Single-visit Feeding Obturator Fabrication in Infants with Cleft Lip and Palate: A Case Series and Narrative Review of Literature

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ABSTRACT
Cleft lip and palate (CLP) is one of the most common craniofacial anomaly affecting newborns. In the early years of life to survive baby requires nutrition from the mother. Lip seal of infant is affected because of cleft palate and thereby feeding is greatly compromised. As there is communication between nasal cavity and oral cavity there are more chances of aspiration of milk into the lungs. The main role of pedodontist is to fabricate a palatal obturator which facilitates feeding. In this article we have discussed fabrication of feeding obturator in single visit in infants with cleft palate.

INTRODUCTION
Cleft lip and palate (CLP) is the most common craniofacial anomaly affecting one in every 600 live births. Global prevalence rates of cleft palate may vary. According to systematic review conducted by Panamonta et al. on the prevalence of CLP varies 1.57–0.57 per 1,000 live births. The American Indians had the highest prevalence rates of 2.62 per 1,000 live births, followed by the Japanese, the Chinese, and the Whites of 1.73, 1.56, and 1.55 per 1,000 live births, respectively. The Blacks had the lowest rate of 0.58 per 1,000 live births. Cleft lip and palate can have either syndromic or nonsyndromic etiology, and majority are nonsyndromic. Family history of clefts, advanced maternal age, pregestational hypertension, gestational seizures are significant risk factors. Paternal tobacco smoking is associated with increased risk. Syndromes associated with cleft lip palate—Van der Woude syndrome, velocardiofacial syndrome, median facial dysplasia, Pierre Robin sequence, Treacher Collins malformation, trisomies 13 and 18, Apert’s syndrome, Stickler’s syndrome, and Waardenburg’s syndrome.

ASSOCIATED MALFORMATIONS
Associated malformations are reported to be more frequent in infants who had both CLP than in infants with isolated cleft palate or infants with isolated cleft lip. Malformations of the limbs or vertebral column, cardiovascular system, congenital heart disease, mental retardation, and chromosomal anomalies are the most commonly associated malformations.

Feeding is the first and foremost requisite for infants. Feeding is relatively difficult in infants with CLP. Until the lip and palate are surgically closed, feeding is a large difficulty for some infants and parents. Surgical closure of the palate can be accomplished later, usually between 9 months and 18 months of age to promote proper speech development. Feeding difficulties can cause problems with weight gain, resulting in a slower growth for the infant with a cleft. Other factors that can cause delayed weight gain and growth in infants with cleft palate or in infants with cleft lip and/or palate include chronic infections, metabolic disorders, manifestations with syndromes, and multiple hospitalizations.

It is of great importance to ensure that the infant with CLP is able to feed to maintain weight and normal growth. Feeding obturators will improve the ability of infant to attain suction and help the infant to feed adequately. It is necessary for the infant to have a sustained weight gain prior to surgery to correct the cleft lip and/or palate. This article aimed to report impression techniques for single-visit feeding obturator fabrication in different types of clefts in infants.

STEPS IN FEEDING OBTURATOR FABRICATION
Two-step impression technique is recommended. Impression is taken when infant is in fully awake and no premedication was given. Infants were placed on helpers lap in supine position (Fig. 1).

Preliminary Impression
Modeling wax is softened in warm water and adapted to the contours of palate with the help of fingers, which is then carefully taken out from infants oral cavity without deformation or distortion (Fig. 2). Palatal (intaglio) surface of adapted modeling wax is dipped...
in a semiliquid stage of plaster mix to create a primary cast on which custom tray is prepared with ethylene vinyl acetate sheet (Fig. 3). This custom tray is attached to ice-cream stick with the help of double-sided adhesive tape (Fig. 4).

**Secondary Impression**
Secondary impression is taken with the fast-setting addition silicone putty (Zhermack elite HD+ putty soft). Secondary impression material is loaded onto the custom tray and custom tray is supported by ice cream sick while making impression (Fig. 5). Custom tray is supported with the help of holding handle of ice cream stick with thumb and index finger and middle finger is placed at the posterior most extension of the custom tray. Proper adaptation can be achieved by encouraging the child to cry this can be accomplished by gently tapping the child on the foot. Very gentle pressure is applied on custom tray in upward and forward directions. During the impression making, two operators were available all the times with high-volume suction and a tweezer to ensure that any obstruction in the airway is cleared. And one operator should be available all the time to observe the infant while taking impression. Absence of crying and face becoming pale are the indications of airway obstruction and to be dealt accordingly. Master cast is prepared with type V dental stone (Fig. 6) on which obturator is prepared using thermoplastic ethylene vinyl acetate sheet (2 layered) using biostar vacuum-forming machine. Final obturator was cut, trimmed, and polished and checked for fit, and before delivery, a hole was placed and 10-inch floss was tied to stabilize during feeding. Appliance was tried in infant’s oral cavity, and parents were instructed about the placement and removal of palatal feeding obturator and instructions were given about cleaning and storage of appliance.

**Case Descriptions**

**Case 1**
A 7-day-old infant with CLP was referred to the Department of Pedodontics and Preventive Dentistry, Malla Reddy Institute of Dental Sciences, Hyderabad, Telangana, India (Fig. 1). General examination revealed no abnormality. Extra-oral and intraoral examinations revealed complete bilateral clefts (class-IV veaus classification). Feeding difficulty and nasal regurgitation were reported by the mother. Feeding obturator was fabricated as mentioned above.
Case 2
A 10-day-old child with unilateral cleft and palate reported to the Department of Pedodontics and Preventive Dentistry, Malla Reddy Institute of Dental Sciences. No other medical abnormality was detected except unilateral complete cleft palate (class-III veaus classification) (Fig. 7).

Case 3
A 2-month-old male child with uvula-pharyngeal cleft was previously reported to the Department of Pedodontics and Preventive Dentistry, Malla Reddy Institute of Dental Sciences, 45 days ago. The feeding obturator was fabricated in the similar manner as described above. The parents of the child reported the feeding plate did not fit properly. This is due to an increase in the growth of jaws. In such cases, refabrication of feeding plate is necessary. Old feeding plate was used as a special tray and it is attached to an ice-cream stick using double-sided adhesive tape. This old feeding plate is loaded with secondary impression material, that is, fast-setting addition silicone putty (Zhermack elite HD+ putty soft) and then impression was retaken. Master cast is prepared with type-V dental stone on which obturator is prepared using thermoplastic ethylene vinyl acetate sheet (two layered) using Biostar vacuum-forming machine.

Final obturator was cut, trimmed, and polished and checked for fit, and before delivery, a hole was placed and 10-inch floss was tied to stabilize during the feeding. Appliance was tried in infant’s oral cavity, parents were instructed about the placement and removal of palatal feeding obturator, and instructions were given about cleaning and storage of appliance (Fig. 8).

Case 4
A 3-month-old female infant with incomplete bilateral isolated palatal cleft was reported. Mother noticed baby was crying excessively during feeding and was not gaining weight, hence consulted a pediatrician regarding the same. The weight of baby at the third month was only 1.5 kg. Feeding obturator was constructed in a similar manner as described above (Fig. 9).

Discussion
Surgical closure of the cleft palate will be usually planned between 9 months and 18 months of age. Till the cleft palate is surgically closed, feeding the infant is relatively difficult for the mother. Babies with cleft palate have difficulty in breastfeeding and bottle feeding because of their altered/decreased ability to create suction. Altered sucking is due to lack of proper anatomical structures of
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hard palate and especially soft palate. The ability to create suction is hampered more in infants with larger clefts than in infants with smaller clefts.

Various feeding methods and modifications are recommended for feeding infants with CLP such as enlarging the size of hole in the tip of bottle (nipple of the feeding bottle), compress the tip against any existing palatal structures, squeeze bottles, and feeding tube usage of Haberman feeder.

Neonatal palatal feeding obturator is indicated when there is difficulty in breast and bottle feeding. Feeding obturator temporarily seals off the connection between oral and nasal cavities, thereby allowing infant to create sufficient pressure, which helps the infant in sucking the milk. Jones et al. reported that palatal obturator allows tongue from protruding into the cleft, thereby allowing normal sucking of milk. The advantages of feeding obturator include decrease in choking nasal regurgitation and nasal discharge decreased apprehension and time required for feeding.

Some authors report that palatal feeding obturator prevents the interposition of tongue in the cleft area, which allows for spontaneous growth of palatal shelves toward each other but time of placement of palatal obturator is very limited and justification for this statement is lacking.

Impression making is the most important procedure in fabrication of palatal feeding obturator in infants. The following factors are to be considered while making impression:

Preparation of Infant
Infant should be fully awake, nonsedated, and some authors recommend not feeding the infant 2 hours prior to impression procedure.

Armamentarium and Setting
Hospital setting was advocated for impression taking, high-volume suction should be available all the times to prevent accidental aspiration of separated impression material or regurgitated contents.

Position of the Child
Various positions such as supine position, face downward position, upright position are recommended during impression making.

Impression Making
Crying of infant during impression making has the advantages such as it ensures molding of impression material to the anatomic contours of palate, and also, crying ensures an open airway. Any absence of crying indicates airway obstruction.

Impression Material
Alginate elastomeric impression material polysulfide and polyvinyl siloxane are used for impression making in infants with CLP.

Impression Technique
Single-step or twostep impression technique is followed by many authors, but the two-step technique has the advantage of fabrication of custom tray that will reduce the amount of material needed to make final impression and also prevents excess material that has the potential to block the airway. In the two-step impression technique, preliminary impression can be fabricated with self-cure acrylic.

Material
Various materials are used for fabrication of palatal obturators such as vacuum adapted low-density polyethylene material (ethylene vinyl acetate), heat cure acrylic autopolymerizing self-cure acrylic. The advantages of ethylene vinyl acetate over acrylic is: its lightweight, moldability, and a good fit to palate and ridges decreased the possibility of soft tissue injury because of soft texture. The feeding obturator should be adjusted every 2–3 weeks and replaced every 2–3 months.

Advantages of Feeding Obturator
A feeding obturator is a device that separates and creates a seal between the oral and nasal cavities. An obturator creates a rigid platform on which a baby can press the tip of feeding bottle and extract milk. It reduces potentially painful ulceration of the nasal septum by the tip of feeding bottle because of the plasticity of the tissue conditioner on the fitting surface of the tissue conditioner. It helps create sufficient negative pressure that allows for adequate sucking of milk. It reduces the passage of food into the nasopharynx, thus reducing the incidence of otitis media and nasopharyngeal infections.
Table 1: Table showing case reports with single step impression

| S. no. | Authors                  | Impression material                                      |
|-------|--------------------------|----------------------------------------------------------|
| 1     | Chandna et al.           | Polyvinyl siloxane putty material                         |
| 2     | Shahapur et al.          | Very high-viscosity polyvinylsiloxane impression material |
| 3     | Dubey et al.             | Putty-type rubber-base impression material                |
| 4     | Pesun et al.             | Fast setting polyvinyl siloxane soft putty viscosity impression material |

Table 2: Table showing case reports with two step impression

| S. no. | Authors                  | Preliminary impression | Final impression                  |
|-------|--------------------------|------------------------|-----------------------------------|
| 1     | Savion et al.            | Impression compound    | Rubber-base impression material    |
| 2     | Agarwal et al.           | Alginate               | Fast-setting elastomeric putty material |
| 3     | Ravichandra et al.       | Impression compound    | Light body poly-vinyl siloxane    |
| 4     | Bhandari et al.          | Viscous vinyl polysiloxane impression material | Viscous vinyl polysiloxane |
| 5     | Bansal et al.            | Heavy body putty       | Heavy body putty Alginate         |
| 6     | Erkan et al.             | Impression compound    |                                   |

Problems Associated with the Use of Obturators

There are hazards associated with while taking impressions for construction of the obturator, such as difficulty in removing the impression due to engagement of undercuts and fragmentation of the impression upon withdrawal from the mouth with subsequent respiratory obstruction and cyanotic episodes. Repetitive construction of new obturators because of baby’s growth is often associated with poor oral hygiene, which can lead to fungal growth on the palate if the proper cleaning procedure for the prosthesis is not followed. Intraoral placement of the obturator is challenging and can add to the burden of maintenance.

Nutritional Gain

Better results in the nutritional gain was observed in infants with CLP who used palatal obturators for feeding when compared to controls. Turner et al. demonstrated that the combined use of a palatal obturator and lactation education resulted in reduced feeding times, an increased volume consumed, and a higher flow rate. Prahl-Andersen et al. reported that feeding was better in obturator group than in the nonobturator group, but there was no significant difference between nutritional gain in obturator group and control group. These results were the same as in the study reported by Masarei et al.

Restoration of Infants Ability to Generate Intraoral Pressure

Kogo et al. reported that feeding plate creates enough negative pressure that is adequate for sucking of milk. Such infants can suck and intake about breast milk per attempt, and breastfeed until naturally weaned. However, in another study by Choi et al., the presence or absence of an intraoral orthopedic plate did not make any difference in the ability of infants with clefts to generate negative intraoral pressure.

Tongue Position

Osuji hypothesized that if an opposing surface in the form of an obturator was provided, cleft infants would produce more normal tongue movements, including compression of the tip of feeding bottle. However, Masarei et al. suggested that regardless of cleft type or obturator status, all infants show poor tongue coordination.
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