the eardrum to aid fluid drainage, and their hearing needs to be checked once a year.

1.8.4 SPEECH AND LANGUAGE DELAY

Due to the opening of the mouth and lip, muscle function may be decreased which could lead to delay in speech or abnormal speech. Speech is both receptive and expressive. Hearing and understanding spoken language (receptive) is learned to manipulate the mouth, tongue, oral cavity, to express (expressive).

Hearing is related to learning to speak. Babies with palatal cleft may have compromised hearing and therefore, if the baby cannot hear, he cannot try to mimic the sound of speech. Thus, even before expressive language acquisition, the baby with the cleft palate is at risk for receptive language acquisition.

Because the lips and palate are both used in pronunciation, individuals with cleft usually need the aid of a speech therapist.

Children with cleft lip and palate may also have trouble speaking .These children's voices don't carry well, the voice may take on a nasal sound, and the speech may be difficult to understand.

Not all children have these problems and surgery may fix these problems entirely after some time .For others, a special doctor, called speech pathologist, will work with the child to resolve speech difficulties.

1.8.5 DENTAL PROBLEMS:

- Teeth may not erupt normally
- Children with clefts are more prone to larger than average number of cavities and often have missing, extra, malformed, or displaced teeth requiring dental and orthodontic treatments.

1.9 WHAT IS THE TREATMENT FOR CLEFT LIP AND PALATE?

Repair of a cleft palate often requires multiple surgeries over the course of 18 years.

3-7 MONTHS - LIP REPAIR:

This is the first surgery for most cleft babies, and aligns the segments of the lip both functionally and cosmetically. Nasal asymmetry is also addressed in this surgery, and the nostril on the cleft side will be brought into a more normal position using sutures at this surgery.

6-14 MONTHS - PALATE REPAIR:

Both the hard and soft palates are repaired at this surgery. It is very important to have the palate closed before a child reaches the age of 18 months, because it is during this time that speech is developed. Without a complete palate to close off the nose from the mouth during speech, children will use other techniques to try to make sounds, and will not be able to make them properly.

The initial surgery creates a functional palate, reduces the chances that fluid will develop in the middle ears, and aids in the proper development of the teeth and facial bones.

Children with a cleft palate may also need a bone graft when they are about 8 years old to fill in the upper gum line so that it can support permanent teeth and stabilize the upper jaw. About 20% of children with a cleft palate require further surgeries to help improve their speech.

Once the permanent teeth grow in, braces are often needed to straighten the teeth.

Additional surgeries may be performed to improve the appearance of the lip and nose, close openings between the mouth and nose, help breathing, and stabilize and realign the jaw. Final repairs of the scars left by the initial surgery will probably not be performed until adolescence, when the facial structure is more fully developed.



Fig 1.3 Preston learning to feed



Fig.1.4Preston waiting for surgery



Fig1.5Preston before surgery



Fig.1.6 Preston just out of surgery



Fig.1.7 Preston after surgery



Fig 1.8 Preston's New Smile!

1.10 WHAT IS THE OUTLOOK FOR CHILDREN WITH CLEFT LIP AND/OR PALATE

Although the treatment for a cleft lip and/or cleft palate may extend over several years and require several surgeries depending upon the involvement, most children affected by this condition can achieve normal appearance, speech, and eating.

Fig 1.9 Stages of surgical corrections outlook



Fig.1.9.1 month old girl before going into surgery to have her unilateral complete cleft lip repaired



Fig 1.9.2 The same girl, 1 month after the surgery.



Fig 1.9.3 Again the same girl, age 5 years old. Note how the scar gets less visible with age.

CHAPTER2: LITERATURE REVIEW:

2.1 INTRODUCTION:

To understand how big the problem is, we have to know how big the number of babies suffering this medical problem are , and what is the extend of the feeding problem which affects this group of babies in daily bases because feeding is an essential need for babies not only to be fed but also to grow and develop .

This chapter will give the extent of the problem by knowing initially the incidence of cleft lip and palate .Afterward; it will describe the feeding difficulties which include the sucking and swallowing problems and their occurrences as reviewed by literature.

2.2 INCIDENCE OF CLEFT LIP AND PALATE

T.H.Bellis reported in his article, *The Incidence of Cleft Lip and Palate Deformities in the South-east of Scotland (1971-1990)*, after he studied five hundred and two cleft lip and palate within the Edinburgh Cleft units catchment area, between January 1971 and 31 December 1990. The incidence is

reported as 1.4 per live births (1 in 711). Overall, a higher percentage of males were affected (58% males to 42% females) (T.H.Bellis 1990).

The University of Minnesota Duluth stated that the incidence of cleft palate not associated with other malformations is 1 in 750 live births (University of Minnesota CD2230).

Bechara Y. stated that the overall incidence without cleft lip is 3.6 cases per 1000 number of clefts (Bechara Y 2007).

Jamilian A. Concluded in his article, Incidence of Cleft Lip and Palate in Tehran, stated that the overall incidence was 2.14 per 1000 live birth; this study revealed the incidence is higher than many other countries (Jamilian A et. al 2007).

The article of, Who is affected by cleft lip and palate, by Debby. Asian and Native Americans have the highest incidence and African Americans have the lowest incidence of cleft lip and cleft palate .Cleft lip occurring with or without cleft palate in about 1 in 750 white birth and cleft palate alone occurs in approximately 1 in 2,000 white births (Debby Golonka 2008).

Murray in her article, Clinical and Epidemiologic Studies of Cleft Lip and Palate in the Philippines, found that the birth prevalence was 1.94 per 1000 live births for cleft lip with or without palate in the Philippines. Recurrence rate in siblings for nonsyndromic cleft of the lip and palate were 23 per 1000 for cleft lip with or without cleft palate, and 14 per 1000 for cleft palate only .The percentage of clefts associated with multiple anomalies was 21% at birth and

6% for individuals examined during the screening process, the findings suggest a high incidence of cleft lip and palate in native -born Filipinos (Murry JC, et. al;1997).

Incidence of cleft lip and palate in the northeast of Mexico: 10 years' study by Blanco done in Latin American countries stated that the incidence of cleft lip and palate are not widely available. A 10 year retrospective study was carried out to determine the incidence of cleft lip and palate at the Autonomous University of Nuevo Leonos University Hospital. The incidence of cleft lip and palate in the cited hospital was 1,1:1000 births clefts of the left side occurring more often than the right. Boys were affected more commonly than girls (Blanco-Darila F; 2003).

The incidence of cleft lip and palate in Korea is studied by Kim in his article, Cleft Lip and Palate Incidence among the Live Births in the Republic of Korea, an epidemiologic study of cleft lip and palate in the Republic of Korea from January 1, 1993 through December 31, 1993. In 1993, the number of total live births was 715, 817 and from 1993 through 1995 a total of 1, 293 new patients with cleft lip and palate who were born in 1993 were identified. The incidence of cleft lip and palate was 1.81 per 1000 that is 1 per 554 live births. The male/female ratio was 2:1 in the cleft lip group (Kim S Kim WJ et. al 2002).

In the article, Analysis of family incidence of cleft lip and /or palate, by Kot M. Kruk-Jeromini J showed that in 17% of children with cleft lip and /or palate, positive family history was found .The cleft type in a child depends not only on

the type found in the mother or father, but also on the child's sex (Kot M et .al 2004).

Stanier mentioned in his article, Genetics of Cleft Lip and Palate: Syndromic Genes Contribute to the Incidence of Non-Syndromic Clefts, that cleft of the lip and /or palate (cl/p) are among the most common birth defects worldwide (Stanier P et .al 2004).

Vanderas AP in his article, Incidence Of Cleft Lip, Cleft Palate Among Races: A review of the literature pertaining to the incidence of cleft lip and palate; suggest that more research is needed to study the risk of developing clefts among the various groups that exhibit different epidemiologic behaviour for each race (Vanderas AP 1987).

Kaufman FL in his article, Managing the Cleft lip and Palate Patient, stated that within an incidence of cleft of 1 in 700 births all practicing paediatricians will at some time be faced with a patient with a cleft. Paediatric management begins in the hospital nursery by ruling out possible associated anomalies (e.g. congenital heart disease or urinary tract) or syndromes. At the same time, cleft palate nursers may be needed to overcome feeding problems (Kaufman FL;1991).

Adding more to the incidence regarding the complication of cleft lip and palate, an article was done by Sheehan P entitled, Incidence and Outcome of Middle Ear Diseases in Cleft Lip and Palate and or Cleft Palate; It was found out that middle ear diseases are common in children with cleft palate, and unlike the case of children without clefts, has prolonged recovery and a substantial incidence of late sequaelae. There was also a higher incidence of below normal

hearing and surgery for chronic otitis media in children undergoing a greater number of ventilation tube insertions. Although most likely reflecting an increased underlying severity of otitis media in these children, also underlines the lack of long-term benefits of ventilation tubes in this group (Sheahan P et. al 2003).

Ahmad Hussein mentioned in his article, Complete Cleft Palate: Anew Scheme of Treatment, cleft lip and cleft palate are the most common congenital anomalies of the head and neck occurring as in 750 live births. In Oriental it is 1:500 in Caucasians it is 1:1000 and black Americans it is 0,4:1000. In Saudi Arabia and Malaysia it was calculated that the incidence of cleft palate only 1:350 of live births and for cleft lip or palate it is 1:250. Incidence in Malaysia was estimated as 1:700. Ahmad emphasizes that complete cleft palate is indeed exhausting for the patient, his family and the treating team, the treatment does not end by closing the cleft, but may extend up to the age of 18 years or more (Ahmad Hussein 2007).

The article An Epidemiologic Study Of Isolated Cleft Lip, Palate, Or Both In Victoria, Australia From 1983 To 2000, done by Linda D. Et al. concluded that the overall prevalence (per 10,000 pregnancies) of cleft +_palate was 6.8. Boys were at greater risk than girls for cl+/-p and girl at greater risk than boys for cp (Linda D. et .al.,2003).

2.3 PEDIATRIC FEEDING DISORDERS:

Feeding disorders are thought to affect 25% of all children at the same time in their lives. Manikam mentioned in his article, *Pediatric Feeding Disorder*, that paediatric feeding disorders are common: 25% of children are reported to present with some form of feeding disorder. This number increases to 80% in developmentally delayed children. The consequences of feeding disorder can be severe, including growth failure, susceptibility to chronic illness and even death. Feeding disorders occur in children who are healthy, who have gastrointestinal disorders and, who have special needs. Disordered feeding in child is seldom limited to the child alone; it is also a family problem. He recommended minimizing exclusive tube feeding (Manikam et al.;2000).

Another article by Claire K. Miller et al. concluded that children with complex problems frequently are involved with many healthcare services. In this article they describe a model of interdisciplinary team care for medically complex children with chronic feeding, swallowing, nutrition and growth problems (Miller Claire K et. al.; 2001).

Glass RP stated in his article, *A Global Perspective on Feeding Assessment in the Neonatal Intensive Care Unit*, that infant feeding is a highly complex and integrated process involving numerous body systems (Glass, RP;1994).

2.4 REVIEW OF SUCKING AND SWALLOWING DIFFICULTIES IN CLEFT LIP AND PALATE BABIES:

Julie Reid mentioned in his, prospective, longitudinal study of feeding skills in cohort of babies with cleft condition, that, he took a sample of sixty-two babies with cleft condition and was examined at 2 weeks to 3 months and 14 months. He concluded that poor feeding skills were detected on one-third of newborns. Poor feeding skills which may extend beyond one year, relatively common in newborn with cleft palate and cleft lip. More than 30 years ago, a review of clinical research in cleft lip or palate concluded that there was a lack of knowledge about feeding problem in babies with this condition (Spriesters Bach et al. 1973) (Julie Reid ,March 2006).

The same study was mentioned that two retrospective investigations have examined the prevalence of feeding problems and demonstrated that babies with cleft palate (CP) and combined cleft lip and palate (CLP) have significantly more difficulty feeding than those with cleft lip (CL) as mentioned by Drillien et al. 1966; furthermore, there is consensus in the literature that feeding sequelae (such as excessive air intake ,nasal regurgitation,fatigue,coughing,chock and gagging on fluid, prolonged feed, and discomfort) are commonly seen in babies with cl/p as stated by Styer and Freeh,1981;Jones et al ,1982;Clarren et al. 1987;Carlisle,1998.

The investigation of feeding difficulties in babies with cl/p is also important because of the potential impact on the baby (Felix-Schollaart et al .,1999 ;Neiman and Savage,1997)the family (Field and Vega-Lahr ,1984 ;Endriga and Kapp-Simon, 1999;Young et al ,2001), and health care resources (CSAG,1998), as reviewed in the same article.

Feeding efficiency was calculated from parental report of the time taken to feed the baby (minutes) and quota consumed (millilitre) and expressed as millilitres per minute (ml/min) (Lau et al1997; Minzuno and Ueda,2001; Minzuno et al,2002) Feeding efficiency was calculated as (ml/min) under conditions where participations were fed with their own bottle and preferred milk .Participants who were nil by mouth or fully breast fed were excluded from this assessment (Julie Reid, March 2006).

Another study done by Julie Reid under the titled of, Sucking Performance of Babies with Cleft Conditions, reached to the conclusion that babies with smaller clefts were more likely to get good suction and compression compared to their counterparts with larger clefts (Julie Reid, Sep 2006).

Also, Jones (1988) conducted a retrospective chart investigation in the United Kingdom and reported that 25% of babies with nonsyndromic CL/P had significant feeding problems. Among them babies with CP were reported to have slightly more difficulty feeding than those with CLP. Moreover, babies with CL fed well which is consistent with parental perceptions of feeding ability reported by others (e.g. Oliver and Jones, 1997) and expert opinion (Shab

and Wong, 1980; Wolf and Glass, 1992; Glass and Wolf, 1999; Bannister, 2001; Miller and Kummer, 2001).

Two studies have reported abnormal oral motor function (OMF) (specifically tongue position) in participants with CP and CLP (Malek and Psame 1983; Campo-Paysaa, 1987).

Furthermore, there is a consensus in the literature that feeding sequelae (such as excessive air intake, nasal regurgitation, fatigue, coughing, choking and gagging on fluid, prolonged feeds, and discomfort) are commonly seen in babies with (CL/P) (Styer and Freeh, 1981; Jones et al., 1982; Clarren, 1987; Carlisle, 1998). Babies with CP and CLP have feeding problems because of impaired suction. However, several researchers have demonstrated that CP does not interfere with either suction or compression (Choi et al., 1991; Mizuno et al., 2002). The investigation of feeding difficulties in babies with CL/P is also important because of the potential impact on baby (Felix - Schollaart et al., 1992; Neiman and Sarage, 1997) and, the family (Field and Vega-Lahr, 1984; Endriga and Kapp-Simon, 1999; Young et al., 2001) and healthcare reservoir (CSAG, 1998). In this study feeding efficiency was calculated from parental report of the time taken to feed the baby (minutes) and quota consumed (millilitres) and expressed as millilitres per minute (ml/min) (Lau et al., 1997; Mizuno and Ueda, 2001; Mizuno et al., 2002).

Drillien et al. (1966) who classified 32% of babies with CL, CP, CLP and PRS as having severe feeding difficulty, according to the length of time taken to feed. Not surprisingly, the rate of poor feeding was much higher than the 1%

reported in the current study supports previous parental reports of poor intake and prolonged feeding time continue well beyond the 3months of life (Zickefoose, 1957; Drillien et al., 1966; Trenouth and Campbell, 1966) Oral Motor Dysfunction, which may have contributed to poor feeding, was mainly confined to participants with PRS (+) (Pierre Robin Syndrome) and recognized syndrome. Oral-Motor Dysfunction (OMD) is thought to rise primarily from neurological immaturity or impairment (Miller-Schuberth 1994) but may also rise from structural abnormalities (Glass and Wolf, 1999). It is likely that both of these hypotheses were applicable to the current CL/P cohort, which included syndromic and nonsyndromic participants.

However, further investigation is required to understand the basis of OMD in babies with cleft condition. Sequelae were commonly associated with feeding episodes in neonates with CL/P, particularly those with poor feeding skills, nasal regurgitation was the most commonly reported behaviour. **Elimination of nasal regurgitation is desirable because the regurgitation may lengthen the duration of a bottle or breastfeed (Sidoti and Shprintzen, 1995), which is unpleasant for the baby, and is potentially stressful for the mother** (Zickefoose, 1957 ; Julie Reid, March2006)

AG Masarei demonstrated that feeding difficulties are reported widely in infants with cleft lip or palate by a study of nature of feeding in infants with unrepaired cleft lip and/or palate compared with healthy noncleft infants, the result shown infants with nonsyndromic complete unilateral cleft lip and palate

or cleft of the soft and hard palate **has less efficient sucking patterns** than their noncleft peers had (AG .Masarei,2006).

Julie Reid describes the sucking performance of bottle-fed babies with cleft conditions; he concluded that babies with smaller cleft (i.e. CL or minor soft palate cleft) were more likely to get a good suction and compression compared to their counterparts with large clefts (Julie Reid ,Sep 2006).

Redford-Badwal et al.DA mentioned in his article ,Impact of Cleft Lip and /or Palate on Nutritional Health And Oral -Motor Development ,that infants born with a cleft may require modifications in feeding practices before surgical closure of the defect, however, few changes in dietary recommendations are necessary .Often , the delivery method of breast milk or formula can be altered in order to require less effort by the infant and decrease caloric output, thereby increasing the calories ingested to facilitate weight gain and growth (Redford-Badwal DA et. al. ,2003).

It was clear from what mentioned in the article, A Simplified Method of Feeding Infants Born with Cleft Palate with or without Cleft Lip, by Pashayan that most infants born with a cleft palate with or without cleft are under grown and have histories of difficult feeding (Pashayan HM et .al. 1979).

The results of the article, Neonatal Care of Infants with Cleft Lip/or Palate: Feeding Orientation and Evolution of Weight Gain in Nonspecialized Brazilian Hospital, by Amstalden-Menders et al. LG. suggest that specific neonatal health care for cleft babies should be part of health policy (Am Stalden-Mendes et. al.,2007).

Nearly the same result was described by Richard ME in his article, Feeding the New Born with Cleft Lip and /or Palate: the Enlargement, Stimulate, Swallow, and Rest (ESSR) Method. He said that, failure of newborns with cleft lip and/or cleft palate to properly gain weight remain frustrating reality for many families regardless of the complex medical technology designed to meet this problem. (Richard ME 1991)

Clarren et al. SK assessed 143 infants with cleft lip and palate in their article, Feeding Infants With Cleft Lip, Cleft Palate, or Cleft Lip and Palate; they found that feeding problems vary with patient's anatomic lesion (Clarren SK et .al., 1987).

CHAPTER 3 THESES/PROPOSAL:

3.1 INTRODUCTION:

Feeding is an essential task the infant should perform soon after birth, but there are groups of babies who lack the power to do so, one of them are babies with cleft lip and palate which is a common paediatric problem shared by the baby, the mother the paediatrician.

Feeding is a frequent process this makes the situation very difficult where the baby needs to be fed and takes his daily requirements whether or not he has a rose bud mouth or clefted lip and palate, which can make the process very difficult.

Another very important point is that the small baby needs to be fed to grow and gain weight, or he will not be legible to have the needed surgery upon him, because if he failed to gain enough weight the corrective surgery will be delayed and the problem will be complicated.

The theses of this project is based on an understanding of the mechanism of normal feeding process and compared it with feeding in cleft lip and palate cases seeks a proper solution to their daily problem during feeds.

First in this chapter, the sucking and swallowing behaviour in normal babies will be discussed which includes nutritive sucking and, non nutritive sucking,

swallowing, respiration, milk flow and readiness to feed. Second, review of sucking and swallowing behaviour in clefted babies and the defective mechanism during bottle feed are reviewed. Lastly, the important points in regard to feeding babies with cleft lip and palate will be mentioned .Some highlights on feeding consideration will be mentioned at the end of the chapter.

3.2 THE MECHANISM OF SUCKING AND SWALLOWING IN NORMAL BABIES (ORAL-MOTOR FUNCTION IN THE NEONATE)

3.2.1 SUCKING BEHAVIOR

In an infant feeding successfully, swallowing and breathing are coordinated in a timely way. If this appears to be given for healthy term infants, it is not so for those born prematurely or with various disorders. (Chantal Lau,1996).

A-Sucking

Sucking is a complex behaviour which results from the integration of muscular activities of the lip, cheeks, jaws, tongue, and palate. Indeed, the ability of transferring milk into the mouth from a bottle or breast and forming a bolus while pushing it to the back of the mouth to generate a swallowing reflex requires a precise timing of all the muscles implicated (Chantal Lau, 1996).

The sucking consists of a rhythmic alternation of suction and expression.

Suction is the negative intraoral pressure exerted by the infant while drawing milk into the mouth. This requires that the oral cavity be sealed so as to allow the generation of negative pressure. Expression is the positive pressure corresponding to the stripping of the nipple between hard palate and the tongue (Chantal Lau, 1996).

The article of, *The Analysis Of Sucking Behaviour In Newborn Infants*, done by Eishima K after an analysis of the sucking behaviour showed that the sucking movements consist mainly of a peristaltic tongue movement and two kinds of negative that the peristaltic tongue movements are synchronized with the jaw movements. It is clear, that infants actively adapt to a varying environment and that the sucking movements change to minimize the energy required (Eishima K;1991).

The sucking has a developmental course, the main changes are:

- a) The bell shape produced by the peristaltic tongue movements is quite high in the neonatal period, decreases in height considerably during the third month and almost disappears by the tenth month of life.

- b) The depth of the cavity produced by the peristaltic tongue movements increases from the third month until the eighth month and decreases after this time.

- c) The wrapping by the root of the tongue at the tip of the nipple gradually weakens during the first month and almost disappears around the sixth month of life.

- d) The neonatal pattern disappeared and the pattern for older infants appeared in one sucking episode in the same infant during the second and third month after birth .There were individual differences in the period of actual change but it usually appears during the third month (Chantal Lau,1996).

Medoff-Cooper B et al., in their Study, Neonatal Sucking as Clinical Assessment Tool: Preliminary Findings, found difference sucking profiles between different groups of babies. (Medoff-Cooper et .al.,1989).

To describe changes in sucking studies have differentiated coarse and fine structures within its temporal organization (Fig 2.1) with a given period.

Coarse structures (see Fig 2.1) are define as the number of burst and pauses , their durations and the number of sucks within each burst .To differentiate between individual sucks and bursts, of sucks occurring less than 1.5 to 2 second apart were considered part of the same burst. Fine structures (see Fig 2.1) describe the characteristics within burst for example the interval between sucks and the amplitude of suck.

Pollitt et al. noted that 30-day old infants ingested the same volume of milk in a shorter period than 2-day-old counterparts did. The increased efficiency in the older infants was not the result of changes occurring within single sucking components such as suck amplitude but rather an improved coordination of different sucking components such as the time spent sucking and the amplitude of suck (Pollitt, E;1978).

Sameroff, who was among the first to devise a method to record separately suction and expression, whereas expression could occur in the absence of suction. It remains to be determined, however, whether the rhythmic alternation of these two components to be present for a successful feeding to occur (Sameroff, AJ;1996).

Tamura et al. Y in their article, *Coordination Of Tongue Movements and Peri-Oral Muscle Activities During Nutritive Sucking*, mentioned that when they used a feeding bottle equipped with micro-video-camera they found that the tongue movements included elevation of the medial part of the tongue in a backward-moving peristaltic wave. Significant correlations were found between jaw motion, tongue movement and sucking pressure (Tamura Y et al.;1996).

C-Non-Nutritive Sucking

Non-nutritive sucking is the sucking behaviour exhibited by infants when no liquid is ingested e.g. when pacifier is used. It is characterized by a series of shorter bursts and pauses (two sucks per second) when compared with nutritive suck (one suck per second).

Sucking is growth promoting via its action as stress reducer; more specifically, children spend less time in fussy and active awake states and returned to stable sleep more rapidly. These beneficial aspects of non-nutritive sucking may be valid for term infants. (Chantal Lau;1996).

3.2.2 SWALLOWING

Swallowing like sucking is a complex behaviour. For the smooth transfer of a food bolus to the stomach, the proper coordination of muscles from the mouth, palate, pharynx, larynx and oesophagus are necessary (Chantal Lau 1996).

Swallowing disorders may arise from weak propulsion of bolus into the pharyngeal cavity or mistiming or delay of the various events which need to occur to prevent it from entering the nasal cavity, airways or both (Chantal Lau;1996).

The article, *The First Year of Human Life: Coordinating Respiration and Nutritive Swallowing*, by Bronwen N. that his study provides the first documented report of the maturation of breathing –swallowing coordination during feeding (Browen ,N; 2007).

3.2.3 RESPIRATION

The coordination of swallowing and breathing has been a long running concern of caretakers. The interruption of airflow during pharyngeal swallowing can last from 350-700 msec (Koenig JS et. al.,1990), with infants respiratory rate ranging between 40-60 breath/minute and one cycle of inspiration/expiration is lasting between 0.7 and 1 second.

In term neonates, with swallowing occurring primarily at the end of inspiration or expiration or during expiration with maturity, there is a trend towards the synchronized coordination of sucking, swallowing and breathing of a ratio of 1:1:1 or 2:2:1 .

It is evident that a delay in any of these three factors will lead to their desynchronization and hence to oral feeding difficulties. These compensatory means reflect the infant's inability to perform rhythmic suction/expression/swallow in parallel to rhythmic inspiration/ expiration. Blocking of the teat/nipple with their tongue is probably done to stop milk flow into their mouth (Chantal Lau 1996).

Many of the same muscles of the jaws, cheeks and tongue as well as of the upper airways is implicated in suction, expression, swallowing and breathing. **So considering the rhythmic nature of these behaviors' and the physiologic systems involved in their coordination, it is easily understood how sucking disorder can arise when anyone of these functions is slightly delayed** (Chantal Lau 1996).

In the article of, Sucking and Breathing Patterns During Breast-and Bottle-Feeding in Term Neonates Effects of Nutrient Delivery and Composition, by Mathew OP, conclude that most of the differences in sucking and breathing patterns can be attributed to **nutrient delivery** rather than nutrient composition (Mathew, OP 1989).

3.2.4 MILK FLOW

With infants who have some difficulty in being started on oral feeding a frequent comment heard in the nurseries is that the nipple hole is too large and milk flows too rapidly. The positive correlation between the latter two variables is well recognized (Mathew OP;1991).

In addition, the hydrostatic pressure of the milk present in an inverted bottle represents a sustained positive pressure which is independent of the size of the nipple hole, leads to continuous dripping of the milk. Even if the infant is resting with the nipple in the mouth, he or she needs to continue to swallow to handle the milk drip and avoid choking. For premature infants and those with oral motor dysfunction, this factor may further delay their introduction to oral feeding. Different nipple shapes or specially designed bottle/nipple apparatus have been used to circumvent some of these problems. But no systematic study has been carried out to determine in which manner these interventions benefit the infants (Chantal Lau;1996).

Mathew O P mentioned in his article, *Sucking, And Breathing Patterns during Breast and Bottle Feeding in Term Neonates, Effects of Nutrient Delivery and Composition*, that most of the differences in sucking and breathing patterns' between breast and bottle feeding can be attributed to nutrient delivery rather than nutrient composition (Mathew O P, 1989).

3.2.5 READINESS TO FEED

To assess the feeding performance of the infants, the following parameters were defined:

Overall transfer:

Regarding the percent volume transferred during an entire feeding/ total volume ordered for that feeding, satisfactory feeding performance was described as an overall transfer of 80% or greater ,takes with the 20minutes allowed for each feeding session .

Efficiency:

The volume transferred per unit time (ml/min) calculated over an entire feeding.

Proficiency:

The percentage calculated as the ratio between volumes transferred during the first 5 minutes and total volume ordered for that feeding i.e. volume transferred during the first 5 min divided by total volume ordered for that feed multiply by 100.

Subject performed equally well whether they used suction/ expression or expression alone, the latter being the predominant sucking pattern used by premature infants. If infant proficiency of 35% or greater and an efficiency of 1.7 ml/min or greater, a predicted 95% of them would demonstrate satisfactory oral feeding performance. Proficiency and efficiency, which are readily measurable by caretakers without the use of any special equipment, may be used as clinical indicators of infant feeding performance. It is recognized that sucking from a bottle is not the same as from the breast. It is clear how complex a behaviour sucking is requiring the function of several systems needs to be smoothly integrated (Chantal Lau;1996).

A study of Eishima K, The Analyze Sucking Behaviour In Newborn Infants, showed that the sucking movements consist mainly of peristaltic tongue movement and two kinds of negative pressure that the peristaltic tongue movements are synchronized with the jaw movements: that infants actively adapt to varying environment, and that the sucking movements change to minimize the energy required (Eishima K;1991).

Neonatal Sucking Behaviour and Its Development until 14 Months, was discussed by Iwayama K et al. The present study detects a developmental course of the sucking behaviour. The main changes are:

(a) The bell shape produced by the peristaltic tongue movements is quite high in the neonatal period, decreases in height considerably during the third month and almost disappears by the tenth month of life.

(b) The depth of the activity produced by the peristaltic tongue movement increases from third month until the eighth month and decreases after this time.

(c) The wrapping by the root of the tongue at the tip of the nipple gradually weakens during the first month and almost disappears around the sixth month of life.

(d) The neonatal pattern disappears and the pattern for older infants appears in one sucking episode in the same infant during the second and third month after birth. These are individual differences in the period of actual change but it usually appears during the third month. (Iwayama K et .al;1997)

Tamura Y describes , Coordination Of Tongue Movements and Peri-Oral Muscle Activities During Nutritive Sucking, the tongue movements including elevation of the medial part of the tongue in backward moving peristaltic wave; significant correlations were found between the jaw motion, tongue movement and sucking pressure. The TM (temporal muscle), MM (masseter muscle) and OM (orbicular muscle of the mouth) were most active when the sucking pressure became positive and the jaw was closing, the SM (suprahyoid muscle) showed highest activity in the negative - pressure phase. These

findings show that each sucking cycle is biphasic, with sucking pressure, perioral muscle activities and jaw motion all closely correlated (Tamaura Y;1996).

The information in the article, Oral Motor Function In The Neonate, by Lau et al. C illustrates the importance of evaluating oral motor function of the infant not only as function of his own ability but also of external and maternal assistance, the studies focusing on the importance of acquiring a better appreciation of the psychosomatic issue to help safeguard mother-infant relationship during difficult times (Lau C et. al;1996).

3.3 REVIEW OF THE MECHANISM OF SUCKING AND SWALLOWING IN CLEFT LIP AND PALATE BABIES:

3.3.1 INTRODUCTION:

One of the first, most vital needs the baby will have upon entering the world is to take nourishment. This is true whether a baby has rose-bud lips and a perfect palate or a complete cleft. Either way, the baby will be hungry and will look to the mother to feed him.

Feeding is one of the first and most basic needs that a parent fulfils for their child. Sucking is an important skill and babies needed to be fed well

especially when a baby is born with a cleft lip and or palate, because it is difficult for them to suck milk from the breast or bottle and they need some adjustments to feeding methods and positioning. The baby should be able to get all the benefits of the feeding experience, i.e. enough nutrition for growth and development, bonding with care and use of the muscle of the mouth.

3.3.2 DEFECTIVE MECHANISM DURING BOTTLE FEEDING

Babies with cleft lip and palate have some difficulties in feeding either from the breast or the bottle because they do not have a separation between the nose and mouth, so they cannot create enough pressure in the mouth to draw milk from the breast. To be fed, these babies need a specifically designed bottle . An important issue is that the baby should have adequate nutrition and gain weight.

The gap in the muscle and soft tissue caused by a cleft palate makes it difficult for babies to position and use the nipple or teat as other babies do when sucking and feeding. Although the babies are eager to make sucking movements with their mouth and jaws, they are unable to create and sustain the pressure required to draw milk so they need bottle with an enhanced flow rate.

These babies may have a nasal regurgitation, if there is great deal amount of liquid in the nose, tilt the baby forward, the baby will swallow any extra milk in the back of the throat and it will drain by gravity.

The goal of feeding should be 2 ounces of formula per pound of weight each in 24 hour period .For average birth weight of 8 pounds, the goal for feeding would be 16 ounces a day divided into 6-8 bottles. The amount will increase if babies start gaining weight. (1 ounce = 30cc, 1 kg = 2.2 pound)

Mechanical movement of the tongue is generally adequate to produce nipple compression; the effectiveness of this compression is dependent upon the size and location of the cleft.

The degree of negative pressure suction is dependent on the size and location of the cleft: -

From mechanical point view:

- 1) If it is small defect, usually there will be minimal reduction in negative pressure during suction.
- 2) If there is posterior cleft it could be occluded by tongue during sucking resulting in minimal reduction of negative pressure but still causing inefficient feeding .
- 3) If the cleft occur in submucous area namely the soft palate and glossopalatal area the major associated problem is the limited development of negative pressure of suction due to impaired movement of the soft palate and glossopalatal seal.

4) If it is large defect mechanically may completely preclude development of negative pressure suction

* **Bottle feeding:**

- Even with small defect when negative pressure suction is generated, feeding is often ineffective resulting in prolonged feeding and inadequate intake, a soft nipple with enlarge opening may increase the effectiveness of the low-pressure suction allowing greater amount of milk to be expressed from the sucking compression.

- If the cleft is large, it is not possible to produce and sustain negative pressure suction

-using an angle necked bottle make upright feeding easier.

3.4 IMPORTANT ISSUES IN REGARD TO FEEDING BABIES

WHO HAVE CLEFT LIP AND PALATE:

3.4.1. CLEFT PALATE:

As noted above, the palate is another name for the roof of the mouth. The palate comprising both the roof of the mouth and the floor of the nose.

3.4.2. BABY BOTTLE

- is a bottle with a teat which allows liquid to be drunk directly from it.
- It is typically used when a mother does not breastfeed.
- It is used to feed an infant with infant formula, expressed breast milk or paediatric electrolyte solution.

Dimension and Design

- A large – sized bottle typically holds 270ml; the small on size 150ml.
- It is composed of the bottle itself, a teat, a ring to seal the teat to the bottle, a cap to cover the teat and optionally a disposable liner.

Teats (or nipples)

- The teat itself is typically slimmer and more flexible than the mother's nipple.
- The contents of a bottle can flow more quickly than breastfeeding.
- Teats offer a selection of flow rates.
- Different flow rate teats either have more holes or larger holes.
- Specialized teats are available for infants with cleft palate.

3.5 FEEDING CONSIDERATION

- The most immediate concern for a baby with cleft palate is good nutrition. The opening into the mouth from the nose causes a leak of air that prevents effective suction.
- Newborn with cleft palate may need to approach feeding in some different way and may benefit from the following recommendations:

Length of Time

- The majority of babies with clefts take 30 – 60 minutes to feed while a significant number of parents report their feeding time could take up to 1 1/2 hours.

Amount

- These infants tend to feed small frequent amount often and seem to fall asleep on the bottle easily.

Burping

- seem to need more frequent burping than other babies because they swallow considerable amount of air when feed.

Temperature

- Although there are no professional studies, mothers reported that their babies liked their formula warmer than usual.

Positioning

- An infant with cleft palate will have greater success feeding in an upright position, because gravity will help prevent milk from coming through the nose of baby. Feeding the baby in a reclining position leads to contamination of the middle ear and ear infection.

Bottle

- A special feeding bottle is needed.

Formula

- There is no particular formula designed for babies with cleft condition.
 - * The most important thing to remember when caring for a child with a cleft palate is looking for signs of dehydration and fatigue caused by malnutrition.
 - * For most babies with cleft palate, breastfeeding as the only feeding method is not successful in providing enough nutrition for growth. This is because of the cleft makes it difficult to draw milk from the breast so they cannot create enough pressure.

CHAPTER 4 ARGUMENTS ABOUT COMMONLY AVAILABLE BOTTLE DEVICES FOR CLEFT PALATE:

4.1 INTRODUCTION:

Feeding interventions recommended for use in cleft conditions which available in the market should be studied thoroughly to visualize the strengths points and weaknesses once, before designing to create a new bottle for cleft conditions.

In this chapter ,reference and comments about the available bottle feeders will be discussed first .Then , basic informations about the delivery system , followed by the available bottle feeder for cleft lip and palate (the Pigeon baby bottle ,Med-Johnson ,Haberman feeder, obturator and breast feeding).A review of current articles discussing the debating about the use of the available interventions come next ,followed by a closing by discussion and conclusions.

4.2References and c omments about the available bottle feeders

While describing the available bottle feeder found in the market and their advantages and disadvantages, it may be of value to refer to two very important aspects:

1- The twenty years of clinical experience of the author as paediatrician who is deals with babies form birth up to 12 years of age.

2- A literature review of important research paper which discuss the feeding interventions for babies with cleft lip and palate.

1-From Clinical experience:

As paediatrician seeking to find a solution to babies with cleft lip and palate, the author reviewed and tested all the available bottle feeder used for babies with cleft lip and palate by the applying them on babies with cleft conditions to understand how they works and how they could help this group of babies. Analyzing their advantages and disadvantages, so as to create a new device for them to use that could help babies with cleft lip and palate.

The information's regarding this subject is collected from:

- A. Observing babies as they used the available bottles.
- B. Parent's comments.
- C. Valid suggestion of caring nurse (if clefted baby of interest werey at hospital sitting).
- D. Recommendations from senior consultants whom they dealt with cleft lip and palate babies.
- E. Lastly from prescription pad enclosed with the bottles.

4.3 Basic information's on the delivery system:

Before starting describing the common available bottle feeder for cleft conditions, some basic information's points about the delivery system should be known:

*Basic Information on Milk Delivery system:

- A. it should approximate normal rate 0.1 to 0.5cc per suck
- B. should stimulate normal sucking patterns
- C. feeder must learn to provide the fluid in rhythm with the infants sucking movement to facilitate coordinated swallowing.

4.4 Most Common Available Bottle-feeding for cleft palate:

4.4.1 The Pigeon Baby Bottle:

Description:

- It is especially designed, for cleft condition babies.
- It is made of latex-free material.
- It has Y cut at the tip of the nipple which has thick and thin side with one way valve which prevents excessive air intake and allow milk to flow only when the baby sucks.
- There is a Y cut at the tip of the nipple and V at the base of the nipple (this is air vent); this should be placed under the infant's nose for the nipple to work properly.
- Flexible bottle which allows the milk to be gently squeezed into the nipple. When baby sucks or compresses the nipple milk is forced into her/his mouth;
- The air control system allows control of the rate of flow to be controlled simply by just loosening or tightening the cap.



Fig 4.1 Pigeon bottle

Disadvantages:

a - Some parents reported leaks from the hole, so it needs to be removed the nipple from the cap and massage that area to unclog the vent and dry the passage.

b- Nipple collapse is a frequent problem.

c- To work, the position of the bottle must be in proper position so that the V shape is under the baby's nose to start working, although at times it is difficult to control a baby during feeding particular if s/he is hungry and crying.

d- From instruction notes it is mentioned:

- The clefted nipple should always be used within Pigeon bottle, because it does not fit in most of standard bottles.

- To avoid breaking up the special nipple, it is not allowed to autoclave to avoid break done the special nipple, it must be sterilized only in two minutes immersions in boiling water or use harsh detergents.

4.4.2 Mead-Johnson Cleft Palate Nurser

Description:

- Specially made bottle combination:

a) The nipple

This is long and soft with crosscut perforation hole.

b) Bottle

This is made of plastic and must be squeezed to allow milk to flow.

The mechanism of action is as follow:

- After the nipple is placed in the baby's mouth, s/he should be allowed to suck and breathe a few times before beginning the bottle compression.
- Slowly perform gentle compression slowly performed then should be speed up while watching the infant's face.
- A longer nipple allows milk to be directed past the cleft and cross cut allows an increased flow.
- Compression of the bottle should be stopped and then resumed on and off to allow the baby to swallow what s/he has sucked.



Fig.4.2 Mead-Johnson bottle

Disadvantages:

Parent reports:

- The most common complaint about Mead Johnson Nurser is it has they have a tendency to leak around the collar.
- There is little that can be done to control the amount of air swallowed during feeding; the baby need to be burped frequently
- Overflow could occur because baby will continue to suck from large opening as the bottle is compressed by the caregiver. However, this could lead to the possibility of overflow and chock.

4.4.3 Haberman Feeder

Description:

- The difference of Haberman from most bottles lies in its nipple or what the company refers to as the teat.
- The teat acts like a separate squeeze bottle which is attached to the actual bottle.
- The teat is designed so that after it is filled with milk, screw on the nipple or teat and then squeeze all the air out of the teat. Separating the bottle from the teat is a perforated disc, which acts as a door.

- There is a disk with holes that separates the bottle from the teat, this disk has a very flexible piece of rubber that works like a door so only when it is squeezed does the flap of the rubber move away separate from the disk allowing milk to flow through which is then unable milk from going back into the bottle.
- The nipple is marked with lines that indicate zero flow, moderate flow and maximum flows, stopping or reducing the flow of milk is controlled by rotating of the nipple in the baby's mouth (the longest line have the easiest flow).
- Gentle pressure may also be placed on the nipple if necessary to promote better flow and feeding.



Fig 4.3 Haberman bottle

Disadvantages:

As reported by parents and clinical observation the following was noted:

- It is very expensive (US \$ 15 – \$20) and need to be replacing after 6 weeks.
- Its nipple is not covered; they don't have by a cap, unlike to cover the nipple like a regular bottle nipple does which could give the possibility of contamination from the nipple to already small baby.
- The nipple leaks in particular when it is used them with non specialised other bottles bought from the stores. They are designed to be used only with Medelabottles, (their manual states).
- The reservoir should be compressed with gentle but put a continuous pressure to allow milk to flow.
- The teat may pop right off, suddenly detach itself.
- They cannot be boiled as other bottles can. Exposing them to hot water can destroy them and cause leakage. Even warm milk can do some damage.
- They are not recommended for children with swallowing difficulties.

Note: It is worth noting to know that an award-winning inventor, Mandy-

Haberman, a British graphic designer whose baby was born with congenital abnormalities that include a cleft palate, especially noted the difference between bottle-feeding (which is primarily sucking) and breastfeeding (primarily pumping). She invented a marvelous device called Haberman bottle feeder for babies with cleft lip and palate which helped a lot of children worldwide, and earned much gratitude for helping not only her child but all the children with this condition so, great thanks to this lady who tried to help her babies and other with the same condition.

4.4 .4 Obturator (Artificial palate):

Description:

- Feeding obturators are passive device designed to provide a normal contour to the cleft alveolus and hard palate (Schaaf et al 1995).
- They separate the oral and nasal cavities and in doing so provide a surface to oppose the nipple during sucking (Glass and Wolf 1999; Miller and Kummer, 2001).
- It has a long plate crossing the nipple's upper part which can occlude the cleft for normal suction.
- It has supplied in small and big sizes.



Fig 4.4 obturator

Disadvantages:

From clinical experience it is found:

- Difficult to use because it must be fixed in the right place which is the upper part of the mouth to occlude the cleft. With a hungry, crying baby this is so difficult to be applied.
- May distort sucking and swallowing patterns.
- The methods are controversial because either the obturator is big which makes sucking difficult for the baby or so small that it will not do its work.

4.4.5 Breast Feeding

- Breastfeeding an infant with cleft lip can be successful but an infant with a cleft palate may have difficulties. It is sometimes requires more upright positioning so that the mother's breast tissue fills the gap in the lip or gum.
- Breastfeeding an infant with a cleft palate is fairly challenging unless the infant's cleft palate is very far at the back of the mouth and very small. Nursing at the breast is best limited to 10 minutes and supplementary bottles are needed if breastfeeding alone does not supply enough food for adequate satisfaction and growth.
- As most people are aware, current research findings indicate that breast milk is best for babies. Even though breastfeeding may be difficult for a baby with a cleft palate, there is an option for the mother may express her milk and give it to her baby via the bottle.
- Breastfeeding is impossible if the cleft is very large.

4.5 Review of Current Articles debating the argument about the use of the available Cleft Palate Interventions :

As it was shown above, the devices which are available in the market and clinical setting have been discussed on the basis of clinical experience. Another very important aspect which may give a guide reader to what models are to the available cleft devices and their associated problems are what are mentioned in scientific article which debate the use of the available devices for cleft babies.

After reviewing fifty five articles published between 1995 and 2002 , Julie Reid wrote an article ,A Review of Feeding Intervention for Infants with Cleft Palate This article describe a number of interventions , including early feeding and assisted feeding methods for such infants with isolated cleft conditions.

Fifty (91%) of 55 articles reviewed were not data driven reports of experts opinions, Reid concluded that there was a paucity of evidence rated as either moderate or strong prevailed and underscoring the scientific evaluation of feeding interventions used with infants who have cleft palate .A number of heterogeneity of samples gave evidence of the studied lack of replication of trial and small sample sizes, which affected the finding underpinning specific feeding interventions (Julie Reid;2003).

Feeding difficulties associated with cleft palate have been documented for many years. In non syndromic cases, the underlying problem is thought to be **failure to generate sufficient negative intraoral pressure (suction)** during feeding (Clarren et al.,1987; Choi et al.;1991; Wolf and Glass,1992; Arevedson, J C 1993; Trenouth and Campbell,1996; Oliver and Jones,1997).

This in turn affects attachment to the breast or artificial nipple and extraction of milk as well as bolus organization and, retention of the bolus in the mouth before swallow initiating the swallow itself (Wolf and Glass 1992).

As sequelae to oral nasal coupling are reported to include excessive air intake, nasal regurgitation, and fatigue, coughing, chock and gagging on fluids, prolonged feeds and discomfort (Styer and Freech 1981;Jones et al. ,1982; Clarren et al. ,1987; Carlisle ,1998).Parents may also fear to the task of feeding their infant(Zikefoose 1957).

A literature regarding the feeding of infants with cleft palate is replete with the potential consequences of feeding difficulties .An example of this is the association in developing countries of feeding difficulties with death in developing countries (Wilcox 1994).Furthermore, morbidity, such as failure to thrive (Pandya and Boorman 2001) and breast-feeding malnutrition (Living Stone et al.,2000), has been described even in developed countries.

Although there is increasing emphasis on neonatal intervention, including

seamless care from hospital to the community setting (Clinical Standard Advisory Group, 1998), debate exists about the most efficacious interventions for infants with feeding problem. Preferred management strategies vary from team to team and many clinicians. Interventions may include modified nipples and bottle, direct breast feeding, particular feeding techniques, a feeding plate and advice on specific nutrition or lactation issues.

Contemporary practice demands that intervention be evidence based that is an integration of individual clinical expertise with best available external clinical evidence from systematic research (Sackett et al.,1997).

This allows the clinicians to deliver the most appropriate intervention to particular patient, and health care administrators mean while demand the most effective out comes for minimal cost (Law and Baum1998).

With this in mind, the aim is to determine what feeding interventions are reported and recommended for infants with isolated cleft condition and to determine the evidence under pinning each of these and to describe problems associated with their use.

The arguments for the using of the available interventions for feeding cleft babies are classified according to the following four broad classes:

Four broad intervention themes were identified this includes:

- 1) Feeding equipments (bottle, teats, cup, spoons).
- 2) Breast feeding.
- 3) Prostheses.
- 4) A combinations of any of the above.

4.5.1 Feeding equipment (bottles, teats, cup, spoons):

A- Compressible bottle and parental counseling:

Shaw et al (1999) described randomized trial concerned with feeding equipment specifically bottles. Infants with nonsyndromatic cleft lip, cleft palate or combined cleft lip and palate (n=101) were randomized at birth to one of two group which compared compressible and standard rigid bottles. Both groups used an NUK or orthodontic nipple .Randomization in this parallel study was based on cleft condition (cleft lip ,cleft palate or combined cleft lip and palate) but did not control for other variables ,such as birth weight ,sex, or parental ethnic origin , which may have influenced out comes .

Although better growth was detected in the compressible bottle group at 12 months of age, early feeding success in both groups may have been partially attributable to early feeding support and parental counselling provided by

specialist health visitor .Since this intervention was not specifically measured, its effect cannot be substantiated without further investigation.

B-Modified nipple and nutritional intervention protocol:

Brine et al (1994) reported the result of a trial concerned of feeding equipment and nutrition intervention protocol .Thirty one infants (median age 15 days, age ranging from 0 up to 54 days) with either a cleft palate or combined cleft lip cleft palate nurser (Mead Johnson) to a conventional rigid bottle used with a standard cross cut nipple .Both group received nutritional intervention which include feeding technique instructions, nutrition counselling at each clinic visit. They used of the same standard formula for 12 months and introduced of solids at 6 months. Follow up ensued was done at 18 month.

The results suggesting that both feeding methods were effective in supporting normal growth .The author reported, however that their data supported the need for feeding and nutritional education and an organized nutritional intervention. This intervention was not specifically measured during this trial.

C- Other feeding equipment:

1-Artificial nipple.

2- Compressible bottle alone.

3- Cups.

1- Artificial nipple:

As state above, cross cut nipples used with either rigid or compressible bottles are said to be useful for infants with cleft conditions when combined with nutritional intervention protocols (Brine et al,1994 , Clarren et al.,1987) claim that infants with isolated cleft palate may benefit most from being fed using cross cut nipple; however, no experimental evidence was offered to support this claim.

An artificial nipple with enlarged orifice and fast flow rate has also been recommended (Jacobs1983, Martin, 1983, Porterfield,1988) and those too without solid base .Some authors caution against the use of these nipples, because the rapid flow may imperil the infants ability to synchronized sucking, swallowing, and breathing if milk is delivered directly to the pharynx (Glass and Wolf,1999, Miller and Kummer, 2001).

Numerous other nipples have been described over the years such as those containing one -way valve for controlling fluid flow and vacuum build up (Shirley and Cocke ,1971; Haberman ,1988).One of these, the Haber man feeder (Medela,1994) incorporates along soft nipple with a slit opening and one-way valve within the bottle nipple .The nipples can be positioned to allow three different flow rates and, when compressed by the feeder delivers milk to the

infant .It has been claimed that soft pliable nipple enables the infants to express fluid independently (Barone and Tallman,1998).

To date ,however , only one small series of cases (n=6),described by Campbell and Trenouth (1987) have been employed .In uncontrolled experiments, reported faster feeding times, less vomiting , satisfactory weight gain and parental acceptance for infants with various cleft conditions were reported (Campbell and Trenouth 1987) .

The use of a conventional rigid bottle and standard pierced nipple combination instead of modified equipment (e.g. compressible bottles, cross cut nipples) was recommended only once (Fischer 1991).

2 - Compressible bottle:

Compressible bottles ,allow the feeder to deliver milk to an infant who is unable to generate suction and extract fluid independently .Compensation for infants with cleft conditions who also have oral stage feeding problems of this kind has been termed assisted feeding (Bannister ,2001).

Many experts have described compressible bottles or bottle liners used with a variety of nipples (Kelly ,1971 ;Paradise and Mc Williams ,1974 ; Clarren et al ,1987; Barone and Tallman ,1998 ; Scheurele ,1998;Glass and Wolf ,1999;Miller and Kummer, 2001) .None of these reports, however, contain data supporting the use of the equipment ; thus the evidence for prescribing it is weak .

Some authors suggest that particular subgroups of infants with cleft conditions may benefit more than others from assisted feeding .For example, Clarren et.al. (1987) claim that infants with combined cleft lip and palate and wide clefts of the hard palate may particularly benefit more than other from assisted feeding. This would be powerful information for the clinician if it were supported by the evidence.

To date, however, there have been no data – driven studies comparing the outcomes for infants with different cleft conditions who used the same feeding equipment and received no other interventions.

Therefore, it is unclear whether the infants who benefit most from the use of compressible bottle can be identified solely by the size and location of their cleft. Conversely, it is unclear whether one intervention alone, such as compressible bottle, provides maximal benefit for improving an infant's feeding ability .A combination of interventions may well be preferable.

3 - Cups:

Cup feeding is an artificial feeding method generally used to complement breast-feeding .It is more commonly used for preterm and low –birth weight infants who are attempting to establish breast feeding but it has also been recommended for infants with cleft palate undergoing the same process

(Danner,1992, Lang et al.,1994) reported their experience using a cup with a number of cases, including one infant who had a unilateral cleft lip and palate.

Unfortunately, there is no indication whether or not the goal of feeding intervention, breast-feeding, was achieved or data reported about the cup feeding duration and outcomes.

To date, cup feeding for infants with cleft condition has not been scientifically evaluated, thus the evidence supporting for use of this method remains conjectural weak.

4.5.2 Breast feeding:

Breast-feeding is defined in this report as direct placement of the infant at the breast for feeding.

a) Breast feeding and palatal obturators:

Feeding obturator have been used to facilitate direct breast feeding for infants cleft condition .One report, a small case series suggested that palatal obturator may improve the volume ingested in some breast-fed infants with combined cleft lip and palate (Kogo et al., 1997).

Kogo et al. (1997) reported that 4 of 10 infants could suck approximately 22g per breast-feed under conditions where each was prescribed aHotz-type palatal palate obturator and the mother's hand expressed with the infant at breast.

Although the obturator did not preclude the need for supplemental feeding, the researchers considered that the volume ingested indicated of improved sucking performance and a promising step toward independent breast feeding. To date, there has been limited scientific evaluation of the use of prostheses and altered postures to assist the direct breast-feed of infants with cleft conditions.

4.5.3 Prostheses:

Feeding obturators are passive devices designed to provide a normal contour to the cleft alveolus and hard palate (Schaaf et al,1995).They separate the oral and nasal cavities and in doing so provide a surface to oppose the nipple during sucking (Glass and Wolf,1999; Miller and Kummer ,2001).

Feeding appliance have been reported by a number of experts (Lifton,1956; Willimas et al., 1968b; Razek ,1980;Jones et al ,1982; Flemming et al ,1985; Balluf and Udin, 1986; Goldberg et al. ,1988; Sauders et al., 1989; Kogo et al., 1997).

The effects of these appliances have been not tested with scientific bases; hence, the evidence for use in improving feeding ability remains weak.

One descriptive study suggested that when the obturator extends 2 to 3 mm beyond the hard palate, some suction will be restored (Kogo et al 1997). Jones et al. (1982) reported reduction chock , nasal discharge ,and bottle feed duration with improved parental confidence ,in their sample of the infants with cleft lip and palate (n=11) who were prescribed feeding obturators .In the main

literature , there has been almost no scientific evaluation of the use of prostheses to promote feeding in infants with cleft conditions.

Obturator for cleft lip and palate were surveyed in an article written by Sorathesn (Sorathesn P,1989) which stated that cleft lip and palate are most common congenital anomalies of the faces. Infants born with cleft lip and palate always have feeding problems. Obturators usually have indefinite retention which leads to easily dislodgement.

Turner L wrote an articles entitled, The Effects of Lactation Education and Prosthetic Obturator Appliance on Feeding Efficiency in Infants with Cleft Lip and Palate, this perspective study examined the effects of lactation instruction and palatal obturator in reducing time needed to feed increasing intake and growth of eight breast milk-bottle -fed new born infants with cleft lip, cleft palate or both.

He conclude that the combined use of palatal obturator and lactation education reduced feeding time and increased volume intake and was associated with good growth (Turner L et .al.;2001).

Osuji Oo in his article, Preparation of Feeding Obturators for Infants with Cleft Lip and Palate, mentioned that sucking is impaired in infants born with complete cleft of the lip and palate .Feeding obturators improved feeding by contributing to weight gain and thriving state of health (Osuji Oo;1982).

4.6 Discussion and conclusions:

In reviewing regarding feeding interventions as recommended for infants with cleft conditions, only relatively small body of literature on feeding interventions with few well-executed controlled trials exists and, in a field where commonly used interventions are underpinned by such a paucity of scientific evaluation, it is important to illustrate which interventions are supported solely by clinical or expert opinion. Interestingly, most of the studies (Brine et al., 1994; Richard, 1994; Shaw et al., 1999; Pandya and Boorman, 2001; Turner et al., 2001) investigated a combinations of interventions (e.g. nutrition intervention and compressible bottle) rather than single interventions (e.g. cross cut nipples).

To summarized this, it seems that no single intervention can be prescribed with confidence to improve feeding out comes for infants with cleft conditions.

Instead, combinations of interventions have yielded the first positive result for directing feeding intervention. Not surprisingly, reports of clinical experience and expert opinion predominated (Julie Reid March 2006). Although it is appropriate to consult experts on what constitutes best practice when a paucity of scientific evidence scarce (Egan et al., 1998), a number of theoretical issues seem to confound the investigation of feeding interventions for infants with cleft palate:-

First, there is no consensus as to what constitutes feeding difficulty , which infants are most at risk , and what constitutes feeding difficulties , which infants

are most at risk , and what the predictors of poor feeding might be .In short , descriptive epidemiological studies which could provide this information have not been undertaken. Instead, feeding interventions have erected structural view of feeding difficulties with little investigation of any other components of feeding, such as oral motor function, swallowing function, or mother - infant (psychodynamic) feeding relationships, which may be important. This is not surprising given the lack of descriptive epidemiological work.

Second, little attention has been given to understanding how various feeding method works, and what effect they have on the infant's overall feeding ability. For example, the effect of:

- (1) Palatal obturator on oral proprioceptive feed back during feeding.
- (2) Cup feeding on the development of appropriate oral motor patterns for sucking.
- (3) Long term feeding problems on long -term eating behaviour are unknown.

Finally, in those studies where interventions were evaluated more than one intervention was frequently included (e.g. bottle and nipple type combined with general feeding and nutritional advice), and it was difficult to determine which aspect(s) of the feeding intervention may have accounted for the improvement.

Analytic epidemiological studies are required to address these intervention questions if they remain relevant subsequent to descriptive epidemiological work (Julie Reid; March 2006).

Likewise, the article describing, Neonatal feeding of infant born with cleft lip and palate: Parental Perceptions of their Experience in South Wales, was studied by Oliver et al. with special preference to parent's perceptions. A questionnaire was distributed to 100 parents of children born with cleft lip and palate. He concluded that before birth most of mothers had intended to breastfeed their children, but after birth, most of infants were bottle-fed (Oliver RG et al. ,1997).

Another related study with a corresponding questionnaire provided was made by Trenouth MJ. His article, Evaluation of Feeding Methods for Cleft Lip and Palate Neonates, evaluates the feeding methods used by the mothers of 25 neonates with cleft lip and / or palate. Most parents had problems in feeding their babies, both with the quantity of feed taken and in particular with the time it took them to feed (Trenouth, MJ 1996).

Another author Pashayan HM mentioned in his article, Simplified Method of Feeding Infants Born with Cleft Palate with or without Cleft Lip, that these babies do not grow well and have history of difficult feeding. A standard nipple that with a crosscut design and a standard glass baby bottle were used. The data indicated that their nutrition was adequate when judged by weight gain. (Pashayan HM;1979).

CHAPTER 5 : NEW BOTTLE FEED METHOD

5.1 Introduction:

It is obvious from the previous chapters how serious the problem is. In dealing with babies with clp which are a common paediatrics problem and will continue for some time to be so, besides it will continue for the babies until the corrective surgery performed .For months of such to have a baby with clp each feed causes suffering.

The special supplies currently available in the market may help to help to some extent to reduce the risk of choking during feedings to some extent. Feeding a child with a cleft palate can take extra time and more effort. Feeding times can be stressful. The baby may be very tired after eating. This is because the cleft palate may oblige the baby to work harder to suck and swallow.

Nutrition is important for every newborn. Babies with a cleft lip and/or palate are special that most will not be able to suck effectively, making feeding hard work for them. Yet, good nutrition is important for the growth and development of the baby.

There are reports of health benefits associated with appropriate and improved management of feeding problems in infants with cleft conditions; some babies with cleft lip and palate can be fed with a bottle and later a spoon without problems, but others have a hard time.

The cleft makes it difficult for the baby to get good suction on a bottle.

Although, sucking and swallowing reflexes are present in a baby with cleft lip and palate, they do not work well. The baby may not get enough to eat, or may get too tired when feeding. Sometimes babies have problems with food coming out of the nose. The baby may choke, cough, and spit.

The goal of feeding a cleft baby is to lessen these problems and ensure good weight gain. Ideally, feeding interventions should reduce stress experienced by the family and promote infant growth and developments and facilitate a normal feeding pattern.

There are several different bottles and nipples on the market which have been specifically designed for babies born with clefts. When choosing feeding supplies, for such babies one should look for the following features:

1. soft, thin-walled nipple that compresses easily.
2. nipple which allows the milk to flow at a moderate speed, neither too fast nor too slow.

The goal is to feed slowly enough not to choke the baby, but fast enough not to tire the baby out her/him.

Timing of Feeding:

Babies with cleft conditions may need small, frequent feedings. In general feeding should not take more than forty five minutes.

3. method should be sought which not interfere with the normal swallowing mechanism or the normal activity of the oral-facial muscle, no matter what combination nipple and bottle are used.

4. The goal is to make feeding easy for the baby while still allowing him / her ample opportunity to suck.

Using a squeezable bottle is one way to increase the flow of milk and conserve the baby's energy. A few such bottles are the Mead Johnson Cleft Palate Nurser, and the Haberman Feeder. When using any squeezable bottle, the bottle should be gently pulsed, not continually squeezed. A squeeze only should be provided when the baby is sucking. Following the infant's own suck rhythm helps ensure that s/he does not aspirate milk into the lungs.

The Mead Johnson Cleft Palate Nurser is simply constructed and easy to use.

Both the Pigeon Cleft Palate Nurser and the Haberman Feeder need assembly and are a little more complicated to use. Many hospitals already stock

Haberman Feeders, since they also can be used to feed. Both are constructed to reduce the amount of air the baby swallows and have methods to control the rate of milk flow.

This chapter is deals chiefly with the invented device for clefted conditions. It initially it was started by giving the background of the invention, then it goes to describe very important devices Goldie device, (which is a computer controlled bottle feeder) and Ruth device (feeding device from non-oral to oral feeding) as an examples of bottle feeding for compromised babies. The above two inventions namely Goldie and Ruth were discussed in detailed with more emphasis on their mechanical and medical issue. The new bottle feeding method for cleft lip and palate babies is then described in detail, starting with the idea for inventing this device, its advantages, and description of the device and how it works.

5.2 Background to the invention:

Cleft lip and palate are common birth defects that require special attention during the initial six months of baby's life .To be more specific, there are three types of cleft lip i.e. unilateral incomplete, unilateral complete and bi-lateral complete. There are also two types of cleft palate, namely the soft palate only, the unilateral complete and the bilateral complete.

However, each of the cleft lip and or cleft palate malformations involves leakage of the air from the mouth through the nose which prevents the infant

from sucking, causing regurgitation of fluids through the nose and difficulty in swallowing and breathing.

For a period of six months until the infant has matured enough for corrective surgery, the infant must be fed .Feeding is not only most immediate problem encountered in the daily care of an infant with a cleft lip and /or cleft palate but it is one of the more difficult to solve and the most urgent for the survival of the baby.

With this in mind during searching for solution for feeding babies with cleft lip and palate ,amore recent U.S patent of Goldie concerns a smart bottle feeding and a system for neonatal nursing, another impressive device done by Ruth as a transitional way of feeding transferring neonate from tube feeding to oral feeding. Both are discussed in details below.

5.3. GOLDIE (computer controlled bottle for oral feeding of a patient):

-PUB No.: US 2008/0039778A1

-PUB. DATE: Feb.14,2008(please refer to appendix A)

The present invention relates to medical devices and more particularly to a computer controlled bottle system for example , for preterm infant oral feeding , which is directed to a method for delivering nutritional fluid orally to preterm infant comprising the steps of measuring some parameters as the infant's inspired breath to breath amplitude ,measuring the her/his intraoral sucking pressure, establishing threshold values for infants inspired breath to breath amplitude and infants intraoral sucking pressure , and delivering nutritional fluid to the infant only when the infants inspired breath to breath amplitude and infants intraoral sucking pressure both simultaneously satisfy their respective threshold values .

The main principle of this device is to establish a threshold values for infants once this is reached, an initial measurable quantity of fluid is delivered to the patient. The computer controlled bottle system incorporates the sensing of both sucking and breathing in order to implement the algorithms which controlled milk flow.

Once the criteria (respiration, sucking, and blood oxygenation threshold) have been satisfied to begin the onset of milk delivery, the computer- controlled bottle software may issue at the self -contained computer controlled bottle fluid delivery motor to deliver milk at predetermined minimum flow rate. This process may be repeated in multiple predetermined incremental steps until the milk rate reaches predetermined maximum value or may be terminated or reset if the respiration and blood oxygenation levels dip below their respective threshold level.

5.3.1-Mechanical point of view:

The device contains a housing for delivering nutritional fluids to the baby ,a nipple , a motor to transfer the fluid ,sensor to measure the patient's intraoral sucking pressure , integrated electronics where substantially all elements of the apparatus are contained within a housing ,in communication with the integrated sensors and capable of issuing commands to control the fluid delivery motor .

The division of the computer controlled bottle is divided into a disposable and a reusable portion. The components of the reusable base are designed to make no contact with the baby or with the infants bodily fluids .During feeding, the nurse fills an internal collapsible bag contained within the disposable portion of the computer- controlled bottle with milk through fill port or a fluid cartridge that can be used .

The computer -controlled bottle system incorporates sensor for both sucking and breathing in order to implement the algorithms which control the led milk flow. Infant sucking is sensed by two pressure transducers housed in the reusable portion of the bottle ; one of the transducers senses pressure resulting when the infants compresses and releases the nipple via mandible excursions: the other transducer senses the intraoral pressure changes associated with the production of suction via peristaltic waves generated by the infant's tongue.

Breathing is sensed by respiration temperature sensor that is positioned under the infant's nares region and responds to airflow produced by inspiration and expiration. The temperature sensor typically measures a cooling effect during inspiration.

The computer controlled bottle system incorporates sensing of both sucking and breathing in order to implement the algorithms which control milk flow and also termination of milk delivery to the infant.

When infant's pulse oximeter which is measured from external physiological sensors which is connected to operating computer system data ,is available the computer controlled bottle control software may be programmed to either terminate or delay the onset of milk delivery until the infant's blood oxygenation level meets or exceeds predetermined threshold level.

5.3.2-Medical point view:

- a- This device is used mainly for preterm baby with different needs from those of cleft lip and palate babies. To be more specific the preterm babies are usually fragile and have respiratory problems with poor coordination's between breathing, sucking and swallowing because of immaturity, but babies with cleft lip and palate are generally full term and their respiratory system is stable. Such babies mainly have structural problem in the roof of the mouth requiring them more time for them to

swallow the amount of milk given .In this respect, based on this major difference, cleft lip and babies in need for a device to give proper time for the baby to swallow the amount of milk given to them. It is clear that the baby need pauses of some time to swallow the milk given without causing him to choke or cough.

On the other hand, preterm babies, however, have problems with coordination of breathing, sucking and swallowing; hence, their problem is more complicated than overcoming the structural problem of cleft lip and palate.

This is where started the idea to create a device that gives a baby the amount of milk followed by pauses to allow enough time for it to be swallowed these amounts. Preterm babies they need a medical device which synchronized their sucking, swallowing and breathing and Goldie's device does this very well.

b- Another important point should be raised in reviewing Goldie device is it need hospital sitting because it is mainly used for preterm babies and need a nurse to operate it, whereas a baby with cleft conditions may not be in need for hospital admission. Instead s/he needs a device which can be used at home where the mother with no special skills can used it .It does not need to use a complicated device that requiring numerous parameters to work such as the Goldie device is called for.

Also, in that case if it is to be used at home, then the new device should be transparent for two reasons:

- First, the caregiver will be able monitor the amount of milk the baby consumed without disturbing her/him.

-Secondly, which is another important point is that it should if possible desirable to look like an ordinary feeding bottle so that the mother will not be hesitant to use it at home.

It is very important point to consider the psychological issue for the caring mother for a baby with facial malformation .In addition to her anxiety about she could have difficulty she may have in feeding her clefted lip and palate baby, more specifically, she may worry how she will be feed her/him when undergoes the corrective surgery and over considerable period of time after this. Therefore, it is desirable to reduce her worries by providing a bottle which looks like normal or nearly normal.

- c- In Goldie device the principle is based on an incremental increase of fluid delivery to the preterm babies in hospital sitting at very low rate which very crucial concern because the requirements is to deliver very small and frequent amount of milk in instalments step wise, but where as in cleft conditions the baby is full term and not necessarily ill. Therefore , it is desirable to release such baby's from hospital as soon as possible for many reason such as reduce hospital acquired infections ,to reduce financial

burden on the family and to increase the bonding between baby and her/his mother.

So baby with cleft lip and palate in need of a device which reduce their unnecessary hospitalization and at the same time give them a solution for the mechanical defect on the roof of their mouth.

This can be done if the clefted baby given a suitable amount of milk at preselected period of time which s/he can swallow it, then followed by a pause of time to allow this.

If such device is created this would reduce the hospital stay for clefted baby which would automatically reduce the financial burden on parents and governments and thus will make major difference.

5.4 RUTH (Feeding device and feeding method for infants)

-PUB. No: US 2004/0188372 A1

-PUB.DATE: Sep.30,2004 (please refer to appendix B)

This is a feeding device and a method for facilitating the transition from non-oral tube feeding to oral feeding.

It especially designed for premature neonates as well as post- surgical infants and medically fragile infants.

In many neonatal intensive care units, premature neonates first receive nutrition through a nasogastric, orogastric feeding tube, because these infants are incapable of coordinating the suck, swallow and breathe cycle required to receive oral nutrition.

The transition from tube feeding to oral nutritive feeding is often quite traumatic. Infants are presented with a bottle and often the rate of liquid flow is too rapid for her/him to initiate timely swallowing in coordination with breathing .Consequently, these infants become distressed because they are overwhelmed by too much fluid being introduced at too fast a flow rate and may gag, choke or aspirate.

Although the method is one way for delivering milk to babies, it has major limitations if used for clefted lip and palate babies:

5.4.1 Mechanical point view:

The device comprises, a fluid reservoir having a fluid outlet, nipple having a fluid outlet, shield attached to the nipple base to aid in forming a seal around an infant's mouth a conduit for conveying fluid from the reservoir to the nipple fluid outlet and manually adjustable valve associated with the conduit which is operated to prevent the flow of the fluid through the conduit and to control its flow rate of the fluid through the conduit.

Preferably, the nipple is one which does not expel fluid when it is compressed but only expresses fluid when negative pressure is applied around the nipple outlet.

The valve is then opened to permit the flow of fluid through the nipple outlet while restricting the flow of fluid so that, no matter how hard an infant sucks, s/he cannot withdraw fluid at a rate greater than a given rate.

If an infant suffers distress from receiving too much fluid at too fast of a rate, the flow is quickly the device restricts the flow until the infant can coordinate the suck /swallow/ breathing cycle and feed without distress.

5.4.2-Medical point view:

A- Ruth's device is aimed for use to preterm infants, postsurgical and for medically fragile babies. Consequently, it is of great need to invent a new device specifically for cleft conditions is urgently needed.

B-It's mode of action depend on restricting of the fluid given to the baby by adjusting the valve either manually or automatically so as to allow a rate slow enough where the baby can tolerate.

This is understandable because preterm baby has poor sucking reflex moreover has a poorly developed respiratory system so Ruth' device fit to her/his needs, however, a different group of babies whose main problem is the structural defect in the roof of the mouth still needs a new device to be invented with their specific needs in mind to deal with different group of babies whom their main problem is the structural defect in the roof of the mouth.

To overcome this problem, it is submitted , they need different system based on a cycles being given a calculated preselected amount of fluid is to be given for calculated period of time with pause to give them chance to swallow the given amount without causing distress or chock .

C-In Ruth 'device it is transitional way of feeding which it is given to the baby in transition for non-oral feeding to oral bottle- feeding whereas the baby with cleft condition needs device to be mainly used as a method of bottle feeding for babies with cleft lip and palate which they can use for one or even two year if needed.

5.5 THE NEW METHOD OF BOTTLE FEEDING:

5.5.1 The idea:

Based on understanding of the feeding problem in babies with cleft lip and palate, from studying the mechanism of sucking and swallowing in normal babies and clefted babies and studying the previous two devices, it was clear

that clefted conditioned babies really in needed to invent a new device to meet their particular needs, supplying a not too generous and not too limited flow. Based on understanding their main problem which is the structural defect in the roof of the mouth which enables them to generate enough pressure for suction .On the hand if a lot of fluid is given passively the body may be unable to swallow it and could get complication like chocking, cyanoses and chest infection later.

So, they need a device that supply calculated amount of fluid calculated on the basis of their age, weight and their tolerance in calculated period of time followed by pause to allow the baby to swallow the given amount without causing chocking and distress, keeping in mind that must reassure the caring mother or care by to present this device looking as conventional bottle feeding, easy to be use and can be adjustable according to baby's needs.

By that, the baby will have enough time to swallow the given amount of milk beside with the technique insulated in it, the mother can adjust the amount according to the baby need and tolerance .Mother can increase the amount of milk according to the weight and age of the baby.

5.5.2 Advantages of the Device:

The following are the advantages of the new device compared to the usual feeders and other feeder for babies with cleft lip and palate:

1-It is considered to be the first device to pump measured amount of milk in a calculated time thus, it can overcome the difficulties of feeding in this group of children.

2-While it is true that the pump measures a certain amount of milk and delivers it to the baby without the need to suck, device does not ignore the fact that sucking is an instinct and one of the baby's need. Hence, it includes a nipple is there to satisfy her/him; also sucking is a kind of exercise and massage for the face muscles. From that, sucking is essential for small babies which were not forgotten by the new device.

3-Most feeders that are designed for this group of babies either has extension to close the opening or extended nipple to overcome the opening in the palate , but the problem is not only the opening but the extension of the teat as well, because it is either smaller or bigger than the defect .In case it is bigger ,it will irritate the baby during feeding and if it is a bit smaller, it will do nothing and this will not solve the main problem which is the flow of milk during sucking .

The baby cannot cope with the over flow of milk (he cannot swallow the sucked amount) because at the defect at the palate. The new bottle feed is designed to pump a measurable amount of milk in preselected time followed by pause to allow him to swallow the given amount without becoming distressed.

Furthermore the given amount can be easily adjustable by the care giver according to the baby tolerance. This is very important point, as the advantage

of the new device, which is not found in other devices for cleft conditions, is to have a device which adjusts the amount of milk that given to the baby according to his tolerance by very easy way mother can do smoothly.

4- The device is transparent so the care giver can monitor the amount the baby takes without disturbing her/him during feeds.

5- Other advantages of this device are that it can also be used for such other categories:

a-Preterm babies:

Babies delivered before 32 weeks has their suction reflexes which are not yet fully developed and their breathing / sucking and swallowing not synchronized. So, they tend to chock on milk which may lead to chest infection compromising the baby furthermore.

In addition, this device can be used at home instead of being restricted at the hospital (some babies at present stay in hospital for feeding purpose only which is not comfortable for them or their families, and great more financial burden beside cause some babies stay in the hospital just for feeding purpose only and to reduce increasing the risk of hospital acquired infections).

Another advantages for this group is that, it has nipple so this can help sucking to be developed.

b.Children with special need:

Child who have neurological problems which could lead to having swallowing difficulties; this device is could help many of mothers who find feeding this group of children difficult.

Whenever they use the ordinary feeder to much amount of milk flows out every time the baby sucks, making it hard for her/him thus he has difficulties in consuming it all.

It would be an advantage of the device to have a measurable amount of fluid is pumped in regular time so the baby would have enough time to swallow this given amount before the next amount is relased.It would lessen the chocking and respiratory distress.

c. This device could also be used for elderly people who are having feeding problems; fluid diet could be given to them in the same way but with some modification to suite this group of patients.

6-Despite its technical advance, the shape of the bottle must have the same shape as with all the techniques has to look like an ordinary feeding bottle from outside because it aimed to be used at home by mothers. The psychological element is very important in dealing with this group of babies and their families because giving birth to a baby with craniofacial anomalies is a stressful event for the mother; and if the bottle from which she is feeding her baby with look very sophisticated she will fed under pressure and this will add to her stress in dealing with her baby with cleft lip and palate.

7-Since the baby is in dynamic growing status, the amount of milk needed will change according to the babies need and weight .The mother can easily adjust the amount of fluid the baby needs by turning the knob to the amount needed; moreover, she can adjust the pause time to the baby's tolerance. Once the baby starts growing up and his weight increases the mother can increase the amount of fluid delivered to baby's mouth by adjusting the outside knob and can shorten the pause period according to the baby increased tolerance. So this bottle feeding is acknowledges the needs of the baby and meets these changing needs in a dynamic way according to his need.

8-For use it is easy to be used at home, the mother simply prepare the milk and adjust the outside knob and set the pause length according to the baby's needs. Then set the pause then the pump will work to give the baby the amount of fluid measured and give pause time to give her/him time to swallow the given amount without chock.

9- The source of power supply could be the home current or an ordinary or rechargeable battery for which can be used beside rechargeable battery.

This can be use when baby intending to go outside the house.

10-The same device can be used also in hospital setting, in the general paediatric section, and even intensive care unit in neonatal department.

5.5.3 Description of the device:

It contains two main parts:

A. Upper segment

B. Lower segment

A. The upper segment consists of:

1-a teat.

2-a closure for the teat.

3-a tube (tubular member passing through the nipple connected to submersible rotary pump for delivering a preselected volume of liquid from the bottle and through the nipple for feeding the infant).

4-a bottle feeder (clear transparent).

5-external knob to adjust the amount of fluid and the pause time.

6-a small computer chip.

7-Knob first knob for adjusting the volume of liquid pumped ,second knob for adjusting the time for a pause and an LED display to indicate the volume of liquid pumped and length of pause.

B. Lower segment housing:

1-battery (for powering the motor).

2- electric charger.

3-programable timer (for selecting an amount of fluid to be delivered to an infant in a cycle and regulating the volume of liquid pumped and the length of pauses between pumping for each feeding cycle).

-The timer includes a microprocessor, a visual display to illustrate the relative volume of liquid pumped and timed interval in a feeding cycle.

4-Pump (a submersible rotary pump, with magnetic coupling for driving the pump in response to rotation of the motor).

5.5.4 Detailed description:

In essence the present invention seeks to tackle the contemplates a nursing device or baby's bottle for feeding infants with cleft lip or palate .The nursing device includes an upper portion including a bottle for containing a supply of nutrients and /or water with an opening at one end thereof.

The upper portion also includes nipple and a means for maintaining the nipple the seal of the engagement with the top of the bottle .This involves neck portion

around the opening which is adapted to receiving a nipple therein and internal threads for engaging the external threads on the bottle.

A pump is inserted in the bottle and the underside of the cap to form a liquid-tight seal. The pump is disposed in the bottle arranged to lie under the surface of the liquid nutrient or water and preferably near the bottom of the bottle.

Tubular means such as flexible hose or semi-rigid conduit connects an output of the pump with forward portion of the nipple delivering pre-selected amounts of liquid nutrients or water through the nipple and into infant's mouth.

A lower portion of the device includes the housing and a motor arranged in the housing to rotate the pump through magnetic coupling. An important feature of the present invention consist of means such as a timer for regulating the amount of nutrient or liquid pumped in a given period of time; this is what regulates the cycle.

The device is next described in relation to with the following drawing below where in like reference numbers indicate which part is being referred.

5.5.5 Description of the Figure:

FIG-5-1

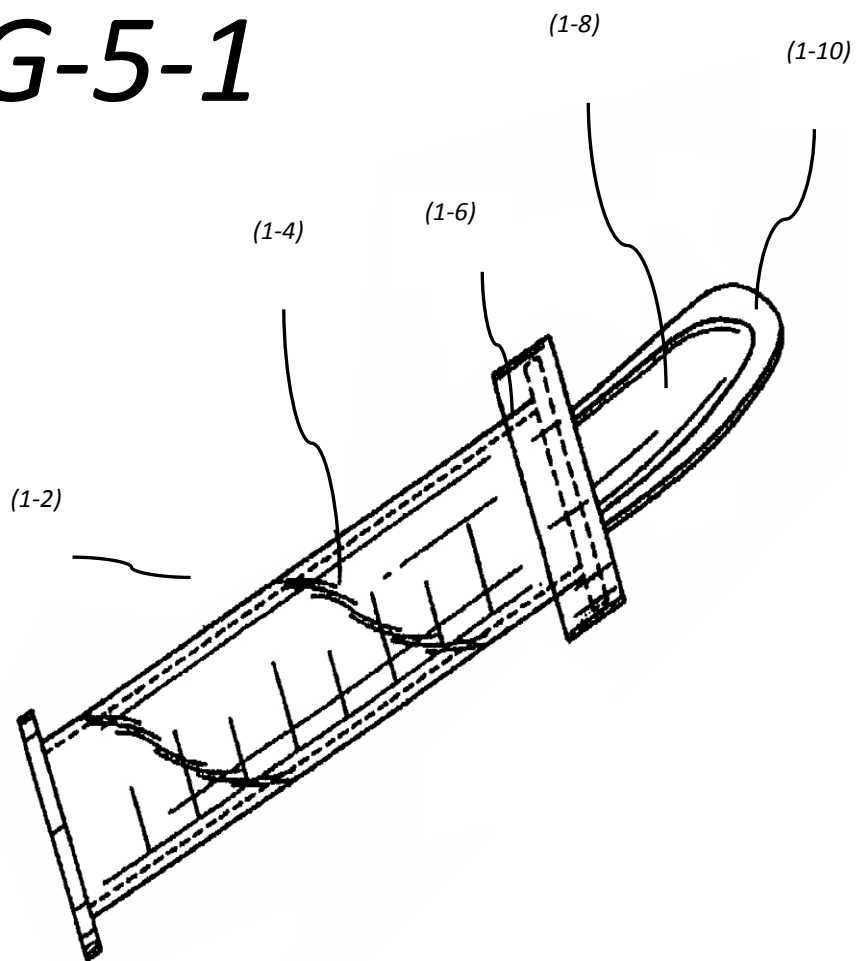


Figure [5.1] aside elevational view of nursing bottle for babies with cleft lip and palate.

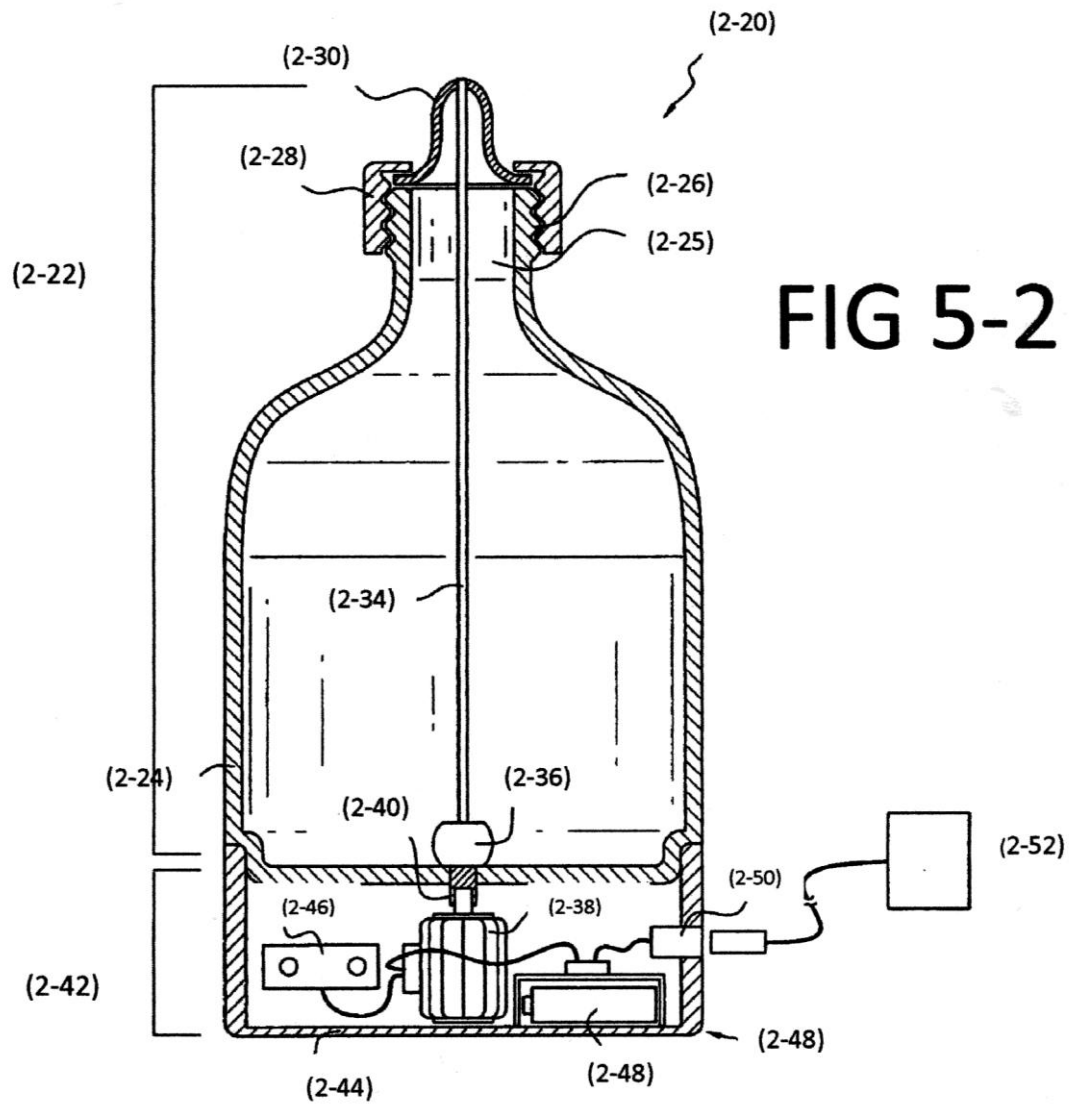


Figure [5.2] cross sectional view of the nursing bottle
for cleft lip and palate babies.

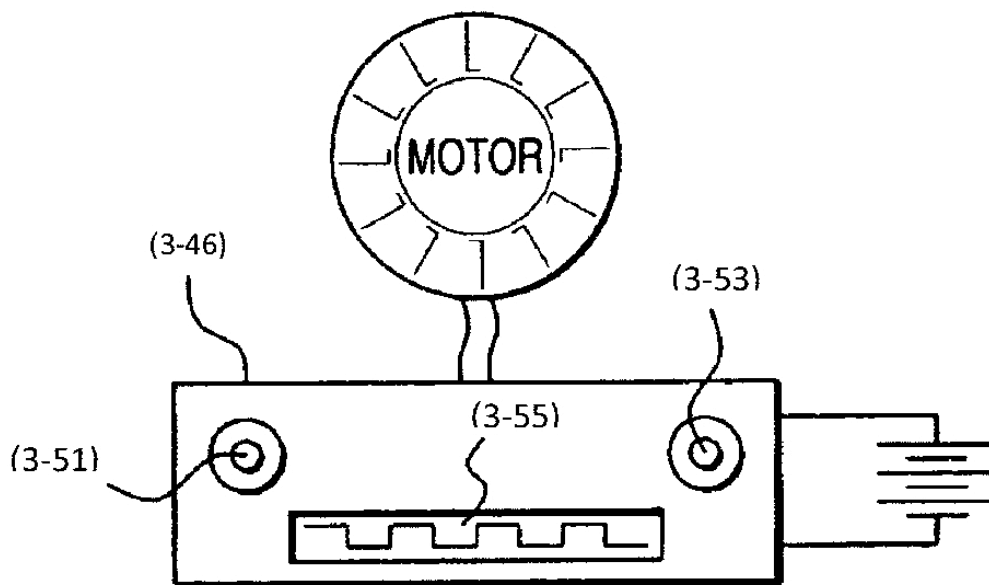


FIG 5-3

Figure [5.3] schematic illustration of programmable timer for use in the present device.

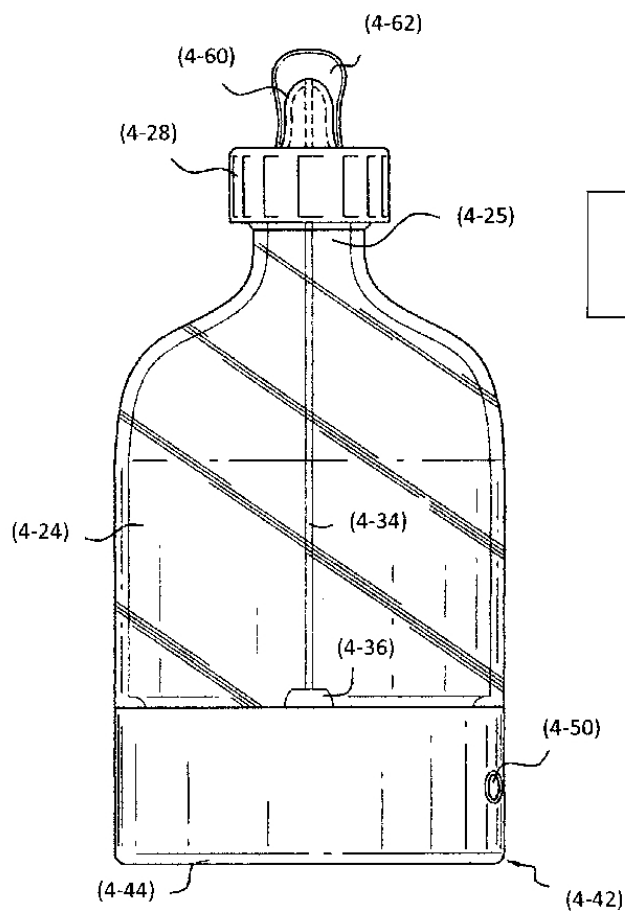


FIG 5-4

Figure [5.4] the external look of the new bottle
feeding

5.5.6 Description of the embodiments of the device:

The baby bottle for babies with cleft shown in Fig.5.1 As shown, a conventional baby's bottle [1-2], includes an elongated container [1-4] having an open end bearing an external thread. A conventional cap [1-6] has an opening with internal thread to fit; a nipple [1-8] extends from it and is attached to the top of the bottle in conventional way. However, the nipple [1-8] includes a substantially solid thin shield of latex rubber or the like .The shield is designed and constructed to prevent the nipple from collapsing into a cleft palate.

A baby bottle, Fig.5.2 [2-20] in accordance with the present device includes an upper section [2-22] having an elongated bottle [2-24] which is shaped like a conventional baby's bottle and of glass or suitable plastic material. Like a conventional bottle ,this one are preferably made of clear or translucent material to allow the caregiver to monitor the amount of nutrient which is dispensed .The upper portion of the bottle[2-24] has an opening [2-25] surrounded by a thread neck [2-26] .The thread neck [2-25] is constructed and dimensioned to receive a threaded cap [2-28] through the opening of which a nipple [2-30] extends in the conventional .Like the one on a conventional baby's bottle ,the nipple [2-30] includes a peripheral flange in its base .This flange fits between the top of the cap and the top of the neck [2-26].

Unlike a conventional baby bottle, however, the nursing device [2-20] includes an elongated tubular member [2-34] which passes through the nipple from a forward opening in the latter for delivering liquid to an infant. The tubular member, of suitable plastic material, may be flexible semi flexible or relatively rigid and of a suitable plastic material and is connected to a small rotatable submersible pump [2-36], the output of which, is connected to a motor [2-38] through a magnetic coupling [2-40] (shown schematically).The motor [2-38] is arranged in a lower section [2-42] of the device.

The lower section [2-42] includes a plastic housing [2-44], which is attached to the bottom of the bottle [2-24] in the conventional way. A programmable timer [2-46] of conventional design regulates the motor [2-38] in order to provide a selected volume of liquid to the infant and may be programmed to provide small amounts of liquid with intermittent pauses to stimulate natural feeding .A battery[2-48] for powering the motor [2-38]is fitted in the lower section [2-42] includes means [2-50] for connecting the batteries to an external charger [2-52] , which is connected to a source of electricity in the conventional way.

The programmable timer [2-46] is shown schematically in Fig.5.3 and typically includes a microprocessor to control the programming. The timer is designed to regulate the volume of liquid pumped and the length of pauses between pumping for each feeding cycle .The volume of liquid may be adjusted by a knob [3-51] and the timing of a pauses by a second knob [3-53] .The LED display [3-55] may also be provided as an indication of volume by for example the height or amplitude shown in the display or the pause .A further

embodiment of the device ,which is similar to the first embodiment is illustrated in Fig.5.4 .The difference between this and the first is that the nipple [2-30] shown in Fig.4 is replaced with a nipple [4-60] having a soft rubber shield [4-62] to cover the defect in the baby's mouth thereby preventing leakage of the liquid due to cleft lip and/or palate.

5.5.7 How it works

1-The mother or the caregiver should adjust the outside knob to show the amount the baby needs and the pause interval. Each knob mark represents a calculated amount of fluid to be delivered in calculated time interval and followed by stop time interval. For example 1ml will be delivered in 30 second and give 1minute's pause time can follow ,to give the baby chance to swallow the given amount according to the baby tolerance.

The mother can choose different speeds; she can give say 1ml to be consumed in 1minute followed by a pause of 30 seconds and so forth. The mother can choose the speed which suits her baby and can change it , as the baby grow and weight increases the mother can indicate a greater volume of fluid and less time for consuming it with a shorter pause to follow.

To elaborate more, the volume of milk consumed by the baby increases as s/he grows up; so newly born baby volume of milk needed is different than a six months old and one year old.

To be more specific a new born baby with a birth weight of 7.2pounds (3.5kg) needs to take 14.4 ounces of milk per day this amount should be divided into six to eight feeds in twenty four hours, so if he takes six feeds per day, he should take 2.4 ounces per feed i.e. 0.04 ounces /second (1.2 ml).The six old baby with a weight of 15.4 pounds needs to consume 30.8ounces per day, each feed is 5.13 ounces and 0.085 ounce /second.

If the baby reached one year of age his weight 19.8 pounds he need to consume 6.6 ounces per feed, each will have 0.11 ounce of milk to be ingested within a second.

As clearly described the need of the baby is changing according to the age, weight and tolerance .The small cleft may allow the baby to generate little suction, but large cleft will affect suction to large extent so the baby needs more time to consume the milk given .Beside, if cleft lies posterior aspect at the soft palate this disturbed the feeding more and the time needed to consume the feed will be more.

There is no standardised feeding time for clp, although many authors describe from half an hour to forty five minutes, parents used to comment that the feeding time could reached from one hour to ninety minutes for each feed.

This is largely depend on the age of the baby, his weight and the cleft site and how big is the defect. All the above factors are inflecting the volume ,the calculated interval to consume it and the pause time to swallow this given amount.

2- Once this step is completed the power source operate the pump to deliver the fluid through a tube directly to the nipple and into the baby's mouth .In order to provide a selected volume of liquid pumped, the timer regulates the volume of liquid pumped, time taken by this pumping the, volume of fluid is consumed and the length of the pause between each feeding cycle.

3-Since the bottle is transparent the mother can observe the amount of milk consumed. Once the baby finish his feeding the mother can close the system by turning the knob off.

4- If the plan is to take the baby outdoors, she can keep the bottle in a charger for a time to charge the batteries, so that the pump etc. can work independently of power supply.

5-Cleaning system is easy. Once the feed is finished a cleansing liquid can be added and the system operates again to sterilize the device which is particularly important in caring for this group of babies.

CHAPTER 6: THE STUDY OF PATTERN OF BABY FEED

6.1 Introduction:

To judge how important is to invent a new way for babies with cleft lip and palate to be feed, a study is conducted in this group of babies to evaluate their feeding pattern compared to full term and preterm babies the study is performed to find the point of defect in babies with cleft lip and palate which help eventually in reaching to optimize way of feeding.

6.2 Why the study was performed

It is clear from previous chapters how difficult is the feeding process in babies with cleft condition. The feeding process was discussed thoroughly from different aspects in previous chapters.

In this chapter, practical study was performed to evaluate the pattern of baby feed in normal babies and to compare it to babies with cleft conditions to test the difficulties the caregiver is facing during feeding this group of babies compared to normal and preterm ones.

Feeding difficulties are analyzed in scientific way to determine the problems encountered during the feeding process in clefted babies and how to manage this problems and study the ways of helping them.

Also it was done to estimate if the new bottle feeding could make difference if used to clefted babies, and if it does to what extend it could help.

This chapter started by explaining why the study was performed, the method done to tested, results which showed how the data analyzed and the statistical method was performed. Then, discussion about the analyzed results followed lastly by estimation of how the new device could help the cleft conditioned babies. At the end the conclusion of the study was illustrated.

6.3 Method:

Feeding pattern in babies was studied in 53 babies aged from 14 day to 2 year, who were divided into three groups:

group1:

The full term controls with a total of 35 babies consist of 19 boys and 16 girls, who had born at full term (when studied their mean age is 8.76 months and mean weight of 8.006kg).(table6.1)

group2:

The preterm controls with a total number of 15 consisted of 7 boys and 8 girls who had been born prematurely (birth weight 1.625+/- 563g) when studied their mean age is 1.377month with, average weight in kg 2.087)(table6.1).

Group 3:

Cleft lip and palate babies which were 3 babies 1 boy and 2 girls (when they were studied their mean age is 6.33monthes and average weight is 6.8kg; two of them already operated after the study has completed. (table 6.1)

Age and growth parameters for the tested groups by anova (table 6.1)

Variables	group	n	Mean	Std. Deviation	F	p
age in months	full term	35	8.7643	5.86269	11.995	.000
	preterm	15	1.3773	.71589		
	clcp	3	6.3333	3.05505		
	Total	53	6.5360	5.83020		
weight at birth	full term	35	3.1714	.54224	42.207	.000
	preterm	15	1.6540	.50061		
	clcp	3	2.6333	.64291		
	Total	53	2.7115	.86078		
weight in kg	full term	35	8.0006	2.47226	41.953	.000
	preterm	15	2.0873	.59923		
	clcp	3	6.8000	1.80278		
	Total	53	6.2591	3.36102		
length in cm	full term	35	69.73	14.182	23.795	.000
	preterm	15	44.00	5.345		
	clcp	3	56.67	8.622		
	Total	53	61.71	16.652		
	Total	53	39.794	6.3492		

The sample group were taken from paediatrics ward in Jahra hospital and vaccination department in Al Oyoon center .Jahra hospital is regional big hospital which drains Jahra area with a population of 420674. Paediatrics ward consist of 5wards each with29 beds PICU (paediatrics' intensive care unit) with 8 ventilators; neonatal section include 53 beds 23 are ICU (intensive care unit) 30 special care unit.

Al Oyoon center is a local dispensary which drain a total population of 39980[this data prepared by medical record and statistics November 2009- source of data Civil Information Guide 2008).

Feeding pattern was tested based on two parts:

-First part:

Questioner completed by the observing doctor which includes data related to growth parameters, gestational age and mode of delivery, and weight at the time of the study

- Second part:

Is to observe and register the amount of milk prepared by the mother ,the amount of milk consumed and the amount of milk consumed in the first 5 minutes of the study, the observer will put notes on pulse rate and respiratory rate during feeds.

Other parameter will be observed and noted as well such as choking excessive air intake, nasal regurgitation, gagging of the fluid, discomfort, cyanosis, fatigue, coughing and prolonged feeds.

-Third part:

Data integrated to calculate the following:

A-feeding efficiency:

Which define as the amount of milk the baby takes during one minute standardised by his weight (1.7ml/min or greater consider to be accepted).

B-overall transfer:

Which is the percentage of volume transferred during the entire feed divided by the total volume ordered for that feed 80% or more considered to be accepted.

C-proficiency:

Is the percentage of volume transferred during the first 5 minutes divided by the total volume ordered to that feed (35% or more is considered to be satisfactory).

The interview of the mother or caregiver and observing the feeding is done after taking consent from parent after giving detailed explanation about the aim of the study which took in average half an hour for each baby .(please refer to the questioner paper appendix C)

6.4 Results: Data analysis and statistical methods:

Result from the full term babies and preterm were compared with the results from cleft lip and palate babies by a nova (using SPSS).

Results:

Chocking:

In full term babies, preterm's and cleft lip and palate babies a high significant relation with $p \leq 0.01$. A statistically similar correlation was present with excessive air intake, fatigue, nasal regurgitation between the groups with $p < 0.01$.

Avery high significant result were found between cough, prolong feed and discomfort between the group studied $p \leq 0.001$

On the other hand no significant result was found in relation to cyanosis and gagging of the fluid between the groups. (table 6.2)

Feeding sequelae between tested groups by anova (Chocking, cyanoses, and excessive air intake ...ect.)(table 6.2)

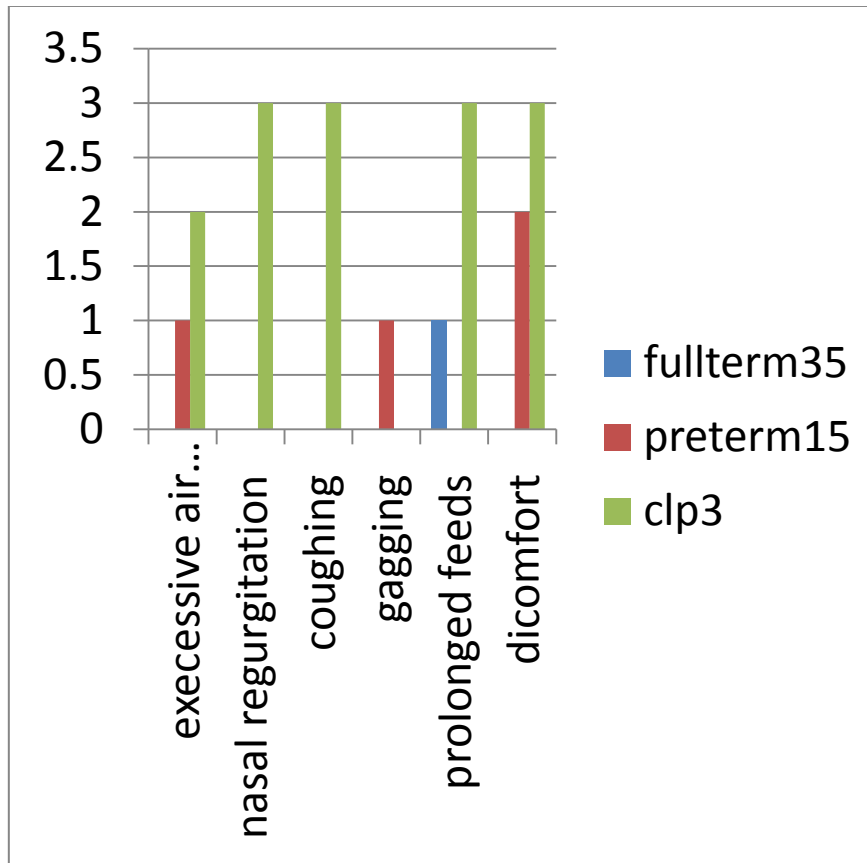
Variables		n=35	n=15	n=3	n=53	
sex	male	19	7	1	27	.724
	female	16	8	2	26	
choking	yes	2	2	2	6	.039
cyanosis	yes	2	0	0	2	.427
excessive air intake	yes	0	1	2	3	.003
fatigue	yes	2	2	3	7	.001
nasal regurgitation	yes	0	0	2	2	.001
coughing	yes	0	0	3	3	.000
gagging on fluid	yes	0	1	0	1	.276
prolonged feeds	yes	1	0	3	4	.000
discomfort	yes	0	2	3	5	.000

Amount of milk consumed:

Showed very highly significant results between the group tested $p \leq 0.001$ F 22.767, the same result were found in regard to period of time to consume it (in min) $p \leq 0,001$ F 15.816. (table 6.2)

Also a highly significant result was found in the total amount of milk consumed (ml) $p \leq 0.001$ F 21.740.

Feeding sequelae (graph 6.1)



Feeding efficiency (ml/min):

As found to be very highly significant between the groups tested $p \leq 0.001$ F 5.528 the same was applied to proficiency which found to be very highly significant $p \leq 0.001$ F 19.941, while over all transfer was found to be highly significant between the groups $p \leq 0.01$ F 2.853. (table 6.3)(graph 6.2)

The significant of feeding efficiency, overall transfer and proficiency between the groups tested by anova (table 6.3)

Variables	group	n	Mean	Std. Deviation	F	p
feeding efficiency (ml\min)	full term	35	1.6351	.57735	5.528	.007
	preterm	15	1.2353	.57704		
	clcp	3	.6933	.34775		
	Total	53	1.4687	.61749		
overall transfer	full term	35	90.614	14.8417	2.853	.067
	preterm	15	80.267	19.3883		
	clcp	3	76.667	2.8868		
	Total	53	86.896	16.5401		
proficiency in present %	full term	35	69.4257	19.14297	19.941	.000
	preterm	15	34.0507	17.09078		
	clcp	3	49.0000	11.53256		
	Total	53	58.2577	24.10989		

Other relation by person correlation (2 tailed): Was preformed (table 6.4)

Person correlation (2tailed) between the variables in full term babies (table 6.4)

Correlations		age in months	weight at birth	feeding efficiency (ml/min)	overall transfer	proficiency in percent %
age in months	Pearson	1	-.098	-.122	-.153	.036
	Correlation					
	Sig. (2-tailed)		.575	.484	.381	.839
	N	35	35	35	35	35
weight in kg	Pearson	.919**	-.064	-.105	-.107	.143
	Correlation					
	Sig. (2-tailed)	.000	.716	.548	.542	.411
	N	35	35	35	35	35
amount of milk consumed(ml)	Pearson	.812**	.059	.138	.099	.234
	Correlation					
	Sig. (2-tailed)	.000	.736	.430	.572	.176
	N	35	35	35	35	35
period of time to consume it(min)	Pearson	.175	-.184	-.770**	-.033	-.321
	Correlation					
	Sig. (2-tailed)	.316	.289	.000	.851	.060
	N	35	35	35	35	35
total amount of milk (ml)	Pearson	.846**	.043	.032	-.294	-.086
	Correlation					
	Sig. (2-tailed)	.000	.804	.855	.086	.624
	N	35	35	35	35	35
milk consumed after 5 minute	Pearson	.748**	.116	.258	.212	.490**
	Correlation					
	Sig. (2-tailed)	.000	.506	.135	.221	.003
	N	35	35	35	35	35

Group of babies tested:**a-A full term****1-age by month:**

Was found to have positive correlation with the amount of milk consumed , period of time to consumed it (min), a total amount of milk ,and milk consumed during the first 5 mints in the opposite side negative correlation between feeding efficiency (ml/min), overall transfer but positive correlation with proficiency and age(table 6.4).

2-weight in kg (kilogram):

Was found to have highly significant correlation between the weight in kg and the amount of milk consumed (ml), total amount of milk (ml) and milk consumed during the first 5 mints .Weight in kg has positive correlation with period of time to consume it (ml/min) and proficiency .In contrast a negative correlation was found between weight in kg and feeding efficiency and over all transfer. (table 6.4)

B-preterm

1-age in months

Found to have positive correlation with amounts of milk consumed, period of time to consume it, a total amount of, milk consumed during the first 5 min and feeding efficiency (ml/min) but negative correlation with proficiency and over all transfer. (table 6.5)

2-weight in kg

Has positive correlation with the amount of milk consumed, total amount of milk consumed during the first 5 min, feeding efficiency, over all transfer and proficiency.

A negative correlation was found between weight in kg and period of time to consume the milk. (table 6.5)

Person correlation (2 tailed) between the variables in preterm (table 6.5)

Correlations		age in months	weight at birth	feeding efficiency	overall transfer	proficiency in percent %
age in months	Pearson Correlation	1	.024	.102	-.128	-.022
	Sig. (2-tailed)		.933	.717	.649	.939
	N	15	15	15	15	15
weight at birth	Pearson Correlation	.024	1	.158	.127	.751**
	Sig. (2-tailed)	.933		.575	.651	.001
	N	15	15	15	15	15
number of months pregnant	Pearson Correlation	. ^a	. ^a	. ^a	. ^a	. ^a
	Sig. (2-tailed)
	N	15	15	15	15	15
weight in kg	Pearson Correlation	.555*	.702**	.152	.074	.556*
	Sig. (2-tailed)	.032	.004	.590	.793	.031
	N	15	15	15	15	15
amount of milk consumed(ml)	Pearson Correlation	.546*	.408	.648**	.610*	.565*
	Sig. (2-tailed)	.035	.131	.009	.016	.028
	N	15	15	15	15	15
period of time to consume it(min)	Pearson Correlation	.204	-.220	-.615*	-.164	-.533*
	Sig. (2-tailed)	.466	.430	.015	.558	.041
	N	15	15	15	15	15
total amount of milk (ml)	Pearson Correlation	.797**	.380	.432	.247	.351
	Sig. (2-tailed)	.000	.163	.108	.374	.200
	N	15	15	15	15	15
milk consumed after 5 minute	Pearson Correlation	.389	.704**	.588*	.500	.821**
	Sig. (2-tailed)	.152	.003	.021	.058	.000
	N	15	15	15	15	15
feeding efficiency (ml/min)	Pearson Correlation	.102	.158	1	.684**	.573*
	Sig. (2-tailed)	.717	.575		.005	.026
	N	15	15	15	15	15
overall transfer	Pearson Correlation	-.128	.127	.684**	1	.552*
	Sig. (2-tailed)	.649	.651	.005		.033
	N	15	15	15	15	15
proficiency in percent%	Pearson Correlation	-.022	.751**	.573*	.552*	1
	Sig. (2-tailed)	.939	.001	.026	.033	
	N	15	15	15	15	15

C-full term and preterm (as one group):

Correlation of variable tested

Was found to have a highly positive correlation to the amount of milk consumed, a total amount of milk, milk consumed during the first 5 min, also age by month has positive correlation with feeding efficiency, over all transfer and proficiency.

Negative correlation was found to be with period of time to consume it.(table6.5)

2-Weight in kg

High positive correlation was found with amount of milk consumed, total amount of milk, milk consumed during the first 5 min, also apposite correlation was found between weight in kg and feeding efficiency, overall transfer and proficiency, while negative correlation was found with period of time to consume it. (6.5)

T-test:

Paired sample statistic was performed

Full term group:

1-Mean heart rate was 136.49 while standard heart rate 120.29/min with negative correlation but not significant correlation. (Table 6.6)

2-The mean respiratory rate 40.74/min and mean standard respiratory rate is 42/min which showed positive correlation with significant relation $p \leq 0.05$.

(Table 6.6)

Preterm group

1-Mean heart rate 147.87/min, mean standard heart rate 155.33/min with positive correlation but not significant.

2-The mean respiratory rate 48.07/min and standard respiratory rate 60/min with positive correlation and not significant relation. (table 6.6a)

Correlations between heart and respiratory rate in full term compare to standard (table 6.6 a, b and c)

The correlation between the mean (table 6.6a)

		Mean	N
Pair 1	heart rate	136.49	35
	standard heart rate	120.29	35
Pair 2	respiratory rate	40.74	35
	standard	42.00	35
	respiratory rate		

Paired Samples Correlations (table 6.6b)

		N	Correlation
Pair 1	heart rate & standard heart rate	35	-.060
Pair 2	respiratory rate & standard respiratory rate	35	.333

Paired Samples difference by T-test. (table 6.6c)

		Paired Differences	
		Mean	Std. Deviation
Pair 1	heart rate - standard heart rate	16.200	23.506
Pair 2	respiratory rate - standard respiratory rate	-1.257	10.937

Full term and preterm (as one group):

1-Mean heart rate 139.90/min and mean standard heart rate 130.80/min which has positive correlation and significant $p \leq 0.05$.

2-Mean respiratory rate 42.94 and mean standard respiratory rate of 47.40/min with positive correlation and a very highly significant relation $p \leq 0.001$.

Correlation between heart and respiratory rate of preterm compared to standard by T-test. (table 6.7a, b, and c)

The correlation between the means (table 6.7 a)

		Mean	N
Pair 1	heart rate	147.87	15
	standard heart rate	155.33	15
Pair 2	respiratory rate	48.07	15
	standard respiratory	60.00	15
	rate		

Paired Samples Correlations (table 6.7.b)

		N	Correlation
Pair 1	heart rate & standard heart rate	15	.210
Pair 2	respiratory rate & standard respiratory rate	15	.300

Paired Samples difference by T-test. (table 6.7c)

		Paired Differences	
		Mean	Std. Deviation
Pair 1	heart rate - standard heart rate	-7.467	11.160
Pair 2	respiratory rate - standard respiratory rate	-11.933	8.293

One way test was performed:

1-The amount of milk consumed:

mean amount of milk consumed was 122 ml in full term group, 36.67 ml in preterm and 110 ml in cleft lip and palate babies with highly significant result $p \leq 0.001$ F 22.0767.

2-Period of time to consume it:

Was found 9.98 min in full term group, 15.33/min in preterm group while cleft lip and palate group need 17 min with very highly significant result $p \leq 0.001$ F 15,816.

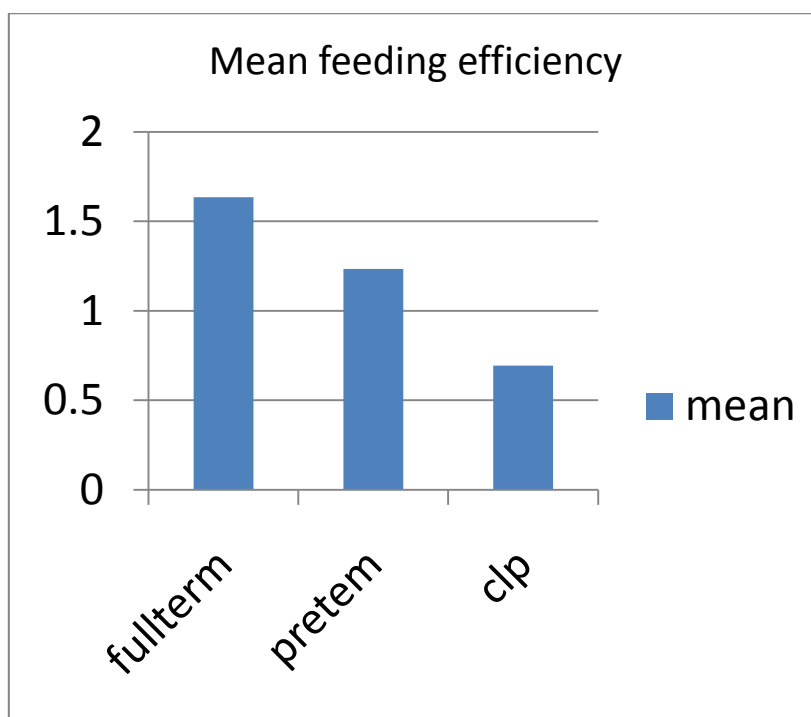
3-The mean of total amount of milk prepared for full term group was 136.14 ml, 44.67 ml in preterm and 110 ml for cleft lip and palate group with very high significant result $p \leq 0.001$ F 21.740.

4- Milk consumed during the first 5 min:

The mean was 93.86 in full term group, 16.20 in preterm and 76 ml in cleft lip and palate group with highly significant $p \leq 0,001$ F 24.845.

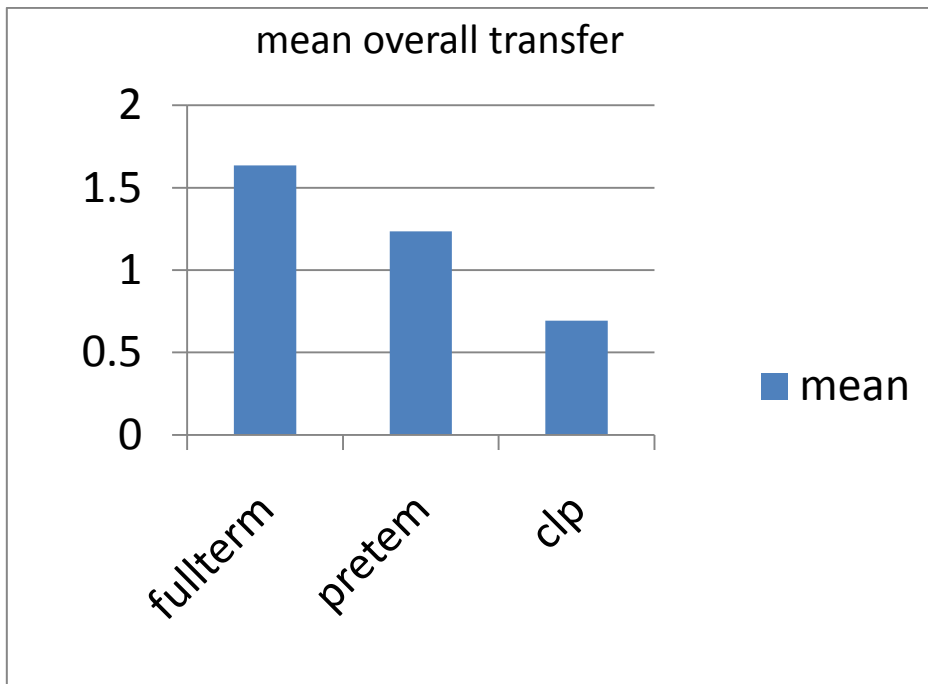
5-Feeding efficiency

In full term group mean feeding efficiency 1.635, in preterm 1.2353 while in cleft lip and palate group 0.6933 with very highly significant result $p \leq 0.001$ $F = 5.528$.(graph 6.2)



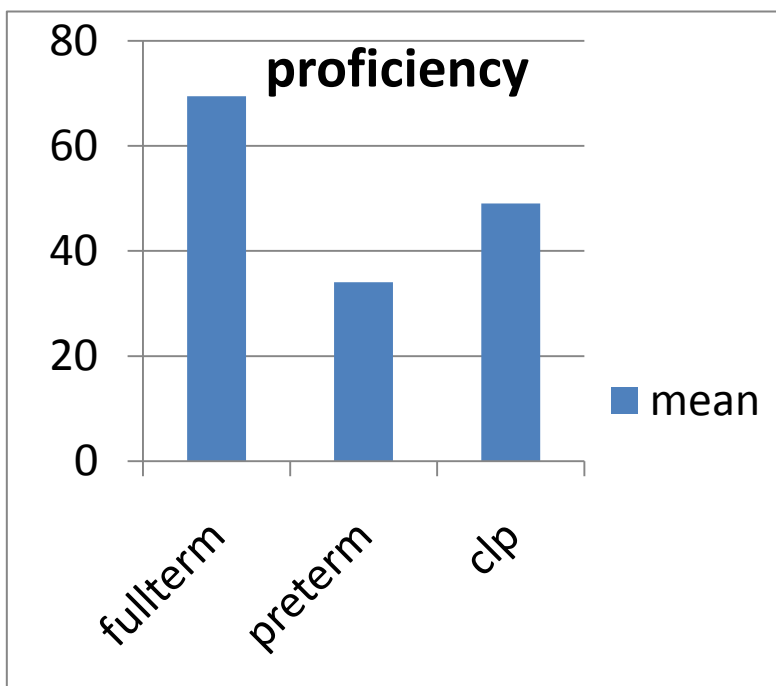
6-Overall transfer

The mean overall transfer was 90.614 in full term, 80.267 in preterm and only 75.667 in cleft lip and palate group which showed highly significant relation $p \leq 0.01$ $F = 2.85$.(graph 6.3)



7-Proficiency

In full term the mean proficiency 69.4257, in preterm 35.050 and in cleft lip and palate it is 49.000 with significant correlation $p \leq 0.001$ $F 19.941$.(graph6.4)



6.5 Discussion:

The project was designed to study the pattern of baby feed to elicit the difference between the normal full term babies , premature and cleft lip and palate babies .As the first approach to the issue of pattern of baby feed in different groups, the calculated parameters namely feeding efficiency , overall transfer and proficiency were studied to evaluate the different ways of feeding in babies ;beside observing the baby during the feed to evaluate the appearance of any sign (i.e. choking ,cyanosis, excessive air intake , fatigue ,nasal regurgitation ,coughing ,gagging o fluid , prolonged feed and discomfort).

The babies studied were divided into three group's full term, preterm and cleft lip and palate babies to be able to studies the different pattern of baby feed.

In full term babies the mean age was 8.76 months with mean weight 8.006 kg, preterm babies mean age 1.377 month with weight of 2.087 kg, and cleft lip and palate mean age 6.33 months and mean weight of 6.8 kg.(table 6.1)

With regard to the observed data (i.e. choking, cyanosis, excessive air intake, fatigue, nasal regurgitation, coughing, gagging of fluid, prolonged feed and discomfort) has been noted in the three groups, all the above data were observed and noted.

The measured showed increased evidence of choking, excessive air intake, fatigue, nasal regurgitation, cough, prolonged feed, and discomfort in cleft lip babies compared to the full term and preterm babies. (table6.2)

Also the results showed that the heart rate in babies with cleft lip and palate is increased during feed as compared to the standard heart rate to this age (heart rate 138/min during feed,110/min standard heart rate) while in the other two groups the full term and preterm the result not significant.(table6.6,6.7)

The same was found in the respiratory rate, the respiratory rate in cleft lip and palate babies 48.67/min during feed while the standard respiratory rate was 40/min which indicate increase of the respiratory rate during feed in babies with cleft lip and palate compared to their standard while this difference was not found in the other two groups full term babies and preterm babies.(table 6.6,6.7)

Feeding efficiency which was define earlier was found to be very low in cleft lip and palate babies 0.693 ml/min (normal value more or = 1.7 ml/min) in preterm babies 1.25 ml/min while in full term 1.635 ml/min (near normal). (table 6.3)(graph 6.2)

This showed clearly that the amount of milk transferred during one minute is very low in cleft lip and palate babies which indicate that the babies with cleft lip and palate babies is not taken the amount of milk he should take during one minute standardizes by his weight as consequence to the structural defect which indicates major defect in pattern of feedings this group of babies; although the other two groups namely the full term is about to reach the normal value, it is true it is low but not as low as cleft lip and palate babies.(table 6.3)

Overall transfer when tested was found to be low in cleft lip and palate babies 76.66%(normal range more or =80%) compared to full term babies which was 90.614%,preterm 80.26% which showed clearly that the amount of milk transferred during the entire feed when divided by the total volume ordered to that feed is less in cleft lip and palate babies compared to the other two groups which suggest that cleft lip and palate associates with consumption of less amount of milk compared to the standard. It was found that babies with cleft lip and palate correlates with low amount of milk transferred which has been validated by epidemiological studies.(table 6.3)(graph 6.3)

The low overall transfer constitutes strong evidence of poor feeding pattern in cleft lip and palate babies.

The result showed different result in proficiency in full term babies reached 69.42%, in preterm babies 34.05% while in cleft lip and palate reached to 58,25%

which means that the amount of milk the baby consumed during the first 5 minute divided on the total amount of the milk prepared is in acceptable range in cleft lip and palate babies but those group of babies will be eager to feed and they will try to suck as quick as possible then they as observed earlier in results of the overall transfer they will be tired and fatigue to continue the rest of the prepared milk which explain why the overall transfer is low in this group of babies while the preterm babies their problem is different, because in preterm babies their main problem is that their sucking reflex is not well developed so they need longer time to finish the milk prepared .(table 6.3)(graph6.2)

So, their overall transferred is in acceptable range ,so prematurity per se appear to reduce the proficiency but the end result is that the amount of milk consumed is in acceptable range compare to total amount of milk prepared while babies with cleft lip and palate babies because of the structural defect in the roof of the mouth they consumed acceptable amount of milk during the first 5 minute compared to the total amount of milk prepared but when they continue to feed because of choking ,discomfort and fatigue they will be unable to consume reasonable amount compared to the total amount o milk prepared.(graph 6.4)

So, this study showed poor feeding performance in babies with cleft lip and palate with cleft lip and palate with regard to feeding efficacy and over all transfer.

Although the period of time to consume the milk need to be standardizes to the given three groups, the results showed that the full term babies took 9.89mins, preterm 15.33minand cleft lip and palate babies took 17 min which is the longest period between the three groups.

This showed that although cleft lip and palate babies need longer time to consume the milk prepared they used to consume less amount and the overall transfer is the least between the 3 groups.

This imply that a lot of effort is done by the babies to complete their feeds and even though they are not consuming the acceptable range when standardised by their weight, which clearly will affect their growth parameter because they consume less amount of milk with greater effort to consume it.

6.6 How could the new device help in correction the feeding difficulties in cleft babies

Based on the survey done pattern of baby feed (although the sample number is small), it is clear that this group of babies suffer a lot during feeding from different problems. If each problem is analyzed separately and test how could the device help in solving each problem.

6.6.1 Choking:

It was found from the study that choking is more in clefted group of babies and this was supported by literature review i.e. structural defect at the roof of the mouth cause the milk to leaks from the nostril and could cause chocking ,so to overcome the problem (which is serious problem may lead to ear infection and more serious chest infections) the fluid should be given in amount tolerated by the baby and it should be followed by pause to give the baby time to swallow the given amount without chocking which is done by the new device in simple and easy way, where the mother can adjust the amount of the fluid given and the pauses length according to the baby tolerance .This could prevent Choking to large extend.

6.6.2 The heart rate and respiratory rate:

The heart rate and respiratory rate shown to be higher than the standard .This because the clefted babies are taken a lot of effort during feeds compared to the other groups of babies.

When the fluid is given in cycles i.e. give amount of fluid followed by a pause the effort the baby expend will be less , subsequently the heart rate and respiratory rate will normalized because the effort the baby is performed during feed is become lower by pumping the milk in organized way .

The baby task will be only swallowing the amount of milk given without causing him to expend a lot of energy to suck swallow and breath. By doing this the clefted baby will not fatigue and tired during feed by ordinary bottle feed.

6.6.3 Feeding efficiency:

Which is define as the amount of milk transferred during one minute ,it was found to be very low in cleft condition .This mean that they are unable to consume the amount of milk they should take within 1 minute .So, if the milk is delivered by the new device for clefted babies is adjusted ,this means that the baby could take the amount he could tolerate within the period of time that suites this particular baby followed by pause time to allow him to swallow it without causing distress .This mean that this process will be smooth and the baby will not suffer a lot beside he will take the more amount of milk as he tolerate. But by ordinary bottle the cleft babies are unable to consume the amount he should during one minute because when baby suck from ordinary bottle the flow of milk cannot be controlled every time the baby suck the flow will continue tell it reach a time there will be an overflow which the baby cannot tolerates then he will start chocking and coughing and he will stop sucking and this reduced the feeding efficiency.

While in the new bottle the milk will be given in calculated amount adjusted according to the baby need and tolerance which is followed by a pause period at that time the baby can swallow the amount given without overflow which compromised the clefted babies and reduce his feeding efficiency.

6.6.4 Overall transfer:

The amount of milk transfer during the entire feed when divided by total volume ordered is found to be less in clefted babies compared to other group tested .This give stronger evidence of poor feeding pattern.

If the new bottle feeding is used to supply the clefted babies with milk the new device will give to help them to increase the amount of milk transfer during the entire feed which subsequently help them to grow and gain weight as a preparation for the corrective surgery which will be preformed later if the clefted baby reached the recommended weight which allow them to undergo the surgery.

The new device will increase the overall transfer by given the amount of milk in easy way where the baby will not suffer much and he will not be in distress or tiered during feed, he will be able to consume his feed in comfortable way because he will have the time to swallow the amount that he could tolerate which is subsequently increase the total amount consumed if compare to the total amount ordered to that feed.

6.6.5 Proficiency:

The clefted baby has low proficiency because the amount of milk the baby consume during the first 5 minute when divided by the total amount of milk prepared is low. This group of babies will be eager to be fed vigorously as quick as possible then, he will be tired and fatigue, this explain also why the overall transfer is low.

The new bottle-feed will give cycle of feeds where the calculated amount of milk is given within preselected period of time followed by rest time where the baby could swallow the milk. By this, the baby expend less energy during the feed because the pump installed in the bottle will do the job instead of the baby, he will consume the amount of the milk he should take with less effort.

6.6.6 Period of time to consume the milk:

It was found that babies with cleft condition takes longer time to consume the milk when compare to other group involved in the study .This is well understood because of the effort they are doing to overcome the structural defect in the roof of the mouth lead them to take longer time to suck and swallow they may stop for some time to rest, or sometime the mother will stop the feed to give chance for the baby to rest and allow him to swallow the milk he sucked.

In summery ; a lot of effort is done by the small clefted baby to complete his feed , he may chock , his heart rate and respiratory rate will increase , he will not take the amount of milk he should take in certain period of time , he may take longer time for feed ,all of this and more which may not be tested in the current study the baby is suffering during his feed with all of this in mind the new device could help to some extend to improve the pattern of feed in clefted babies to optimize the process of feeding as normal as possible.

6.7 Conclusion of the study:

Our study showed the existence of poor feeding pattern in cleft lip and palate babies compare to preterm and full term babies. Based on issue the new bottle feed could give a help to these babies with clefted conditions, which need to be tested on clefted babies.

CHAPTER 7: DISCUSSION AND CONCLUSION OF THE THESES

7.1 Introduction:

This last chapter will focus on the discussion of the theses, and then what conclusion the whole study reached .Finally future work was stated to be conducted later on.

7.2 Discussion of theses:

In previous chapters it was shown clearly that cleft conditions are a common problem not only this but also the clefted babies has major feeding problems encountered every day of their lives and among the worst of which, are the feeding problems suffered by both mother and baby as much, every two hours for a period which may extend up to two years.

The structural defect in the roof of the mouth causes the baby to chok, decrease his milk intake and taking longer to be feed.

This brings a need for a bottle which can overcome these feeding problems, a bottle that which supplies a calculated amount of milk in line with the baby's weight and age.

The pump which is insulated in the device will pump a measured amount of the fluid according to need in a calculated period of time followed by a pause which where the baby can swallow this amount in comfort. In some cases, a baby cannot cope with swallowing because of the defect in the palate easy way, because this group of babies needs to rest in between the sucks to allow time to swallow the sucked milk without causing distress or choking .This process will continue in smooth repeated cycles until the baby has consumed a due amount according to his age and weight.

In view of this, it is now believed that there is commercial potential for an improved feeding device modelled on the present invention. The advantages of the device, listed below should make it marketable because of the number of children with clp who cannot be fed using previous devices.

The device includes a nipple so that the baby can develop an ability to suck and at the same time can exercise and massage the muscles of the face.

However, with a device modelled on the present invention, the mother can adjust the bottle to pump measured amounts of nutrient so that the child obtains enough nutrients in enough time without adversely affecting his general condition, which will help him to gain enough weight to allow him to undergo corrective surgery.

Devices modelled present invention are also applicable to pre-natal infants i.e. those born before 32 weeks .The suction reflex in such infants may not be fully developed and the baby may choke on nutrient form ,a conventional baby bottle leading in some cases to ear and more seriously chest infections .

Furthermore, the use of this invention may allow the infant to leave hospital sooner, since the mother will be able to feed at home.

Further, babies with special needs who have problems with swallowing may also benefit from the use of the device while ,, the device avoids the problem associated with spitting relatively large amounts of milk during feeding .

In addition, this device can be used to feed fluid foods to elderly people who are having feeding problems because of senility.

To sum up, of this the new device could help babies with clp and other group of babies to feed and solve the anxious problems which are faced by mothers and small babies on a daily bases.

7.3 conclusions

From the above study we conclude that cleft lip and palate is a common paediatric problem which causes distress also to both parents and caring doctors because the babies face every day problems of feeding which affects

their growth and development and may delayed the consequent corrective surgery.

The new invention, a new bottle feeder for babies with clp, could give some help to this group of babies in regard to their feeding problems.

7.4 Future work

In regard to breast feeding which is considered to be the best way of giving nutrition to babies both in the way it is delivered and its content, so the future work most needed is to design a mechanical device to help of babies with clp to be breast fed using the same principle as was used for bottle feeding.

A shield with an artificial teat could be placed on the mother's breast which contained small pump. The could that pump breast milk to the baby's mouth in the same way as the bottle pump for calculated period of time followed by arest period to allow the baby to swallow the milk.

The breast milk device for the babies with clp would have reservoir connected to the shield to accumulate the milk expressed from the mother's breast for use in the cycle of feeds.

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Appendix A:



US 20080039778A1

(19) **United States**
 (12) **Patent Application Publication** (10) **Pub. No.: US 2008/0039778 A1**
Goldie et al. (43) **Pub. Date: Feb. 14, 2008**

(54) **COMPUTER CONTROLLED BOTTLE FOR ORAL FEEDING OF A PATIENT**

Publication Classification

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(51) **Int. Cl.**
A61J 9/00 (2006.01)
A61M 31/00 (2006.01)
 (52) **U.S. Cl.** **604/67; 215/11.1**

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(57) **ABSTRACT**

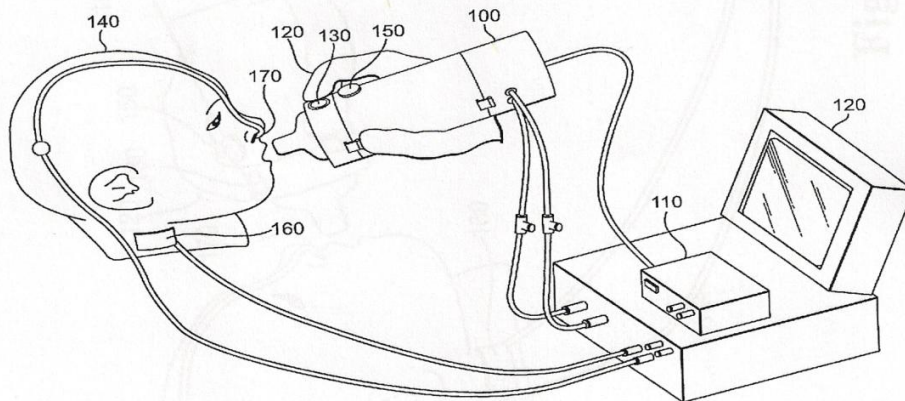
(21) Appl. No.: **11/575,602**
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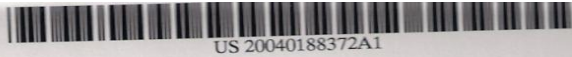
Related U.S. Application Data

(60) Provisional application No. 60/612,413, filed on Sep. 23, 2004.

Generally, the present invention relates to medical devices and more particularly to a computer controlled bottle system for example, for a preterm infant oral feeding. An embodiment of the invention is directed to a method for delivering nutritional fluids orally to a preterm infant comprising the steps of measuring the infant's inspired breath to breath amplitude, measuring the infant's intraoral sucking pressure, establishing threshold values for infant's inspired breath to breath amplitude and infant's intraoral sucking pressure, and delivering nutritional fluids to the infant only when the infant's inspired breath to breath amplitude and infant's intraoral sucking pressure both simultaneously satisfy their respective threshold values.



Appendix B



(19) **United States**
 (12) **Patent Application Publication**
 Ruth et al.

(10) **Pub. No.: US 2004/0188372 A1**
 (43) **Pub. Date: Sep. 30, 2004**

(54) **FEEDING DEVICE AND FEEDING METHOD FOR INFANTS**

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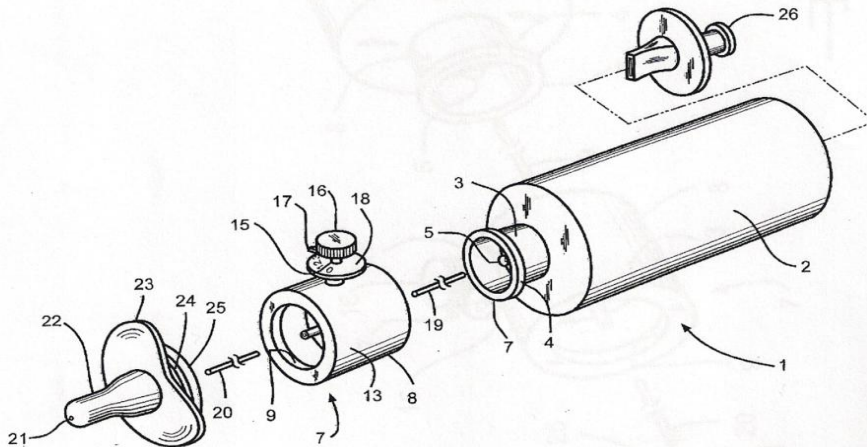
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Publication Classification

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(57) **ABSTRACT**

A feeding device and a method for facilitating the transition from non-oral tube feeding to oral feeding is disclosed. The device comprises a fluid reservoir having a fluid outlet, a nipple having a fluid outlet, a shield from the reservoir to the nipple base, a conduit for conveying fluid from the reservoir to the nipple fluid outlet and a manually adjustable valve that is operable to prevent and control the flow of fluid through the conduit. The method comprises the steps of providing a device of the type just described, acclimating an infant to the device by closing the valve and inserting the nipple into the infant's mouth. The valve is then opened to permit the very slow flow of fluid through the nipple outlet. Additional feeding regimens are provided in which restriction of the flow of fluid is gradually relaxed over a series of feedings until the infant is able to withdraw about sixty cubic centimeters of fluid during a twenty minute feeding without distress.



Appendix C The quistuneere:

Serial number:

Gender...

Name:

Birth Date:

Birth weight:

Mode of Delivery:

Number of months pregnant:

Weight: Length: H.C (head circumference):

Total amount of milk prepared:

Amount of milk consumed:

Period of time to consume it:

Amount of milk consumed after 5 min:

Pulse:

Respiration rate:

Choking:

Cyanosis:

Excessive air intake:

Fatigue:

Nasal regurgitation:

Coughing:

Gagging on fluid:

Prolonged feeds:

Discomfort:

Feeding efficiency (ml/min)...

Overall transfer...

Proficiency: