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The Prosthetic Obturator Appliance In The Treatment Of Cleft Lip And Palate In Newborns: Series Of Cases

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Abstract – Cleft lip and cleft palate are common defects in head and neck area. The treatment is mainly surgical but while waiting for the primary surgery which is not immediate, a pre-surgical management must be undertaken for the success of the diet and the surgery. In the present study, the use of the passive palatal obturator was chosen to demonstrate its efficacy in the pre-surgical management of cleft lip and/or palate in newborns.

This is a serial case report of newborns with cleft lip and / or palate aged 2 to 27- day-old. Two suffered from BCLP (bilateral cleft palate), one from UCLP (unilateral cleft palate) and one IBCP (incomplete bilateral cleft palate). The conventional palatal obturator design-manufacturing stages was adopted. The impression was made with Polyvinyl siloxane impression material and flexible thermal-forming (ethylene vinyl acetate sheet) material was used for manufacturing the feeding obturator. A combined method (feeding obturator and lactation education) has been adopted for feeding success.

As results, with palatal obturator in the mouth, each newborn exhibited good sucking-swallowing-breathing coordination at the time of suckling. During the 3-month follow-up period, weight gain was observed in the reported infants in which those affected by UCLP and CP gained more (1920g, 2200g) than others (700g, 1100g).

The combined use of a palatal obturator and lactation education was associated with weight gain.

Keywords – Cleft,Obturator, Palate, Prosthetic

INTRODUCTION

Oral clefts are among the most common craniofacial birth defects in the head and neck region and the second most common congenital malformation in the human body [1-2]. According tothe World Health Organization (WHO), 1 in 500 to 700 newborns are born with ethnic and geographical variation [3-4]. In addition to psychological damage to the child and parents, cleft mouths cause speech disorders increased risk of ORL infection, lung infection, maxillofacial and orthonatic growth disorders, and feeding difficulties [5]. In anatomical-functional terms, they can lead to difficulties in coordinating sucking, swallowing and breathing during feeding, thus increasing the risk of choking, nasal discharge, excessive air intake and prolonged feeding time. These difficulties resulted in weight gain problems or pathological growth due to lack of nutritional intake. The treatment of these oral clefts is primarily surgical, but the role of prothetic and orthopaedic therapy is paramount to the success of all other treatment [6]. However, according to the literature, cleft lip surgery can only be performed at around three months [7-8]. Until this time, the provision of nutrition from the first days of life is crucial, firstly to allow the newborn to recover physiologically from the birth weight and gain adequateweight, and secondly because it is the child's first link with the mother [5], hence the importance of the obturator palate plate.

The management of these malformations is multidisciplinary, and the creation of a palatal obturator plate is a specialised procedure.

The overall objective of this study was to evaluate the effectiveness of the obturator palate plate in Malagasy cleft-bearing neonates.

OBSERVATION

This is a study of a series of clinical cases of newborn babies with oral clefts who were hospitalised in the Complexe Mère-Enfant, neonatology department of the University Hosptial Center "Professeur Zafisaona Gabriel Androva Mahajanga – Madagascar" (CHUPZaGa) or referred by a health worker to the hospital center for a specialised consultation.

I- Presentation of case series

I-1- Case 1

The baby is a male infant, two days old. At birth, the newborn weighed 2912g. the ratio of birth weight to lenght of pregnancy was eutrophic. No associated malformations were mentionned in his file.

On medical history, no family member of the newborn is affected by this malformation. The newborn did not come from a consanguineous marriage. Furthermore, the mother presented a moderate infectious risk (fever with untread influenza syndrome) during the pregnancy.

During consultation, the parent's main complaint was that their baby had difficulty feeding. Pending the appropriate therapeutic decision, the newborn was fed via a nasogastric tube with artificial milk.

In this case, the suching reflex was present, but the oral cleft prevents him from making atight labial seal and from exerting intra-oral pressure for successful sucking.

The patient lost 92g from his birth weight (2912g). The neonate had a bilateral cleft lip, collapsed nostrils and non-existent nostril openings. Endo-buccal examination revealed a discontonuity of the alveolar ridge with an anterior medial bud and a defect in the fusion of the hard palate (1.9cm wide) and the soft palate. The maxillary ridges are rounded with sufficient height. The vestibule is deep with a high insertion of lateral brakes and muscle flanges. The tongue is of normal volume and tone but in a high position at rest and interposes it self between the palatal fragments.

The diagnosis of a bilateral complete cleft lip and palate was made.

As this was a prosthetic treatment, a prosthetic prognosis score was established based on the anatomical elements and biological indices of the prosthetic bearing surface. In this case, the favourable anatmical factors were predominant with a score of 5/9 (**Table I**).

Figure I: Exobuccal view of bilateral cleft lip and palate

I-2- Case 2

This a mal neonate, five days old, referred and consulted for feeding difficulty due to a cleft mouth. The parents also complained of nasal regurgitaion of the mother's milk during each feeding.

To ensure the infant's nutrition, a nasogastric tube was put in place by the attending physician.

The pregnancy history revealed a leucorrhoea and a break in folic acid intake.

In the neonatal observation, the newborn was eutrophic with a birth weight of 3550g. No pathology or malformations were mentioned.

The sucking reflex was present. The patient weighed 3284g (a weight loss of 266g compared to birth). A left unilateral cleft lip with left nostri collapse and deviation of the nose to unslit (right) side were noted in the newborn (**Fig. 2**).

A discontinuity of the homolateral alveolar rdge and a complete cleft 1.5cm wide were noted. The palatal fragments were unequal with the right fragment was predominating. Her tongie was in an elevated position and interposed between the two fragments of the cleft.

The diagnosis was a left unilateral complete cleft lip and palate.

In scoring the prosthetic prognosis, favourable anatomical predominated with a score of 6/9 (**Table II**).

Fig. II. Exo-oral view of the left unilatera cleft lip in case 2

I-3- Case 3

A female neonate, seven days old, was seen in consultation for difficulty inbreastfeeding with nasal regurgitation of breast milk and subsequent refusal to sukle. Due to this circumstance, a nasogastric tube was placed by the neonatl doctor to ensure adequate food intake using breast milk.

The pregnacy history revealed that the mother was well monitored and a notion of decoction in the first trimester of pregnancy was reported.

At birth, the newborn was eutrophic with a birth weight of 3000g. No general pathology and an associated malformation were not diagnosed.

Suction evaluation showed that the patient had a sucking reflex. When sucking, he made a tight lip seal but the intraorale pressure was insufficient.

The patient was 2890g (a loss of 110g from birth). Her face was symmetrical. Her lips were thin with normal tone. The neonate was found to have bilateral non- complete hard palate cleft 1.4cm wide (**Fig. 3**).

The tongue was of normal volume and tone but in a high position at rest due to the presence of the cleft palate.

The diagnosis of a bilateral non-complete cleft palate was made.

The prosthetic prognosis was good with a score of 8/9 (**Table. III**).

Fig. III. View of incomplete bilateral cleft palate (case 3)

I-4- Case 4

A 27-day old male infant has a feeding difficulty. The mother complained of sucking difficulty which made feeding impossible. She decided to feed her baby with breast milk and formula using a spoon. Regurgitation and a choking episode led the mother to take her baby for consultation.

The maternal history during pregnancy revealed leucorrhea, gestational hypertension and no folic acid intake.

Due to the oral cleft, the creation of the anterior labial joint is impossible, as is the sucking movement.

At birth, the baby weighed 3300g. No general pathology or associated malformations were mentioned in his health record.

On clinical examination, the patient weighed 3000g with a loss of 300g from birth weight. Exo-oral examination revealed a complete bilateral cleft lip. Endo-oral examination revealed a discontinuity of the alveolar ridge with an anterior medial bud, a defect in the fusion of the hard palate (2 cm wide) and the soft palate (**Fig. 4**).

The newborn was observed to have a complete bilateral cleft lip and palate.

Fig. IV. Exo- and endo-oral view of bilateral complete cleft lip and palate in case 4

II- Procedure for mouth impression

Due to technical difficulties related to the size and age of the child. The impression was taken under sedation in the operating theatre. The parents were informed at length about the risk of sedation, and gave their signed consent 24 hours before the procedure.

The impression and ventilation was performed intermittently with close monitoring of oxygen saturation. The size of the mouth opening did not allow the use of an impression tray. It was planned to take the impression using the fingers (index and middle fingers) as a support for the impression materials. Wearing gloves is not indicated in order to prevent the impression materials from sticking to them (**Fig. V**). The impression was taken following the "wash technique" in order to have dimensional accuracy and stability (**Fig. VI**). Once the impression had been taken, a check of the recorded anatomical details of the impression obtained, followed by a check of the baby's oral cavity for any fragments of impression material and a decontamination of the impression.

The model is first modified by filling in any undercuts, especially in the area of the fissure with the impression silicone.

At thermoformable plate (ethylene vinyl acetate) which is a transparent and flexible material of 1.5mm thickness, reserved for Dental vacuum forming machine (Keystone®) is used for the fabrication of the obturator palatal plate. Once designed, the plate was cut to the predetermined anatomical limit according to the working model (**Fig. VII.**).

The obturator plate was delivred on the same day as the impression. The plate was adjusted to take advantage of its transparency. The mother was then asked to breastfeed in a semi-sitting position. During the observation of the feeding, the newborn was able to feed without any disconfort with the palatal plate, despite the mother's difficulty in finding the appropriate brastfeeding position. All newborn showed good « suck-swallow-breathe » coordination during feeding, no episodes of choking or fatigue or nasal regugitation were suspected (**Fig. VIII**).

Instructions were given to the parents regarding the insertion and removal of the obturator palatal plate.

Parents were reminded that regular follow-up should be performed after obturator palatal plate placement until three months of age to assess the baby's weight gains, to detect and correct any problems related to the plate. Follow-up examinations were scheduled successivety: 24 hours, one week after plate placement and monthly until three months. The parents were informed that the appliance could be replaced after 2-3 months, taking into account the infant's maxillofacial growth.

For breastfeeding, we used the 2019 recommendations of the Academy of Breastfeeding Medecine. Breast milk remains the ideal type of feeding for all infants. To increase the efficiency of breastfeeding, a breastfeeding-friendly strategy was implemented by informing and educating the parents about the feeding method right after the plate was placed:

- Due to the delayed rise of breast milk, bottle feeding with a second age rubber teat was advise.
- A position corresponding to this type of breastfeeding has been taught, the baby in fed in a semi-vertical position (above 60°) to facilitate swallowing and avoid nasopharyngeal reflux.
- The obturator palatal plate must be worn for every feeding session.
- A quiet place and comfortable seating were required for each feeding session.
- The duration of each feeding should not exceed 30 minutes with breaks for respiratory protection and burping.
- Identification of respiratory cues (colour, respiratory rate, sucking rhythm) was the norm.
- The « Dan Cer » position was taught to achieve a good latch and to suppot the baby's chin and cheeks.
- A medical and nutritional consultation is essential to meet caloric, water and nutritional needs.
- Immediate consultation is needed if the infant has dysphagia.

These strategies were accompanied by encouragement and psychological support from the parents, especially the mother.

The infant's oral cavity is cleaned daily with a compress soaked in a 0.14% sodium bicarbonate solution to prevent fungal growth (mouth care).

The obturator plate should be brushed with warm water and washing-up liquid. If no breastfeeding is planned after cleaning, it is kept in a clean, dry jar to minimise any kind of contamination.

Monitoring and evaluation focuses on four areas:

- Assement of the infant's oral status
- Evaluation of suckling: suckling efficiency and compliance with breastfeeding recommandation by the mother
- Assement of weight gain: weight gain was assessed monthly and at the three month, the « rule of 10 » criterion was evalued for a possible indication of primary cheiloplasty.
- Monthly: according to WHO growth charts with weigt-for-age indicator: birth to 6 months (percentiles), monthly weighing required at each follow-up eaxmination.
- At three months af age: weight requirement for primary surgery according to the « rule of 10 »: an infant must be at least 10 weeks old, weih at least 10 pounds and have a haemoglobin level af at least 10g/dl before surgery.

III- Resultats obtained and follow-up

III-1- Case 1

During the follow-up periods, any sores or ulcerations of the orale mucosa were detected. At the two-month follow-up, the mother request to breastfeed was tried in a « rugby ball » position for their comfort. The infant sucessfully breastfed but mixed feeding was adopted on the advice of the paediatrician.

The palate fit well in the baby's oral cavity until the age of three months and did not show any tears or soiling. At the breastfeeding assessement, the mother followed all breastfeeding recommendations well and the infant had any discomfort. The infant showed a weight gain of 1100g during the first three months of life (**Table. IV**). Placing him on yhe WHO growth chart, this weight gain was below average for hi sage (< 50 th percentile) (**Fig. IX**). This weight gain is to the peadiatric departement for a consultation.

III-2- Case 2

The newborn was able to suck without difficulty, wiht good « suckling-deglutition-breathing » coordination. It was noted that there were no signs of disconfort or nasal regurgitation of breast milk (**Fig. 4**).

During follow-up clinical examinations, any ulceration or fungal infection was found in the infant's oral cavity. He was still able to suckle with the palate in his mouth. The mother followed all recommandations breastfeeding. Exclusive breastfeeding was adoptede from the age of 1 month.

During the first trimester of life, the infant had a weight gain of 1920g (**Table. IV**). The weight gain was below average for his age (< 50th percentile) (**Fig. IX**). However, this gain made her eligible for primary cheiloplasty.

III-3- Case 3

The neonate was able to suckle correctly with the plate and good « suck-deglutition-breathing » coordination (**Fig. VIII**).

During the first trimester of life, the infant had a weight gain of 2200g (**Table. IV**).

A palate renewal was considered to make her an eligible candidate for uranoplasty, scheduled at 9 mounths of age (**Fig. X**).

III-4- Cas 4

Breastfeeding was initiated with the plate in the mouth and the infant in a semi-seated position (**Fig. VIII**).

During the first trimester of life, the infant gained 700g, compared to its birth weight (**Table. IV**).

Compared to WHO growth chart, this weight gain was below average for her age (<50th percentile) (**Fig. IX**).

DISCUSSION

Four newborns were observed in this study ranging in age from 2 to 27 days. Ofthese, two had bilateral cleft lip and palate, one had unilateral left cleft lip and palate and one had bilateral cleft palate.

According to Cologne *et al.* (2011), pre-surgical mangement of cleft li pis as important as surgical treatment. Specialised consultations start in the first week of life with the preparation of a palatal plate. These allow optimal pre-surgical and post-surgical preparation [9].

In the present study, the complaints of the parents during were summarized as « difficulty in feeding ». The same reason for consultation has been reported by Chandna *et al.* (2011), Dubey *et al.* (2013), Shilpi Tiwari *et al.* (2014), Kar *et al.* (2015) in their studies regarding newborns with oral clefts [10,11,12,13]. According to the literature, the incidence of feeding difficulties in newborns with oral clefts is very high. The prevalence ranges from 25 to 73% [14,15]. These reasons were related to the width of the cleft, which varied from 1.4 to 2 cm in the neonates observed in this study. According to Reid *et al.* (2007) and Merrow *et al.* (2016), the width of cleft determined the the child's ability to generate suction, the greater of malforamation and the greater of feeding difficilties [16, 17].

Intraoral impression was the first clinical step in the design of the obturator palatal plate for neonates with an oronasal communication. In the literature, the impression of a neonate is taken in a vigorous state [6,10,11]. In our case, the impression was taken under sedation due to technical difficulties related to the size and age of child. Gupta *et al.* (2012) stated that it was difficult to control the flow of impression material in the area of the cleft and underscuts in anneonate. Moving the child's head forward to avoid aspiration of the impression material was the only precaution suggested but this method would not ensure complete control of the impression material to avoid the complication of impression material being pushed too deeply into the nasal cavity or distally through the pharynx [18]. Sedation allows for the timely verification and removal of residual material lodged inth patient's oral cavity, especially in the nasopharynx, which could be a source of complication and sbsequent hospitalisation. In the present study, the « Wash technic » was adopted for the impression taking. Azhari *et al.* (2017) and Bhandari *et al.* (2018) adopted the same impression technic in their studies for making an obturator palatal plate in a neonate [6, 19]. Polysiloxane(silicone) was the best material due to different viscosities. According to Narendra *et al.* (2013), the advantage of this impression material was a resistance to tearing. As a result, removal would be atraumatic for the neonate and the risk of injury to the oral mucosa is eliminated [20].

The ideal obturator palatal plate should have a polished surface, retrain less organic debris, offer less risk of microbiological imbalance, less risk of stomatitis or oral candiddiasis, and promote oral hygiene [21]. In our study, we chosed the thermoformable plate (ethylene vinyl acetate). The same material was used by Chandna *et al.* (2011), Hansen *et al.* (2016) and Alramady *et al.* (2021) in their studies on obturator palatal plate in neonates [10,22,23]. This soft, transparent and flexible material allowed the device to be manufactured in one step as well as saving time, it was delivred on the same day given the urgency of feeding the neonate. According to Chandna *et al.* (2011), vacuum formed materials are light in weight, soft in nature with a smoother surface [10].

Breastfeeding is universally recgnised as the optimal mode of nutrition for all infants and the WHO recommands exclusive breastfeeding for the first six months of life [24]. In addition, breastmilk helps prevent respiratory, gastointestinal and ear infections. In the present study, at mouthing and during the three-month follow-up period, the four observed newborns were able to create a good « suck-swallow-breathe » coordination during suckling, no nasal regurgitation or choking episodes were observed. These results are in line with those of Chandna *et al.* (2011), Dubey *et al.* (2013), Hasen *et al.* (2016) in their studies of similar cases [10,11,22]. The obturator palatal plate is the only feeding device to fill the dehiscence created by this deformity. Thus the passive obturator palatal plate helps their tongues to compress and stabilised the nipple or teat in the oral cavity during suckling. Then they generated sufficient negative intraoral pressure to allow adequate suction to induce lactation.

As this has a pre-chirurgical management, criteria were imposed by the surgical team for the neonate to be eligible for primary surgery or cheiloplasty which was schedulded at three months of age. This timing has in the « rule of 10 » advoced by Wilhelmsen and Musgrave (1966) [25]. In this study, the obturator palatal plate is not used alone but in combination with education of parents, especialy the mother, about breastfeeding the newborn with these defects. During the follow-up period, weight gains were observed in newborns of wich those affected by unilateral cleft lip and palate made more gains (1920g-2200g) than others (700g-1100g). These results corroborate those of Bhandari *et al.* in 2018. In their studies, using the obturator palatal

plate and educating the parents on the position of the newborn during breastfeeding, the infant made a weight gain of 1945g during three months of follow-up [19].

Despite the weight gains of each newborn, two infants were ineligible for primary cheiloplasty. As for weight status in relation to the WHO growth chart, none of observed newborns reached the apprpriate weight for their age. A study conductede by Miranda *et al.* (2016) on the growth of chidren with cleft lip and palate under two years of age, referring to the weight-for-age indicator and body mass index, showed that they had a growth problem in the first half of lives [26]. And according to Michel *et al.* (2018) in their studies on the perinatal assessment of weight gain in newborns with orofacial clefts, infants with cleft lip and palate had a significantly high rate of pathological weight curves compared to those with cleft palate [27].

CONCLUSION

Feeding of cleft mouth infants is an international challenge. From birth onwards, the search for an effective feeding strategy is paramount to the success of subsequent surgical management.

This study was able to demostrate the efficacy of the obturator palatal plate on oral function and growth in cleft lip and palate infants. It emphasises the need to refer cleft lip and/or palate infants to specialist care whenever possible. In this study, the design protocol remains the conventional technique due to a lack of digital design and manufacturing equipment. Despite the counter version on the use of the obturator palatal plate in the literature, it remains the only feeding device capable of bridging the dehiscence created by the malformation so that the neonate can breastfeed like healthy children. As for the results on weight gain, they do not only depend on the use of the plate but several factor scan influence it.

In perspective, a more in-depth study on the factors influencing the feeding and growth of newborns with cleft and/or palate would be more judicious for the sucess of pre-surgical management in Madagascar.

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Illustrations

Table I. Scoring through anatomical elements and biological indices of the prosthetic bearing surface (case 1)

Anatomical factors	Favourable	Unfavourable
Alveolar ridge	+	
Vestibule	+	
Condition of the mucous membranes (thickness-texture-adhesion)	+	
Teeth (toothed or toothless)		+
Tongue (situation-volume-tone)	+	
Labio-jugal strap (situation-tone)		+
Soft palate		+
Extent of the gap (complete-partial)		+

Saliva viscosity	+	
Prosthetic prognosis score	5	4

Table II. Scoring throught anatomical elements and biological indices of the prothetic bearing surface (case 2)

Anatomical factors	**Favourable**	**Unfavourable**
Alveolar ridge	+	
Vestibule	+	
Condition of the mucous membranes (thickness-texture-adhesion)	+	
Teeth (toothed or toothless)		+
Tongue (situation-volume-tone)	+	
Labio-jugal strap (situation-tone)	+	
Soft palate		+
Extent of the gap (complete-partial)		+
Saliva viscosity	+	
Prosthetic prognosis score	6	3

Table III. Scoring throught anatomical elements and biological indices of the prothetic bearing surface (case 3)

Anatomical factors	**Favourable**	**Unfavourable**
Alveolar ridge	+	
Vestibule	+	
Condition of the mucous membranes (thickness-texture-adhesion)	+	
Teeth (toothed or toothless)		+
Tongue (situation-volume-tone)	+	
Labio-jugal strap (situation-tone)	+	
Soft palate	+	
Extent of the gap (complete-partial)	+	
Saliva viscosity	+	
Prosthetic prognosis score	8	1

Table. IV. Weight gain

Monitoring									
Case	Age (month)	Weight (Kg)	Age (month)	Weight (Kg)	Age (month)	Weight (Kg)	Age (month)	Weight (Kg)	Weight gain (Kg)
N°1	At birth	3	1	3.30	2	3.80	3	4.10	1.10
N°2	At birth	3.55	1	4.12	2	4.80	3	5.61	1.92
N°3	At birth	3	1	3.60	2	4.40	3	5.20	2.20
N°4	At birth	3.3	1	3	2	3.4	3	4	0.7

Fig. V. Wash impression technique and sedation

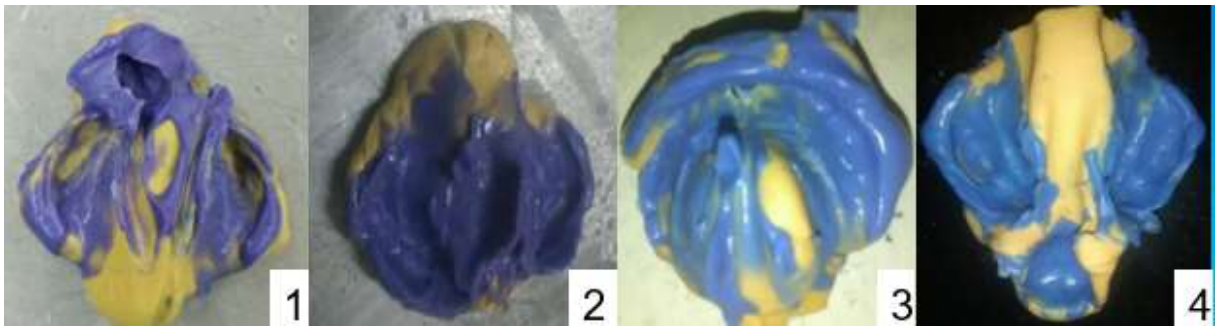


Fig. VI. Palates impressions

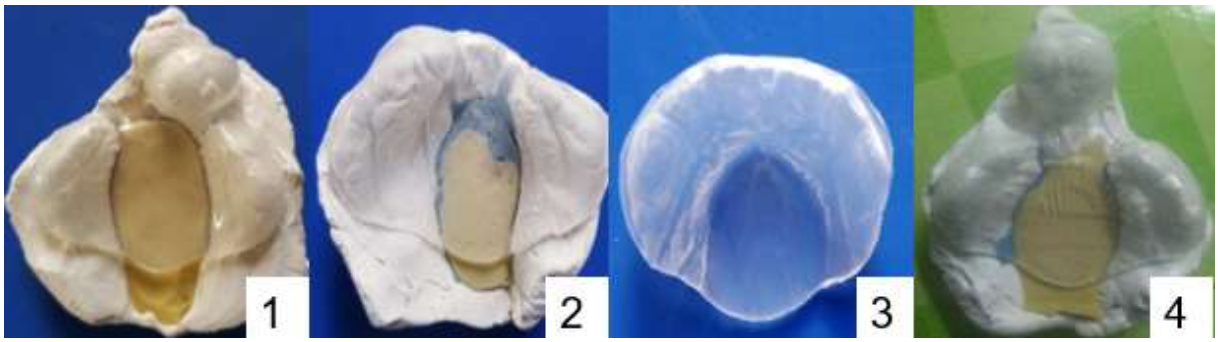
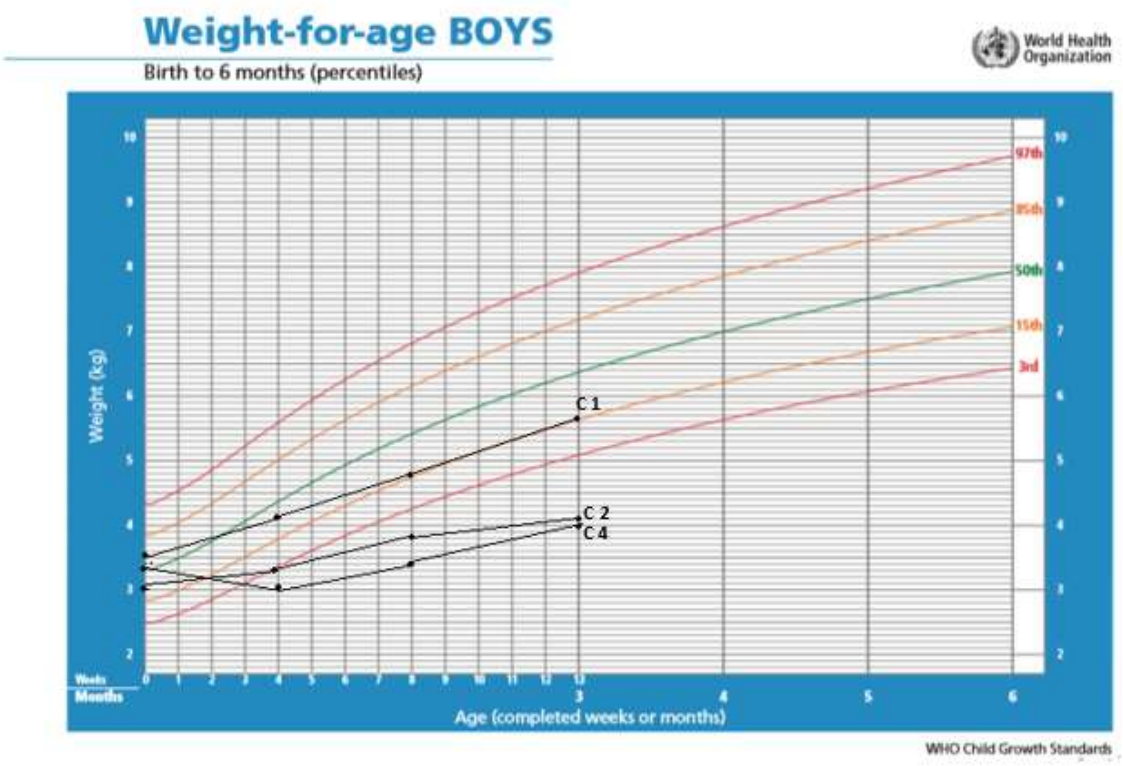


Fig. VII. Laboratory stage of obturator palatal plate fabrication

Fig. VIII. Suckling just after the plate is placed



C1: case 1, C2: case 2 and C4: case 4

Fig. IX. Infant weight status according to the WHO growth chart

[WHO Child Growth Stantards (https://www.who.int/tools/child-growth-standards/standards/weight-for-age)]

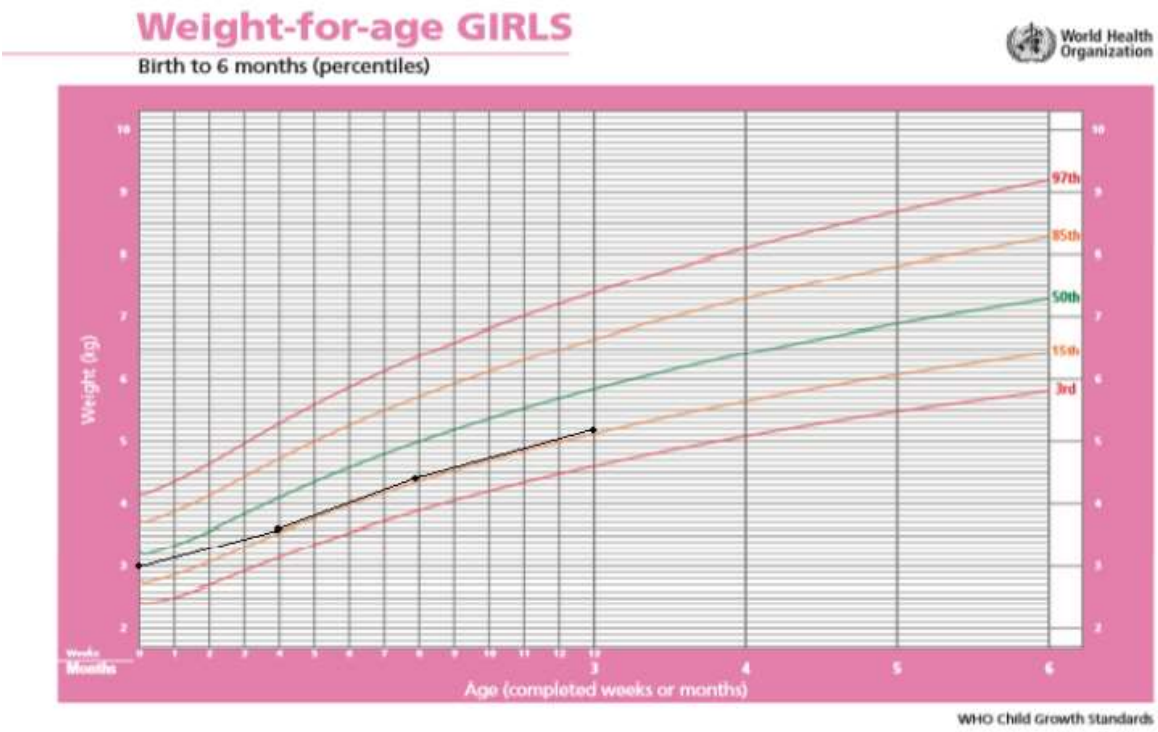


Fig. X. Infant weight status according to the WHO growth chart (case 3)

[WHO Child Growth Stantards (https://www.who.int/tools/child-growth-standards/standards/weight-for-age)]